



# **Products and Solutions 2017**

## *Roche Diagnostics*





## *Diagnostics – the building block of healthcare*

Healthcare is undergoing a paradigm shift. As people live longer, grow older and face serious illness – such as cancer, heart disease and diabetes – there are new challenges for both patients and care-givers. The strain on healthcare systems and resources is undeniable but not insuperable.

A more intelligent and effective approach to healthcare is now in our grasp – one in which in vitro diagnostics plays an integral role.

Through providing the right information, diagnostics enable healthcare professionals to work more knowledgeably so that they can make better treatment decisions. Driving this change are the new biomarkers and testing technologies, which give laboratories an expanded role in delivering improved patient outcomes.

Roche, as global leader in diagnostics\*, is pioneering this shift in the healthcare landscape. Through our unrivalled investment in research and development; our novel and medically differentiated assays; our integrated systems; connected workflows and technologies, we are transforming laboratory practice now and forever. As we continue to innovate across the patient care pathway, we are pursuing our vision of making data available anytime and anywhere and delivering real value to healthcare systems.

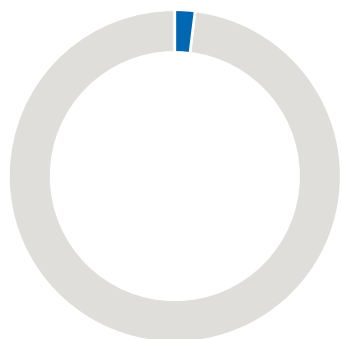
The result is better, healthier lives for patients, and healthcare systems poised for the long term.

That's the power of knowing.  
That's Roche Diagnostics.

## The value of in vitro diagnostics

*Laboratories play a pivotal role in clinical decision-making*

IVD accounts for ~ 2 % of worldwide healthcare spending

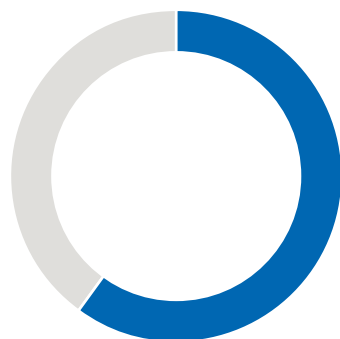


### Increased value of Diagnostics

In vitro diagnostics (IVDs) have long been considered as the “silent champion” of healthcare, influencing over 60 % of clinical decision-making, while accounting for only about 2 % of total healthcare spending.

The role of IVDs is set to grow with today's changes in healthcare. With the development of Personalized Healthcare (PHC),

IVD influences > 60 % of clinical decision-making



patients can now benefit from targeted treatments based on the presence of specific genetic defects or biomarkers in their blood or tissue. Targeted therapies and diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers.

## Roche is the leader in Personalized Healthcare\*

Diagnostics

Pharmaceuticals



*At Roche we combine technical competence with therapeutic insights.*

With our leading Pharmaceuticals and Diagnostics businesses under one roof, we are positioned to deliver Personalised Healthcare. Roche's vision is to unlock the full potential of personalised healthcare for patients through the development of breakthrough medicines and leading diagnostics.

In pursuit of this vision, we are developing our capabilities and building strategic partnerships so new information and insights lead to the right treatment for the right patient at the right time.

With a proven track record in delivering breakthrough medicines and diagnostics and deep expertise in molecular biology and data science, Roche is a unique partner to drive this next step in the evolution of healthcare.

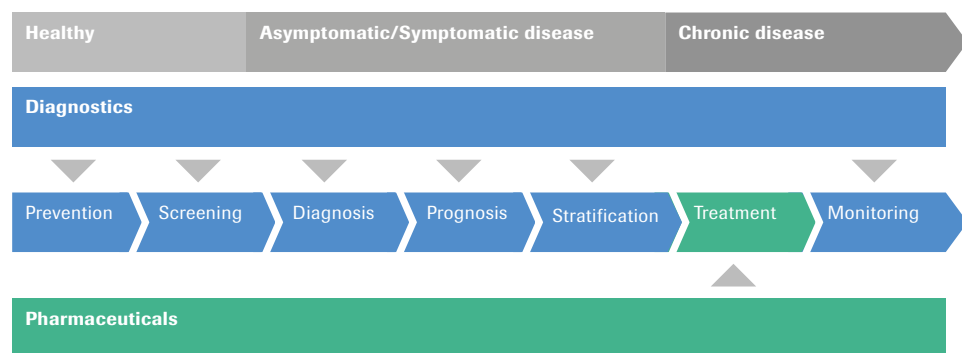
\*Roche Annual Report 2015/Roche HY 2016 sales report: “Today 27 % of Roche Pharma's sales are generated by products with a companion test on the label (Roche half-year sales 2016)”

## Our business strategy

*Differentiation with testing efficiency and medical value throughout the entire healthcare value chain*

In modern healthcare, in vitro diagnostics go far beyond simply telling a doctor whether a patient has a certain disease or not. Today, they are an integral part of

decision-making along the entire continuum of a patient's health or disease, enabling physicians to make full use of IVDs along the healthcare value chain.



*Today, IVDs are an integral part of decision-making along the entire continuum of a patient's health or disease, enabling physicians to make full use of IVDs along the healthcare value chain.*

## Roche Diagnostics commitment

*Providing innovation and excellence today and tomorrow*

### **We offer a pioneering partnership to make the maximum contribution to patient care**

As a leader in IVD solutions\*, we are your dedicated partner supporting you through our technologies for centralized and decentralized settings, in molecular and tissue testing as well as automation and IT solutions.

In a pioneering partnership we provide products that increase testing efficiency and to deliver medical value, whilst supporting you with our expert people worldwide.

Global and local expertise and dedicated service and support teams in over 130 countries are there to support you every step of the way. Our commitment and rich pipeline of differentiated solutions and technologies are there all the way to support you in providing improved patient care – today and also tomorrow.



\*Roche Market Book 2015

## Roche Diagnostics' areas of expertise

*Covering all in vitro diagnostic segments  
in all major healthcare areas*

Roche Diagnostics serves customers spanning the entire healthcare spectrum – from research institutions, hospitals and commercial laboratories to physicians and patients. Performed on blood, tissue or other patient samples, in vitro diagnostics are a critical source of objective information for improved disease management and patient care.

Roche Diagnostics offers the industry's broadest range of diagnostic tests\*. Our pioneering technologies and solutions not only help ensure an accurate diagnosis, they can detect the risk of disease, predict how a disease may progress, and enable the right treatment decision at the outset.

We help patients gain control over chronic conditions by enabling both physicians and patients to monitor treatment progress. And, through our successful collaboration with laboratories, we provide the fast and reliable results needed for life-changing decisions.



*“We are committed to delivering the best possible diagnostic solutions to improve people’s lives. Sustainable healthcare depends on diagnostics, and as the leader in the industry, we have the opportunity to shape healthcare delivery and to optimize resources in order to ultimately benefit society as a whole.”*

*Roland Diggelmann, COO Roche Diagnostics*

### We focus on all major healthcare areas

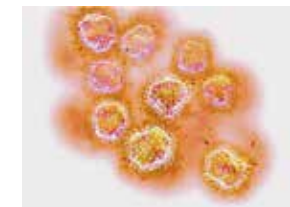
Oncology



Cardiology & metabolism



Infectious diseases



Blood safety



Women's health



Critical care

\*Roche Market Book 2015

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**Immunochemistry**  
*Clinical chemistry*  
**Laboratories**  
*IT solutions*  
**Elecsys**  
*SWA solutions*  
**cobas**  
*Pre- and post-analytics*

## Serum Work Area solutions

Laboratories have to manage critical workflow processes and provide uninterrupted service. Our **cobas**® platforms offer fully harmonized end-to-end solutions covering everything from sample entry to result reporting and archiving. With their scalable modular design, they can be customized to meet any laboratories needs.

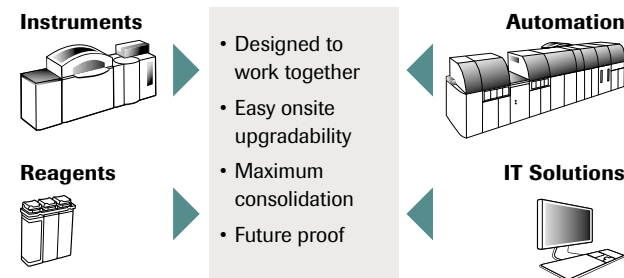
Roche's automated pre- and post-analytical solutions are integral to providing complete flexibility and process optimization. We offer a full array of stand-alone and networked solutions to meet all of your laboratories needs. From laboratory layout to full implementation of systems and services, you can get everything from a single source.

Roche's flexible **cobas IT** systems include middleware applications, laboratory information systems and hospital point-of-care solutions. They enable you to use your resources more effectively, while monitoring laboratory performance and increasing quality and confidence.

Our innovative and comprehensive test portfolio meets demands for workflow consolidation while also addressing previously unmet medical needs. Our ready to use reagents and our advanced assay technologies (Elecsys® ECL, DuREL) are the basis for high quality results, combined with proven workflow convenience.

An integrated solution combining IVD and IT reduces risk and complexity for your laboratory.

For more information please  
visit [www.cobas.com](http://www.cobas.com)



# cobas® modular platform

## Flexible family concept for tailor-made solutions



www.cobas.com



Today, laboratories are challenged to deliver reliable and high-quality diagnostics, while at the same time ensuring efficient analytical workflow. To meet these demands, Roche has developed the **cobas** modular platform. It is an intelligent and flexible solution based on a common architecture that delivers tailor-made solutions for diverse workload and testing requirements. The **cobas** modular platform is designed to reduce the complexity of laboratory operation and provide efficient and compatible solutions for network cooperation.

### Unique reagent concept for maximum handling convenience and minimal logistic efforts



No mixing  
No preparation



Ready to use  
Fail-safe



Easy logistics  
Minimal storage space

### Your benefit

#### Increased efficiency

- Consolidation of 98 % or more of Serum Work Area workload
- Consistent and predictable turnaround times for smooth laboratory operation
- Further enhanced automation through a broad offering of pre- and post-analytic and **cobas IT** solutions from Roche

#### Reduced complexity

- Ready-to-use reagents for maximum convenience of handling, minimal logistic effort and cost-effective operation
- Common look and feel of the user interface of on all systems for reduced training time and flexible staff allocation

#### Consistent and fast patient results

- Standardized results across the entire **cobas** modular platform ensured by using the same reagents
- 9 min. immunochemistry STAT assay for superior support of emergency samples

#### Reliable and future proven

- Proven Hitachi instrument reliability ensures maximum uptime for economic operation and reliable service to physicians
- Over 52,000 analytical units installed worldwide

### Product characteristics

- Flexible combinations of clinical chemistry (c) and immunochemistry (e) modules for Serum Work Area or dedicated immunochemistry/clinical chemistry solutions
- More than 110 assays and applications on the clinical chemistry platform, ready-to-use in **cobas c** packs
- More than 100 assays on the immunochemistry platform, ready-to-use in **cobas e** packs

#### cobas® 8000 modular analyzer series

Large volume



<c 702> <c 701> <c 502> <e 801> <e 602>

#### cobas 6000 analyzer series

Mid volume



<c 501> <e 601>

#### cobas 4000 analyzer series

Low volume



<c 311> <e 411>



>450 configurations



7 configurations



3 configurations



cobas®

# cobas<sup>®</sup> 8000 modular analyzer series

## Intelligent LabPower



www.cobas.com



The **cobas** 8000 modular analyzer series is the newest member of the Roche **cobas** modular platform family.

One **cobas** 8000 modular analyzer series configuration consists of up to 4 analytical modules and is built with a core unit, an optional ISE unit (**cobas** ISE module), a high volume throughput clinical chemistry module (**cobas c** 702 module, **cobas c** 701 module), a mid volume throughput clinical chemistry module (**cobas c** 502 module) a high throughput immunoassay module (**cobas e** 801 module) and a mid volume throughput immunoassay module (**cobas e** 602 module).

### Your benefit

#### Maximize productivity and efficiency

- Maximizes throughput and consolidation power without compromising workflow
- Manages peak times efficiently
- Improves sample turn around time and availability

#### Support best patient care

- Broad reagent menu and the high number of reagent channels onboard maximizes the testing consolidation power
- Patient single tube with low sample volume
- High quality reagents and reliable Hitachi systems create confidence in results
- Seamless STAT integration for short sample turn around time (TAT) and fast results availability

#### Grow sustainably

- Scalable tailor-made solutions with more than 450 configurations

- Easy and fast on-site expandability for highly efficient change management
- Connectivity to pre- and post-analytics allows integration and further automation for less variability and more predictability in the process, providing confidence in results

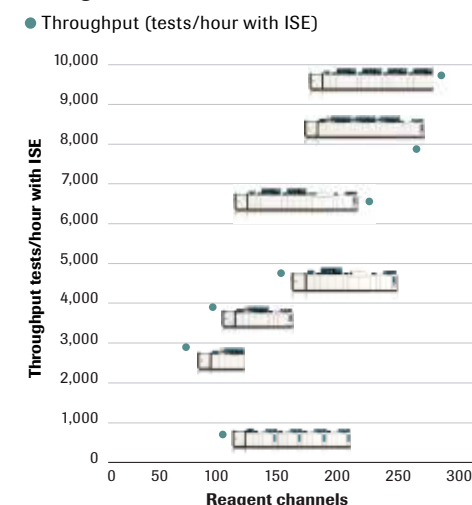
### Product characteristics

- High speed: From 170 to 1,200 immunoassay tests/hour and 2,000 to 9,800 clinical chemistry tests/hour depending on configurations
- Up to 280 reagent channels
- Multidimensional modularity: more than 450 configurations for tailored solutions with fast on-site expandability
- More than 120 clinical chemistry and more than 100 immunochemistry assays

Source: cobas 8000 Operator Manual.



### Some examples from possible configurations



cobas 8000 modular analyzer series

# cobas® 8000 modular analyzer series

## At a glance



### Core Unit

- Loading capacity of 300 samples (15 racks/tray, 5 samples/rack)
- Throughput of up to 1,000 samples/hour
- Dedicated STAT port
- Optional sample rotation unit



### cobas ISE module

- Sodium, potassium, chloride
- 900 or 1,800 tests/hour
- ISE specific sample probe with clot detection
- Independent processing line



### Module Sample Buffer (MSB)

- Capacity for 20 sample racks; additional capacity of 100 samples per module
- Environmental controlled compartment for 5 Auto QC racks
- Backup operation port
- Random access for the racks; racks can go from everywhere to everywhere



## Clinical Chemistry Modules

### cobas c 702 module

- Clinical chemistry, homogeneous immunoassays
- Throughput of up to 2,000 tests/hour
- 70 reagent channels
- Specimen integrity via serum indices, clot and liquid level detection
- Contact free ultrasonic mixing
- 2 sample probes
- 4 reagent probes
- Pipetting cycle time of 1.8 seconds



### cobas c 701 module

- Clinical chemistry, homogeneous immunoassays
- Throughput of up to 2,000 tests/hour
- 70 reagent channels
- Specimen integrity via serum indices
- Clot and liquid level detection for sample
- Foam and liquid level detection for reagent
- Contact free ultrasonic mixing
- 2 sample probes
- 4 reagent probes
- Pipetting cycle time of 1.8 seconds



### cobas c 502 module

- Clinical chemistry, homogeneous immunoassays, HbA1c (whole blood measurement)
- Throughput of up to 600 tests/hour
- 60 reagent channels
- Continuous reagent loading during operation
- Specimen integrity via serum indices
- Clot and liquid level detection for sample
- Foam detection and reagent volume control for reagent
- Contact-free ultrasonic mixing



### Reagent Manager

- 10 reagent positions
- Reagent RFID reader
- Continuous reagent loading during operation
- Automatic reagent cassette decapping
- Automatic reagent cassette unloading

## Immunoassay Modules

### cobas e 602 module

- Heterogeneous immunoassays
- Throughput of up to 170 tests/hour
- 25 reagent channels
- Carryover-free disposable tips
- Clot and liquid level detection for sample
- Foam and liquid level detection for reagent



### cobas e 801 module

- Heterogeneous immunoassays
- Throughput of up to 300 tests/hour
- 48 reagent channels
- Carryover-free disposable tips
- Clot and liquid level detection for sample
- Foam and liquid level detection for reagent



### Reagent Manager

- Reagent RFID reader
- Continuous reagent loading during operation
- Automatic reagent packs unloading

Source: Roche data on file.

# cobas® 6000 analyzer series

## The success story continues



www.cobas.com



The **cobas** 6000 analyzer series is a member of the **cobas** modular platform. It offers medium workload laboratories tailor made solutions for clinical chemistry and immunochemistry testing.

The more than 20,000 active modules are the best testimonial for the successful concept that perfectly fits customer needs.



### Your benefit

#### Increased efficiency

- Perfect fit of throughput and reagent channels achieved across the seven different configurations
- Consolidation of 98 % of the Serum Work Area testing
- Simplified lab processes and reduced costs

#### Quality of results

- High quality results by ensuring sample and result integrity (e.g. test-specific serum indices, disposable immunoassay tips and cups, and clot detection)
- Innovative tests on a standardized, automated platform

#### Maximum uptime

- Highly reliable system based on more than 35 years of experience
- High quality support provided by Roche organizations worldwide

#### Optimized workflow

- Consolidates more than 200 tests on one system
- Combines STAT with routine testing without disruption
- Sample Rotor Buffer for optimal sample routing and fast TAT
- Easy and fast on-site expandability

### Product characteristics

#### High system reliability

- More than 12,000 systems in operation worldwide
- Proactive automated maintenance for over 99 % uptime on a 24/7 base

#### Unique reagent concept

- No preparation and no mixing required, economic usage with high stabilities and convenient kit sizes

#### First class performance

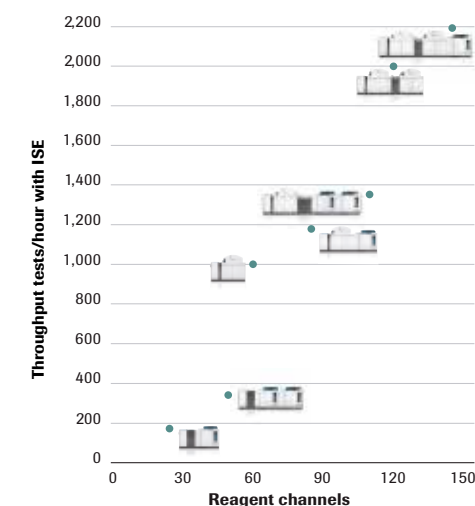
- State-of-the-art immunoassay testing using ECL technology
- High quality results by ensuring sample and result integrity

#### Professional management of lab processes

- Wide range of pre- and post-analytical solutions from small task target automation to total lab automation

### Delivers customized solutions for various work and testing requirements

● Throughput (tests/hour with ISE)



# cobas® 6000 analyzer series

## The success story continues



www.cobas.com



### True workflow consolidation

#### 1 Core unit

- Loading and unloading capacity of 150 samples
- Throughput of up to 600 samples/hour
- Dedicated STAT port
- Simple operation with continuous loading and unloading

#### 2 Rack rotor

- Capacity for 20 sample racks
- Freely definable STAT positions
- Option of three Auto QC racks
- Random access for the racks

#### 3 cobas c 501 module

- ISE measurements (K, Na, Cl)
- More than 110 assays and applications on the clinical chemistry platform including proteins, enzymes, DATs, TDMs, substrates and electrolytes
- HbA1c (whole-blood measurement)
- Throughput of up to 1,000 tests/hour
- 60 reagent channels directly accessible for pipetting
- Automatic reagent loading and unloading during operation



cobas 6000 analyzer series

- Specimen integrity via serum indices, clot and liquid level detection
- Foam and liquid level detection for reagent
- Contact-free ultrasonic mixing

#### 4 cobas e 601 module

- More than 100 assays on the immunochemistry platform including anemia, bone, tumor markers, hormones, cardiac and infectious diseases
- 9 min. STAT applications for hsTnT, TnI, CK-MB, NT-proBNP, Myoglobin, PTH and hCG
- Throughput of up to 170 tests/hour
- 25 reagent channels, directly accessible for pipetting
- Carryover-free disposable tips
- Clot and liquid level detection for sample
- Foam detection and reagent volume control for reagent

Just as every patient requires individualized care, every laboratory is unique. Striking a balance between high standards and efficient operation requires tailor-made solutions.

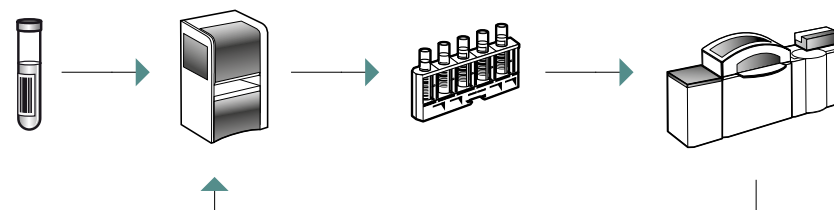
**cobas p 312 pre-analytical system is the ideal companion for the cobas® 6000 analyzer series, for a fully harmonized and complete solution.**



The **cobas p 312** pre-analytical system is a standalone solution offering maximum efficiency at a minimal space requirement. Through convenient sample loading, the **cobas p 312** is the ideal single point of entry for reducing complexity. Standardization through automation of laboratory process is key for fast and consistent results, while reducing errors.

The **cobas p 312** pre-analytical system executes the following key tasks:

- Sample registration at a single entry point
- Sorting and distribution of samples
- Recursive workflow
- Archiving



Source: Roche data on file.

# cobas® 4000 analyzer series

## *Freedom to realize your lab's potential*



www.cobas.com



The **cobas** 4000 analyzer series is a member of the **cobas** modular platform family and designed for laboratories processing 25,000 to 500,000 tests per year or 50 to 400 samples per day. It consists of the **cobas c 311** analyzer for clinical chemistry and the **cobas e 411** analyzer for immunochemistry testing. Together with **cobas infinity** standardized 3R (Request, Result, Reporting) solution and the ability to integrate the **cobas p 312** pre-analytical system, the **cobas** 4000 analyzer series provides a comprehensive Serum Work Area solution that brings workflow efficiency to the next level.

### Your benefit

#### Increased efficiency

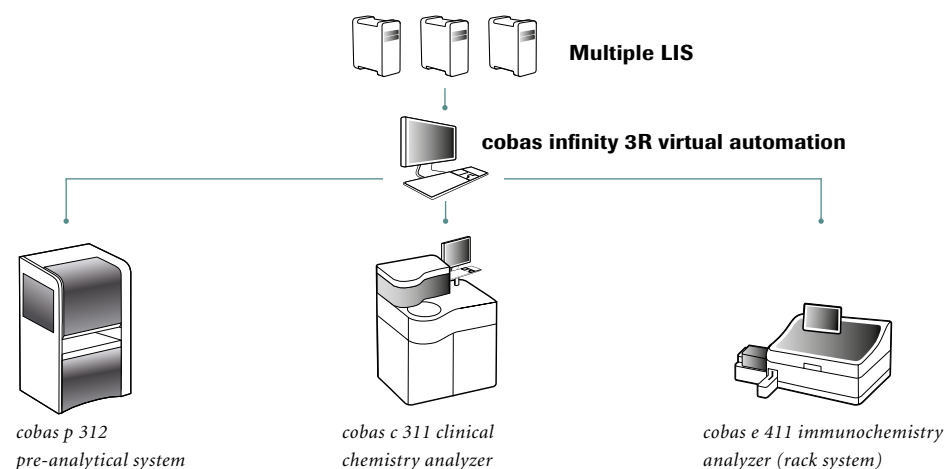
- Consolidation of 98% or more of Serum Work Area workloads

#### Maximum uptime

- Highly reliable system based on more than 35 years of experience
- Excellent support by Roche organizations worldwide

#### Quality of results

- Integrated safety features for results you can trust
- Predictable turn-around time



### Product characteristics cobas c 311 analyzer

#### First class performance

- More than 120 assays and applications available including DATs, TDMs, specific proteins and whole blood HbA1c
- Throughput: up to 300 tests/h; ISE: 150 samples/h (corresponding to 450 tests/h)

#### Intelligent sample workflow

- 108 sample positions with continuous random access and flexible STAT priority settings

#### Unique reagent concept

- Convenient handling of **cobas c** packs
- Economic usage with high stabilities and convenient kit sizes

#### High system reliability

- Programmable automated maintenance functionalities

### Product characteristics cobas e 411 analyzer

#### First class performance

- More than 100 assays available
- Throughput: up to 86 tests/h
- Superior immunoassay testing using ECL technology



- 9 min. STAT applications including Troponin, CK-MB, Myoglobin,  $\beta$ -hCG and PTH
- Disposable tips and cups for carryover-free sample pipetting

#### Intelligent sample workflow

- 75 sample positions (rack system)
- 30 sample positions (disk system)
- Continuous random access and flexible STAT priority settings

#### Unique reagent concept

- Convenient and error-free handling of **cobas e** packs
- Economic usage with high stabilities and convenient kit sizes

#### High system reliability

- More than 15,000 analyzers installed worldwide
- High uptime of 99.8%

Source: Roche data on file.

# cobas c 111 analyzer

*Small box. Big performance.*



www.cobas.com



The **cobas c 111** analyzer is the smallest member of the **cobas**<sup>®</sup> serum work area platform family and the ideal solution for clinical chemistry testing in laboratories running ten to 50 samples per day. With a comprehensive test menu and easy integration of STAT samples, it can support testing of both routine clinical chemistry panels and rapid turnaround critical care markers. In addition, the **cobas c 111** analyzer uses the same reagent formulations as the larger **cobas** clinical chemistry analyzers. This standardizes patient results, which is vital to integrated laboratory networks serving outpatient services, emergency departments and clinics, as well as private laboratories serving primary care physicians.



cobas c 111 analyzer

## Your benefit

### High quality of results

- Comprehensive testing capabilities
- Results you can trust

### Increased efficiency

- Essential routine testing on a small footprint
- Simplified system operation

### Maximum uptime

- Highly reliable system delivering > 99 % uptime<sup>1</sup>
- Excellent support provided by Roche organizations worldwide

### Optimized workflow

- Reducing complexity for a range of laboratories, both networked or standalone
- Consistent results across the **cobas** platform

## Product characteristics

### World-class performance

- More than 40 assays and applications available including whole blood HbA1c, hsCRP, and D-dimer
- Externally rated world-class performance<sup>2</sup>

### Good fit for labs <50 samples/day

- Throughput of up to 100 tests/hour
- Compact benchtop system for labs with limited floor space
- Easy, intuitive software handling

### High system reliability

- Robust system design
- Wizard-guided maintenance procedures
- More than 5,500 analyzers installed worldwide

### Network compatibility

- Ability to connect to local IT environment
- Common reagent chemistry across the **cobas**<sup>®</sup> platform



<sup>1</sup> Roche data on file.

<sup>2</sup> Bowling, J.L., Katayev, A. (2010). *Labmedicine*, 41(7): 398-402.

# COBAS INTEGRA® 400 plus

## *The specialist in the routine laboratory*



[www.cobas.com](http://www.cobas.com)



The COBAS INTEGRA 400 plus analyzer is the perfect solution for laboratories running 50 to 400 samples per day. Its broad test menu comprises over 120 assays and applications that consolidate clinical chemistry with specific proteins, therapeutic drug monitoring and drug abuse testing. This compact tabletop analyzer offers maximum versatility to improve efficiency and reduce costs. It uses the convenient **cobas c** pack reagent format, which standardizes patient results across integrated laboratory networks.

### Your benefit

#### High quality of results

- Results you can trust

#### Increased efficiency

- Comprehensive testing capabilities on a compact footprint
- Simplified processes and reduced costs

#### Optimized workflow

- Consistent results across the **cobas**® platform

### Product characteristics

#### First class performance

- More than 110 assays and applications available including clinical chemistry, specific proteins, TDMs, DATs and whole blood HbA1c

#### Good fit for labs processing

##### 50 to 400 samples/day

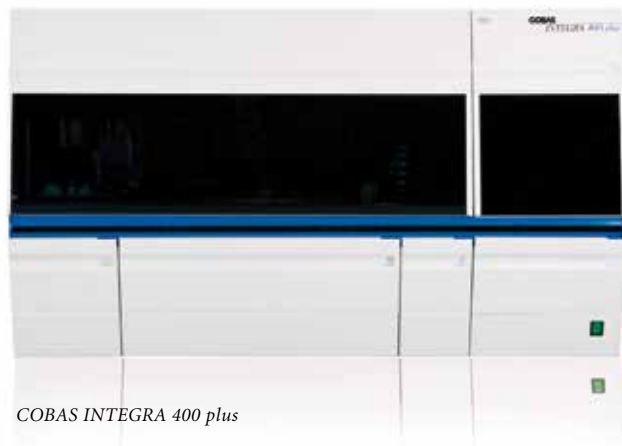
- Throughput of up to 400 tests/hour
- Compact benchtop system for labs with limited floor space

#### High system reliability

- Robust system design
- Clot detection and accurate pipetting
- More than 6,000 analyzers installed worldwide

#### Unique reagent concept

- Convenient handling of **cobas c** packs
- Economic usage with high stabilities and convenient kit sizes



COBAS INTEGRA 400 plus

# cobas c 513 analyzer

## *Setting a new precedent in HbA1c lab efficiency*



www.cobas.com



The prevalence of patients with diabetes has been significantly increasing in recent years and is anticipated to rise by a further 55% until 2040.<sup>1</sup> Managing the resulting growth of HbA1c testing volume is putting a strain on healthcare providers.

The **cobas c 513** analyzer is a dedicated high throughput HbA1c solution designed to cope with this increasing HbA1c testing volume. The analyzer offers a fully automated and highly efficient workflow by delivering up to 400 patient results per hour, yet requiring minimized operator intervention from sample registration to result delivery. Its closed tube sampling function delivers maximum safety to the operator.

The **cobas c 513** analyzer runs Roche's established Tina-quant® HbA1c Gen.3 test which is standardized according to IFCC and transferable to DCCT/NGSP in order to ensure high quality and standardized results. With no interference by most known HbA1c variants, Roche's Tina-quant HbA1c assay delivers accurate risk identification, diagnosis and monitors the level of HbA1c delivering results that clinicians and patients can trust.

### Your benefit

#### **Manages high HbA1c workload**

- Up to 400 HbA1c patient results/hour

#### **Fully automated and highly efficient workflow**

- Minimized operator intervention from sample registration to result delivery
- Closed tube sampling delivers maximum safety to the operator

#### **Result reliability**

- Standardized according to IFCC and transferable to DCCT/NGSP
- Delivers risk identification, diagnosis and monitors the level of HbA1c

### Product characteristics

#### **Analyzer**

- High throughput of up to 400 HbA1c patient results/hour
- Test capacity of >14,000 determinations on board
- Closed tube sampling
- No need for sample pre-mixing
- Proven and trusted **cobas** technology
- **cobas** link for remote services

#### **Reagents**

- Ready to use **cobas c** pack large
- Tina-quant® HbA1c Gen.3
- Standardized according to IFCC transferable to DCCT/NGSP
- Direct result reporting (in IFCC and NGSP units)



<sup>1</sup> Prediabetes. CDC Web Site.  
<http://www.cdc.gov/diabetes/prevention/prediabetes.htm>.  
Accessed March 17, 2015.

# Automation & IT solutions

## Personalized Lab Automation

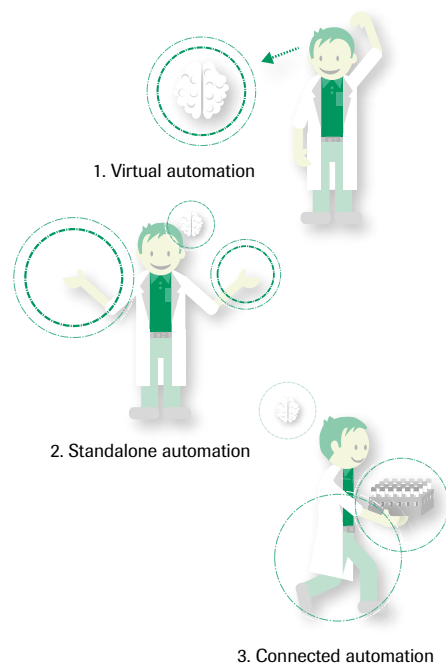


www.cobas.com



At Roche, laboratory automation solutions deliver the **quality** and **reliability** you expect, with the **personalization** required by low-, mid- and high-volume laboratories.

With a complete portfolio in the market, Roche's Personalized Lab Automation provides customized solutions for every lab.



3 Levels of Automation

### 1. Virtual automation

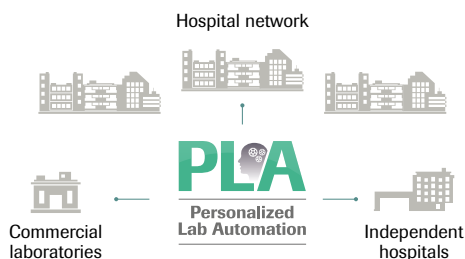
To have the control you need, ensuring quality and efficiency across your lab, virtual automation gives you the capability to track your samples and reduce manual tasks through **cobas IT** solutions.

### 2. Standalone automation

Pre- and post-analytical tasks are automated, offering maximum efficiency through flexible standalone solutions. It significantly reduces manual steps in the lab, enhancing error handling, safety and process quality.

### 3. Connected automation

In addition to having all the benefits of standalone automation, connected automation offers transportation. Physically connecting different instruments allows for maximum predictability of time to test results.



Customized solutions for every lab

### 1. Virtual automation

#### cobas middleware solutions

Workflow manager for your laboratory, consolidating Roche instruments, third-party instruments and host systems to enable efficient sample and data flow

#### cobas® infinity IT solutions

Scalable IT solution that goes beyond workflow management and operates across various lab disciplines. It provides modules from connectivity, work area management and extended laboratory IT functionality

### 2. Standalone automation

#### cobas p 312 pre-analytical system

Maximum efficiency in a minimal space. A compact solution with single point of entry for all lab disciplines, sorting, decapping and archiving IVD test tubes

#### cobas p 512/p 612 pre-analytical systems

High throughput solutions for sorting, decapping, extensive sample quality inspection, aliquoting, and re-capping of IVD test tubes

#### cobas p 501/p 701 post-analytical units

Refrigerated archiving systems enabling automated sample retrieval and add-on test management

### 3. Connected automation

#### cobas® 8100 automated workflow series

Fully automated solution featuring intelligent sample routing and prioritizing STAT workflow

#### cobas® connection modules (CCM)

Designed for high throughput labs. Connection of flexible pre-analytical systems to analytical and post-analytics systems through a fast track

# cobas® middleware solutions

## *Intelligent workflow management for your laboratory*

**cobas** middleware solutions are the workflow manager for your laboratory, consolidating Roche instruments, third-party instruments and host systems to enable efficient sample workflows. Different IT solutions are available to meet regional customer needs (**cobas IT** middleware & **cobas**® infinity IT solutions).\*

The intuitive automated validation and quality control tools reduce operator intervention, while allowing laboratory production to be monitored through real-time dashboards.

### Your benefit

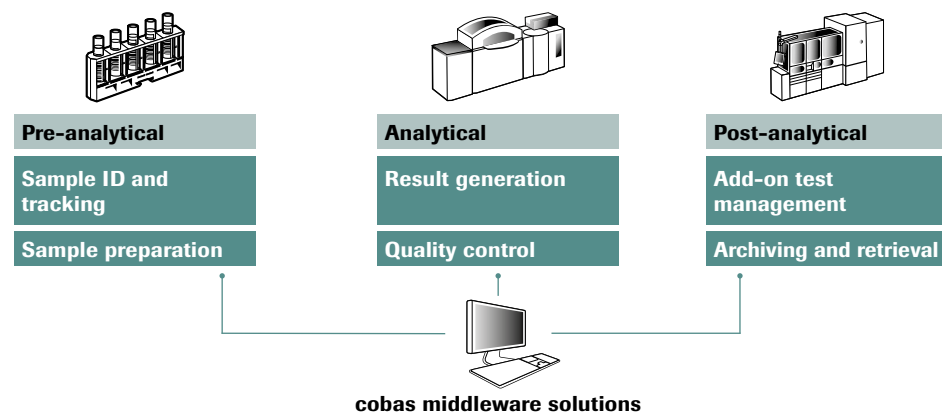
#### Effective use of your resources

- Manage your laboratory instruments and the people that use them from a single application
- Expert system allows you to focus on critical information

#### Improve quality performance

- High level of traceability and transparency through audit trail for each sample
- Support to achieve compliance with regulations

### Intelligent workflow management for your laboratory



### Easily accessible management information

- Task-oriented for proactive exception management
- Sample archive management for automated or manual post-analytical phase

### Save time and reduce duplication of effort

- Configurable automated validation with multiple levels of expertise ensuring reproducible outcome
- Task-oriented and easy-to-use user interface

### Efficient workflows for today and the future

- Connects multiple instruments and softwares, multiple LIS from multiple sites
- Scalable to follow the growth of your organization
- Automated or manual pre-analytics and post-analytics with complete traceability

### Helping to improve your quality processes

- Quality control management including multi-rules and drift control

\*Please check with your local Roche representative for availability of the IT solution in your country.



# cobas® infinity IT solutions

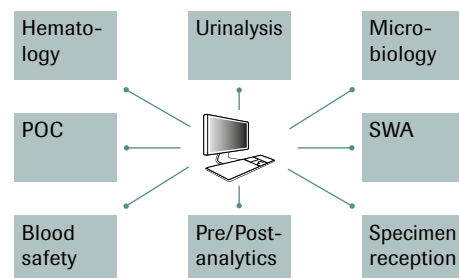
*One expert package to empower all of your expertise*



www.cobas.com

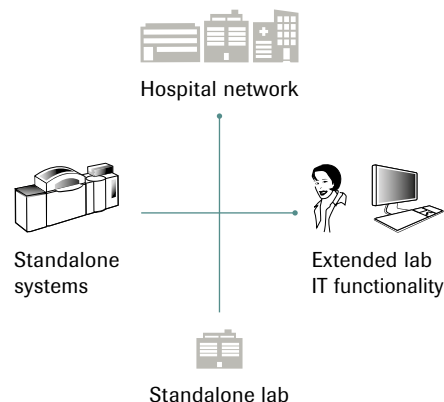


**cobas infinity** IT solutions is a web-based application with scalable modules that are designed to manage complex lab processes and give sample testing and result data an efficient and transparent flow. It automates the three main areas of lab operations: pre-analytics, analytics and post-analytics; but also extends beyond the lab to ordering, blood collection validation and reporting.



*Flexible intelligence across lab disciplines and POC and work areas.*

**cobas infinity** IT solutions enables a paperless workflow, and is structured around work areas that focus on the tasks in hand. The unique workflow engine removes the need to write complex rules to manage the sample automation. Autovalidation enables efficient result management, and integrated quality management tools organize the quality process to support accreditation.



*One decision for all choices – scalable to your needs again and again.*

## Your benefit

### Right solution for every environment

- Specialized modules designed for different test disciplines – matching the structure and processes of different areas of the laboratory. It helps automate many manual tasks and optimizes productivity
- Scalable and expandable for every kind of laboratory, now and in the future



### Makes work flow

- The unique workflow engine drives sample and data flow, streamlining job tasks and optimizing all process steps in the different levels of automation
- Consistent look and feel across all user interfaces help staff learn quickly and enables better communication in and across disciplines including Point of Care
- Designed for easy of use on PC's, tablets and mobile phones to see whats important and act fast- from wherever you are

- A comprehensive Integrated Quality Management tool that not only manages assay performance but also enables your organization to improve overall quality processes supporting accreditation



*Designed to be easy to use, everywhere.*

### Dynamic production monitoring

- Real time information for timely decision-making with the live view tool
- The Insights module retrieves retrospective accessible data from all process steps and turns the unsorted data into meaningful statistical reports to demonstrate lab performance

# cobas® infinity IT solutions

*One expert package to empower all of your expertise*



www.cobas.com



## cobas infinity central lab

- Empowering lab experts to manage complex processes
- Designed for labs to manage complex sample testing and result data flows in an efficient and transparent way

## cobas infinity central lab – 3R

- Standardized for request, result, and reporting in small labs
- Pre-configured central lab module for smaller labs for simple set-up with basic functionalities

## cobas infinity microbiology

- Turns testing complexity into efficient workflow
- Designed for work area and processes specific for microbiology. It offers management of cultures, related biochemical testing and anti-biotic susceptibility

## cobas infinity total quality management

- Empowering management of a high level quality culture
- Designed for proactive documentation-, issues-, indicators- and audits management to achieve and maintain accreditation

## cobas infinity live view

- See what's important
- Shares real time information for lab technicians and lab managers on PC, tablets and mobile devices. While out of the office, laboratory users can access valuable real-time information on turnaround time, sample load and delayed samples in a core lab

## cobas infinity insights

- Demonstrate your value as a trusted partner
- Designed to turn objective lab statistics into meaningful information to improve process performance and understand the value of the lab

## cobas infinity lab link

- Links health care professionals to your lab, from order to result
- Connects customers with the lab to streamline interactions when ordering tests, checking patient results and automating the collection process for phlebotomists

## cobas infinity POC tablet

- Move and work
- A tablet app designed to help POC Coordinators (POCCs) manage their complete POC testing program whilst moving around
- The app enables POC Coordinators to realise the full potential of working with a tablet, allowing them to become really efficient

## cobas infinity POC mobile

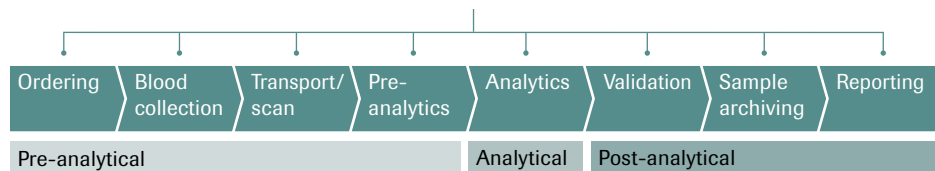
- Always with you
- A mobile application designed for POC coordinators in hospitals to keep control and act on what is important while away from their PCs

## cobas infinity blood safety

- Part of the Roche Blood Safety Solutions
- Optimizing process management and monitoring
- Designed to increase workflow efficiency by optimizing the specific work area processes of the blood donor testing environment



### cobas infinity central lab



*Manages more than the complexity of lab operations.*

# Standalone and connected automation

## Personalized solutions for every lab



[www.cobas.com](http://www.cobas.com)



*Standalone automation offers maximum efficiency through flexible solutions that automate pre- and post-analytical steps in the laboratory*

### Your benefit

#### Quality comes first

At an early pre-analytical stage, the automation solutions from Roche perform a comprehensive inspection of sample quality and volume, maximizing an overall optimization of lab workflow through:

- Early error detection
- Reduced workload and reagents waste
- Shortest time to consistent results

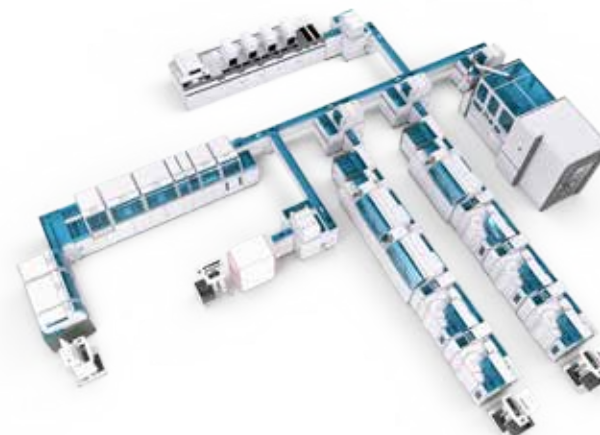
#### Workflow your way

Personalized workflows enable you to choose from primary, aliquot or mixed workflow

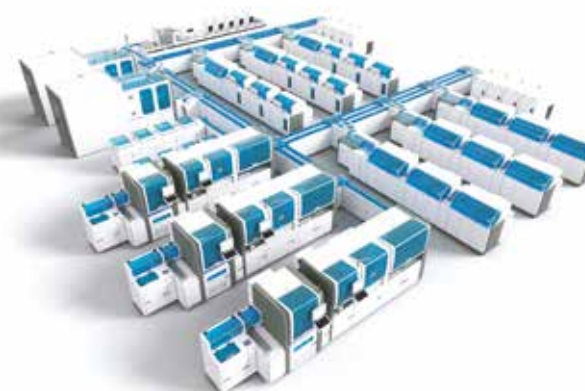
- Primary sample workflow – if the focus is on cost efficiency
- Aliquot workflow – if the focus is on sample integrity and parallel testing
- Mixed workflow – to optimize the benefits of both

#### Short and predictable time to results

- Improving patient care by offering reliable results within predictable short turnaround time, even during peak workflows



*Connected automation, besides having all the benefits of standalone automation, adds transportation by physically connecting pre-analytics, analytics and post-analytics*



*Connected automation solution for high volume laboratories offering industry leading throughput, increasing efficiency and performance while remaining scalable guaranteeing business continuity.*

# cobas p 512 and cobas p 612 pre-analytical systems

*Adapting to today's needs.*

*Flexible for tomorrow's demand.*

Evolution of **cobas p** 512/612 pre-analytical systems – new and innovative standalone solutions for high throughput laboratories. **cobas p** 612 differs from **cobas p** 512 system due to the aliquot functionality.

These standalone automation solutions are validated for cross-contamination compliance and therefore may be used to automate and simplify processes in clinical laboratories and blood banks.

## Your benefit

### Innovation

The best answer to face emerging challenges in laboratory operations.

- Upgradable to connected automation
- Easy to add functionalities
- Comprehensive inspection of sample quality
- Increased productivity in the same footprint

### Quality comes first

The new generation of **cobas p** 512/612 systems perform a comprehensive inspection of samples at an early stage, optimizing the lab workflow and ensuring the best use of time and resources.

- Tube type identification
- Sample volume check
- Spin status detection
- Sample quality check

### Flexibility

Adapts to the lab's sample handling needs.

- A solution compatible with all lab disciplines
- Adapted sorting areas to your workflow to stay flexible
- Single point of entry and bulk loading of tubes for convenient sample loading
- Long walk-away time



cobas p 512 pre-analytical system



www.cobas.com



## Product characteristics

- Freely definable input and output sorting areas
- Input with capacity of 600 samples and output of 1,200 samples
- Connection to a bulk loader
- Connection to single or double centrifuge
- Handling of Roche and non-Roche racks and centrifuge buckets
- Throughput up to 1,400 samples/hour
- Registration of primary samples
- Orientation of barcode in a "good-to-read" position
- Tube type identification
- Sample volume and quality check

- Spin status detection:  
Detects if blood samples have been already centrifuged or not
- Early detection and sorting of tubes with errors and issues
- Selective decapping of sample tubes
- **cobas p** 612 system includes an aliquoting section with barcode labelling of secondary tubes
- Sorting of tubes directly into analyzers target racks
- Archiving of processed samples with optional recapping
- Upgradeability to connected automation

Source: Specifications sheet cobas p 512/612.



Complete configuration: cobas p 612 pre-analytical system with single centrifuge cobas p 471 and bulk loader module

## cobas p 312 pre-analytical system

*Compact automation for maximum efficiency*

**cobas p 312** pre-analytical system is a standalone solution offering maximum efficiency with minimal space requirements. In less than 1 m<sup>2</sup>, **cobas p 312** pre-analytical system can be used for decapping, sorting and archiving IVD test tubes.

May be used to automate and simplify processes in clinical laboratories and blood banks. This compact standalone solution is validated for cross-contamination compliance.

### Product characteristics

- Compact automation in less than 1 m<sup>2</sup>
- Throughput up to 450 samples/hour
- Registration of samples
- Selective decapping of samples
- Archiving of samples
- Flexible and freely definable input/output sorting area
- Traceability and control of lab process



*cobas p 312 pre-analytical system*

## cobas p 501 and cobas p 701 post-analytical units

*The automated archive*



[www.cobas.com](http://www.cobas.com)

### Product characteristics

- Can be operated as standalone or connected to **cobas**® 8100 and **cobas** connection modules
- Storage throughput: up to 950 tubes/hour
- Retrieval throughput: up to 70 tubes/hour (retrieval, without influence on storage throughput)
- Anytime easy access of samples due to the walk-in refrigerator area
- Storage capacity:
  - cobas p 501**: 13,500 tubes
  - cobas p 701**: 27,000 tubes
- Retrieval of samples within three minutes after ordering



- Identification of primary sample tubes
- Automated storage, disposal and retrieval of sample tubes
- Selective recapping of tubes for storage
- Selective decapping of tubes for retrieval

*Source: Operator Manual for cobas p 501/701.*



*cobas p 501 post-analytical unit*



*cobas p 701 post-analytical unit*

# cobas® 8100 automated workflow series

## 3-D intelligence in lab automation



www.cobas.com



**cobas** 8100 intelligent tube transport provides a short predictable time to results, including prioritization for emergency samples. With flexible workflows, early error detection and fully automated add-on handling, **cobas** 8100 allows for personalized solutions to suit individual laboratory needs, guaranteeing that quality comes first.

**cobas** 8100 covers the needs of high-throughput laboratories achieving 1,100 samples/hour. Designed with options for connectivity to Serum Work Area analyzers, hematology, coagulation, selective third-party analyzers and archiving, **cobas** 8100 fully automates the laboratory process from beginning to end.

### Your benefit

#### Quality comes first

At an early pre-analytical stage, Roche automation solutions check the sample quality and volume, maximizing workflow efficiency.

- Early error detection
- Reduced workload
- No reagent waste

#### Workflow your way

Personalized workflows enable you to choose from primary, aliquot or mixed workflow.

- Primary sample workflow – if the focus is on cost efficiency
- Aliquot workflow – if the focus is on sample integrity and parallel testing
- Mixed workflow – to optimize the benefits of both

#### Short and predictable time to results

- 3D intelligent tube transport improves patient care by offering reliable results within predictably short turnaround times, even during peak workflows
- Multi-level and bidirectional tube transport: empty tube holders and holders with tubes run separately to avoid traffic jams
- Tubes always have a clear destination and do not circle the track, guaranteeing first-in first-out sample processing
- Tubes can bypass modules if processing is not required
- Prioritized STAT workflow

#### Flexible tube storage

A solution with **cobas** 8100 offers 3 storage concepts, ensuring fast access as soon as a tube is needed.

- Short-term storage for an immediate re-run
- Mid-term storage in the Add-on Buffer Module – for optimized add-on request processing within the same day
- Long-term storage



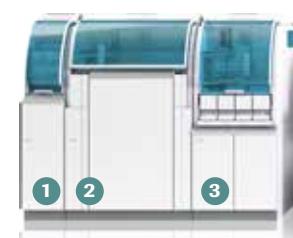
Solution with cobas 8100 automated workflow series

### Product characteristics

**cobas**® 8100 is made up of three stations: output, input and aliquot stations. Each station can be configured according to the number of samples and individual laboratory

needs in order to optimize the required workflow now. In the future, it can easily grow as needed.

#### Output station



- ① Restopper flex-cap/screw cap
- ② Add-on/output buffer
- ③ Output buffer/sorter
- ④ Input buffer
- ⑤ Automatic centrifuge unit

#### Input station



- ⑥ Sample check module
- ⑦ Destopper
- ⑧ Barcode labeler/tube feeder
- ⑨ Aliquot module

#### Aliquot station



**cobas**®

# cobas® connection modules (CCM)

## *Everything designed to work together as one*



www.cobas.com



**cobas** connection modules allow the connection of the standalone automation systems, **cobas p 512** and **cobas p 612**, to analytics and post-analytics through a fast track.

You can still take advantage of the huge flexibility of the standalone automation concept, while adding predictability of time to results by getting connected through **cobas**® connection modules.

### Your benefit

#### Multidisciplinary connectivity

- Serum Work Area – **cobas**® 6000/8000 analyzer series, MODULAR ANALYTICS
- Hematology – Sysmex HST/XN-9000 hematology analyzers
- Coagulation – Stago STA-R Evolution® Expert Series System and Stago STA-R Max® System
- Urinalysis – **cobas**® 6500 urine analyzer series
- Molecular Diagnostics – **cobas**® 6800/8800 system
- Post-analytics – **cobas p** 501/701 post-analytical unit

#### Quality comes first

CCM performs a comprehensive inspection of samples at an early stage, optimizing the lab workflow and ensuring the best use of time and resources.

- Tube type identification
- Sample volume check
- Spin status detection
- Sample quality check

#### Workflow your way

Personalized workflows enable you to choose from primary, aliquot or mixed workflow.

- Primary sample workflow – if the focus is on cost efficiency
- Aliquot workflow – if the focus is on sample integrity and parallel testing
- Mixed workflow – to optimize the benefits of both workflows

#### Flexibility

Adapts to the lab's sample handling needs.

- A solution compatible with all lab disciplines
- Single point of entry and bulk loading of tubes for convenient sample loading

- Adapted sorting areas to your workflow to stay flexible. Automates sorting areas also for non-connected work areas
- Long walk-away time
- Flexibility of layouts with the possibility to easily adapt for future changes

### Possible solutions

#### The fast track to sample flow efficiency

**cobas** connection modules connects pre-analytical system to multidisciplinary targets streamlining and optimizing laboratory processes.

**cobas** connection modules is a connected automation solution validated for cross-contamination compliance and therefore may be used to automate and simplify processes in clinical laboratories and blood banks.



Please note that not all versions are distributed in all countries. For further details contact your local affiliate.

# Overview of Serum Work Area tests



www.cobas.com



|                                        | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module | COBAS INTEGRA®<br>400 plus |
|----------------------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| <b>Anemia</b>                          |                         |                                      |                                     |                            |
| Ferritin                               |                         | •                                    | •                                   | •                          |
| Folate                                 |                         |                                      | •                                   |                            |
| Folate RBC                             |                         |                                      | •                                   |                            |
| Iron                                   | •                       | •                                    |                                     | •                          |
| Iron binding capacity<br>– Unsaturated |                         | •                                    |                                     | •                          |
| Soluble transferrin receptor           |                         | •                                    |                                     | •                          |
| Transferrin                            |                         | •                                    |                                     | •                          |
| Vitamin B12                            |                         |                                      | •                                   |                            |
| Active B12 <sup>7</sup>                |                         |                                      | •                                   |                            |
| Lactate Dehydrogenase                  | •                       | •                                    |                                     | •                          |
| <b>Bone</b>                            |                         |                                      |                                     |                            |
| Calcium                                | •                       | •                                    |                                     | •                          |
| N-MID Osteocalcin                      |                         |                                      | •                                   |                            |
| P1NP                                   |                         |                                      | •                                   |                            |
| Phosphorus                             | •                       | •                                    |                                     | •                          |
| PTH                                    |                         |                                      | •                                   |                            |
| PTH (1-84)                             |                         |                                      | •                                   |                            |
| β-CrossLaps                            |                         |                                      | •                                   |                            |
| Vitamin D total                        |                         |                                      | •                                   |                            |
| <b>Cardiac</b>                         |                         |                                      |                                     |                            |
| Apolipoprotein A1                      |                         | •                                    |                                     | •                          |
| Apolipoprotein B                       |                         | •                                    |                                     | •                          |
| Cholesterol                            | •                       | •                                    |                                     | •                          |
| CK                                     | •                       | •                                    |                                     | •                          |
| CK-MB                                  | •                       | •                                    |                                     | •                          |
| CK-MB (mass)                           |                         |                                      | •                                   |                            |
| CK-MB (mass) STAT                      |                         |                                      | •                                   |                            |
| CRP hs                                 | •                       | •                                    |                                     | •                          |
| Cystatin C                             |                         | •                                    |                                     | •                          |
| D-Dimer                                | •                       | •                                    |                                     | •                          |
| Digitoxin                              |                         | •                                    | •                                   | •                          |
| Digoxin                                |                         | •                                    | •                                   | •                          |
| GDF-15                                 |                         |                                      | •                                   |                            |
| HDL Cholesterol direct                 | •                       | •                                    |                                     | •                          |
| Homocysteine                           |                         | •                                    |                                     | •                          |
| Hydroxybutyrate<br>Dehydrogenase       |                         | •                                    |                                     | •                          |
| LDL Cholesterol direct                 | •                       | •                                    |                                     | •                          |
| Lipoprotein (a)                        |                         | •                                    |                                     | •                          |
| Myoglobin                              |                         | •                                    | •                                   | •                          |
| Myoglobin STAT                         |                         |                                      | •                                   |                            |
| NT-proBNP                              |                         |                                      | •                                   |                            |
| NT-proBNP STAT                         |                         |                                      | • <sup>1</sup>                      |                            |
| Troponin I                             |                         |                                      | • <sup>1</sup>                      |                            |
| Troponin I STAT                        |                         |                                      | •                                   |                            |
| Troponin T hs                          |                         |                                      | •                                   |                            |
| Troponin T hs STAT                     |                         |                                      | •                                   |                            |
| <b>Coagulation</b>                     |                         |                                      |                                     |                            |
| AT III                                 |                         | •                                    |                                     | •                          |
| D-Dimer                                | •                       | •                                    |                                     | •                          |

<sup>1</sup> Not on cobas e 411

<sup>4</sup> Not on cobas e 801

<sup>7</sup> In development

<sup>2</sup> Not on cobas c 311

<sup>5</sup> Only on cobas e 801

<sup>3</sup> Not on cobas c 701 or 702

<sup>6</sup> Only on cobas c 501 or 502

|                                 | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module | COBAS INTEGRA®<br>400 plus |
|---------------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| <b>Drugs of Abuse Testing</b>   |                         |                                      |                                     |                            |
| Amphetamines (Ecstasy)          |                         | •                                    |                                     | •                          |
| Barbiturates                    |                         | •                                    |                                     | •                          |
| Barbiturates (Serum)            |                         |                                      |                                     | •                          |
| Benzodiazepines                 |                         | •                                    |                                     | •                          |
| Benzodiazepines (Serum)         |                         |                                      |                                     | •                          |
| Cannabinoids                    |                         | •                                    |                                     | •                          |
| Cocaine                         |                         | •                                    |                                     | •                          |
| Ethanol                         |                         | •                                    |                                     | •                          |
| LSD                             |                         | • <sup>2</sup>                       |                                     | •                          |
| Methadone                       |                         | •                                    |                                     | •                          |
| Methadone metabolites<br>(EDDP) |                         | •                                    |                                     | •                          |
| Methaqualone                    |                         | •                                    |                                     | •                          |
| Opiates                         |                         | •                                    |                                     | •                          |
| Oxycodone                       |                         | • <sup>3</sup>                       |                                     | •                          |
| Phencyclidine                   |                         | •                                    |                                     | •                          |
| Propoxyphene                    |                         | •                                    |                                     | •                          |
| <b>Endocrinology</b>            |                         |                                      |                                     |                            |
| Amylase – pancreatic            | •                       | •                                    |                                     | •                          |
| Amylase – total                 | •                       | •                                    |                                     | •                          |
| ACTH                            |                         |                                      | •                                   |                            |
| Anti-Tg                         |                         |                                      | •                                   |                            |
| Anti-TPO                        |                         |                                      | •                                   |                            |
| Anti-TSH-R                      |                         |                                      | •                                   |                            |
| Calcitonin                      |                         |                                      | •                                   |                            |

Please check with your local Roche representative for availability of the assays and tests in your country.

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|----------------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| Cortisol                         |                         |                                      | •                                   |                            |
| C-Peptide                        |                         |                                      | •                                   |                            |
| FT3                              |                         |                                      | •                                   |                            |
| FT4                              |                         |                                      | •                                   |                            |
| hGH                              |                         |                                      | •                                   |                            |
| Hydroxybutyrate<br>Dehydrogenase |                         | •                                    |                                     | •                          |
| IGF-1 <sup>7</sup>               |                         |                                      | •                                   |                            |
| Insulin                          |                         |                                      | •                                   |                            |
| Lipase                           | •                       | •                                    |                                     | •                          |
| PTH STAT                         |                         |                                      | •                                   |                            |
| T3                               |                         |                                      | •                                   |                            |
| T4                               |                         |                                      | •                                   | •                          |
| Thyroglobulin (TG II)            |                         |                                      | •                                   |                            |
| Thyroglobulin confirmatory       |                         |                                      | •                                   |                            |
| TSH                              |                         |                                      | •                                   |                            |
| T-uptake                         |                         |                                      | •                                   | •                          |
| <b>Fertility</b>                 |                         |                                      |                                     |                            |
| Anti-Müllerian Hormone           |                         |                                      | •                                   |                            |
| DHEA-S                           |                         |                                      | •                                   |                            |
| Estradiol                        |                         |                                      | •                                   |                            |
| FSH                              |                         |                                      | •                                   |                            |
| hCG                              |                         |                                      | •                                   |                            |
| hCG plus beta                    |                         |                                      | •                                   |                            |
| LH                               |                         |                                      | •                                   |                            |
| Progesterone                     |                         |                                      | •                                   |                            |



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|-----------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| Prolactin                   |                         |                                      | •                                   |                            |
| SHBG                        |                         |                                      | •                                   |                            |
| Testosterone                |                         |                                      | •                                   |                            |
| <b>Hepatology</b>           |                         |                                      |                                     |                            |
| Alkaline phosphatase (IFCC) | •                       | •                                    |                                     | •                          |
| ALT/GPT with Pyp            | •                       | •                                    |                                     | •                          |
| ALT/GPT without Pyp         | •                       | •                                    |                                     | •                          |
| Ammonia                     | •                       | •                                    |                                     | •                          |
| AST/GOT with Pyp            | •                       | •                                    |                                     | •                          |
| AST/GOT without Pyp         | •                       | •                                    |                                     | •                          |
| Bilirubin – direct          | •                       | •                                    |                                     | •                          |
| Bilirubin – total           | •                       | •                                    |                                     | •                          |
| Cholinesterase Acetyl       |                         | • <sup>3</sup>                       |                                     |                            |
| Cholinesterase Butyryl      |                         | •                                    |                                     | •                          |
| Gamma Glutamyl Transferase  | •                       | •                                    |                                     | •                          |
| Glutamate Dehydrogenase     |                         | •                                    |                                     | •                          |
| HBeAg                       |                         |                                      | •                                   |                            |
| HBsAg                       |                         |                                      | •                                   |                            |
| Lactate Dehydrogenase       | •                       | •                                    |                                     | •                          |
| <b>Infectious diseases</b>  |                         |                                      |                                     |                            |
| Anti-HAV                    |                         |                                      | •                                   |                            |
| Anti-HAV IgM                |                         |                                      | •                                   |                            |
| Anti-HBc                    |                         |                                      | •                                   |                            |
| Anti-HBc IgM                |                         |                                      | •                                   |                            |
| Anti-HBe                    |                         |                                      | •                                   |                            |
| HBeAg                       |                         |                                      | •                                   |                            |
| Anti-HBs                    |                         |                                      | •                                   |                            |
| HBsAg                       |                         |                                      | •                                   |                            |
| HBsAg confirmatory          |                         |                                      | •                                   |                            |
| HBsAg quantitative          |                         |                                      | •                                   |                            |
| Anti-HCV                    |                         |                                      | •                                   |                            |
| Chagas                      |                         |                                      | •                                   |                            |
| CMV IgG                     |                         |                                      | •                                   |                            |
| CMV IgG Avidity             |                         |                                      | •                                   |                            |
| CMV IgM                     |                         |                                      | •                                   |                            |
| HIV DUO <sup>7</sup>        |                         |                                      | • <sup>5</sup>                      |                            |
| HIV combi PT                |                         |                                      | • <sup>4</sup>                      |                            |
| HIV-Ag                      |                         |                                      | • <sup>4</sup>                      |                            |
| HIV-Ag confirmatory         |                         |                                      | • <sup>4</sup>                      |                            |
| HSV-1 IgG                   |                         |                                      | •                                   |                            |
| HSV-2 IgG                   |                         |                                      | •                                   |                            |
| HTLV-I/II                   |                         |                                      | •                                   |                            |
| Rubella IgG                 |                         |                                      | •                                   |                            |
| Rubella IgM                 |                         |                                      | •                                   |                            |
| Syphilis                    |                         |                                      | •                                   |                            |
| Toxo IgG                    |                         |                                      | •                                   |                            |
| Toxo IgG Avidity            |                         |                                      | •                                   |                            |
| Toxo IgM                    |                         |                                      | •                                   |                            |
| TPLA (Syphilis)             |                         | • <sup>6</sup>                       |                                     |                            |
| <b>Inflammation</b>         |                         |                                      |                                     |                            |
| Anti-CCP                    |                         |                                      | •                                   |                            |
| ASLO                        |                         | •                                    |                                     | •                          |

<sup>1</sup> Not on cobas e 411<sup>2</sup> Not on cobas c 311<sup>3</sup> Not on cobas c 701 or 702<sup>4</sup> Not on cobas e 801<sup>5</sup> Only on cobas e 801<sup>6</sup> Only on cobas c 501 or 502<sup>7</sup> In development

|                          | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module | COBAS INTEGRA®<br>400 plus |
|--------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| C3c                      |                         | •                                    |                                     | •                          |
| C4                       |                         | •                                    |                                     | •                          |
| Ceruloplasmin            |                         | •                                    |                                     | •                          |
| CRP (Latex)              | •                       | •                                    |                                     | •                          |
| Haptoglobin              |                         | •                                    |                                     | •                          |
| IgA                      |                         | •                                    |                                     | •                          |
| IgE                      |                         |                                      | •                                   |                            |
| IgG                      |                         | •                                    |                                     | •                          |
| IgM                      |                         | •                                    |                                     | •                          |
| Immunglobulin A CSF      |                         | •                                    |                                     |                            |
| Immunglobulin M CSF      |                         | •                                    |                                     |                            |
| Interleukin 6            |                         |                                      | •                                   |                            |
| Kappa light chains       |                         | •                                    |                                     | •                          |
| Kappa light chains free  |                         | • <sup>6</sup>                       |                                     | •                          |
| Lambda light chains      |                         | •                                    |                                     | •                          |
| Lambda light chains free |                         | • <sup>6</sup>                       |                                     | •                          |
| Prealbumin               |                         | •                                    |                                     | •                          |
| Procalcitonin            |                         |                                      | •                                   |                            |
| Rheumatoid factor        |                         | •                                    |                                     | •                          |
| α1-Acid Glycoprotein     |                         | •                                    |                                     | •                          |
| α1-Antitrypsin           |                         | •                                    |                                     | •                          |
| <b>Metabolic</b>         |                         |                                      |                                     |                            |
| Bicarbonate (CO2)        | •                       | •                                    |                                     | •                          |
| Calcium                  | •                       | •                                    |                                     | •                          |
| Chloride                 | •                       | •                                    |                                     | •                          |
| Fructosamine             |                         | •                                    |                                     | •                          |

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|--------------------------------|-------------------------|--------------------------------------|-------------------------------------|----------------------------|
| Glucose                        | •                       | •                                    |                                     | •                          |
| HbA1c (hemolysate)             | •                       | • <sup>3</sup>                       |                                     | •                          |
| HbA1c (whole blood)            | •                       | • <sup>3</sup>                       |                                     | •                          |
| Insulin                        |                         |                                      | •                                   |                            |
| Lactate                        | •                       | •                                    |                                     | •                          |
| Magnesium                      | •                       | •                                    |                                     | •                          |
| Potassium                      | •                       | •                                    |                                     | •                          |
| Sodium                         | •                       | •                                    |                                     | •                          |
| Total Protein                  | •                       | •                                    |                                     | •                          |
| Triglycerides                  | •                       | •                                    |                                     | •                          |
| Triglycerides Glycerol blanked |                         | •                                    |                                     |                            |
| Vitamin D total                |                         |                                      | •                                   |                            |
| <b>Oncology</b>                |                         |                                      |                                     |                            |
| Acid phosphatase               |                         | •                                    |                                     | •                          |
| AFP                            |                         |                                      | •                                   |                            |
| CA 125                         |                         |                                      | •                                   |                            |
| CA 15-3                        |                         |                                      | •                                   |                            |
| CA 19-9                        |                         |                                      | •                                   |                            |
| CA 72-4                        |                         |                                      | •                                   |                            |
| Calcitonin                     |                         |                                      | •                                   |                            |
| CEA                            |                         |                                      | •                                   |                            |
| Cyfra 21-1                     |                         |                                      | •                                   |                            |
| hCG plus beta                  |                         |                                      | •                                   |                            |
| HE4                            |                         |                                      | •                                   |                            |
| Kappa light chains free        |                         | • <sup>6</sup>                       |                                     | •                          |
| Lambda light chains free       |                         | • <sup>6</sup>                       |                                     | •                          |

Please check with your local Roche representative on availability of the assays and tests in your country.



|                             | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module<br>COBAS INTEGRA®<br>400 plus |
|-----------------------------|-------------------------|--------------------------------------|-------------------------------------------------------------------|
| NSE                         |                         |                                      | •                                                                 |
| proGRP                      |                         |                                      | •                                                                 |
| PSA free                    |                         |                                      | •                                                                 |
| PSA total                   |                         |                                      | •                                                                 |
| SCC                         |                         |                                      | •                                                                 |
| S-100                       |                         |                                      | •                                                                 |
| Thyreoglobulin (TG II)      |                         |                                      | •                                                                 |
| Thyreoglobulin confirmatory |                         |                                      | •                                                                 |
| β2-Microglobulin            |                         | •                                    |                                                                   |
| <b>Renal</b>                |                         |                                      |                                                                   |
| Albumin (BCG)               | •                       | •                                    | •                                                                 |
| Albumin (BCP)               |                         | •                                    | •                                                                 |
| Albumin immunologic         | •                       | •                                    | •                                                                 |
| Creatinine (enzymatic)      | •                       | •                                    | •                                                                 |
| Creatinine (Jaffe)          | •                       | •                                    | •                                                                 |
| Cystatin C                  |                         | •                                    | •                                                                 |
| Potassium                   | •                       | •                                    | •                                                                 |
| PTH                         |                         |                                      | •                                                                 |
| PTH (1-84)                  |                         |                                      | •                                                                 |
| Total Protein               | •                       | •                                    | •                                                                 |
| Total Protein, Urine/CSF    |                         | •                                    | •                                                                 |
| Urea/BUN                    | •                       | •                                    | •                                                                 |
| Uric acid                   | •                       | •                                    | •                                                                 |
| α1-Microglobulin            |                         | •                                    | •                                                                 |
| β2-Microglobulin            |                         | •                                    |                                                                   |

|                                    | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module<br>COBAS INTEGRA®<br>400 plus |
|------------------------------------|-------------------------|--------------------------------------|-------------------------------------------------------------------|
| <b>Therapeutic drug monitoring</b> |                         |                                      |                                                                   |
| Acetaminophen (Paracetamol)        |                         | •                                    | •                                                                 |
| Amikacin                           |                         | •                                    | •                                                                 |
| Carbamazepine                      |                         | •                                    | •                                                                 |
| Cyclosporine                       |                         |                                      | •                                                                 |
| Digitoxin                          |                         | •                                    | •                                                                 |
| Digoxin                            |                         | •                                    | •                                                                 |
| Everolimus                         |                         |                                      | •                                                                 |
| Gabapentin <sup>6</sup>            |                         | •                                    |                                                                   |
| Gentamicin                         |                         | •                                    | •                                                                 |
| Lidocaine                          |                         |                                      | •                                                                 |
| Lithium                            |                         | •                                    | ISE                                                               |
| Methotrexate <sup>6</sup>          |                         | •                                    |                                                                   |
| Mycophenolic acid                  |                         | •                                    | •                                                                 |
| NAPA                               |                         | •                                    | •                                                                 |
| Phenobarbital                      |                         | •                                    | •                                                                 |
| Phenytoin                          |                         | •                                    | •                                                                 |
| Phenytoin free                     |                         |                                      | •                                                                 |
| Primidone                          |                         |                                      | •                                                                 |
| Procainamide                       |                         | •                                    | •                                                                 |
| Quinidine                          |                         | •                                    | •                                                                 |
| Salicylate                         |                         | •                                    | •                                                                 |
| Sirolimus                          |                         |                                      | •                                                                 |
| Tacrolimus                         |                         |                                      | •                                                                 |
| Theophylline                       |                         | •                                    | •                                                                 |

|                        | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module<br>COBAS INTEGRA®<br>400 plus |
|------------------------|-------------------------|--------------------------------------|-------------------------------------------------------------------|
| Tobramycin             |                         | •                                    | •                                                                 |
| Valproic acid          |                         | •                                    | •                                                                 |
| Valproic acid free     |                         |                                      | •                                                                 |
| Vancomycin             |                         | •                                    | •                                                                 |
| <b>Women's health</b>  |                         |                                      |                                                                   |
| Anti-Müllerian Hormone |                         |                                      | •                                                                 |
| AFP                    |                         |                                      | •                                                                 |
| β-Crosslaps            |                         |                                      | •                                                                 |
| DHEAS                  |                         |                                      | •                                                                 |
| Estradiol              |                         |                                      | •                                                                 |
| FSH                    |                         |                                      | •                                                                 |
| free βhCG              |                         |                                      | •                                                                 |
| hCG                    |                         |                                      | •                                                                 |
| hCG plus beta          |                         |                                      | •                                                                 |
| hCG STAT               |                         |                                      | •                                                                 |
| HE4                    |                         |                                      | •                                                                 |
| LH                     |                         |                                      | •                                                                 |
| N-MID Osteocalcin      |                         |                                      | •                                                                 |
| PAPP-A                 |                         |                                      | •                                                                 |
| PIGF                   |                         |                                      | •                                                                 |
| sFlt-1                 |                         |                                      | •                                                                 |
| P1NP                   |                         |                                      | •                                                                 |
| Progesterone           |                         |                                      | •                                                                 |
| Prolactin              |                         |                                      | •                                                                 |
| SHBG                   |                         |                                      | •                                                                 |

|                  | cobas c 111<br>analyzer | cobas® modular<br>platform: c module | cobas modular<br>platform: e module<br>COBAS INTEGRA®<br>400 plus |
|------------------|-------------------------|--------------------------------------|-------------------------------------------------------------------|
| Testosterone     |                         |                                      | •                                                                 |
| CMV IgG          |                         |                                      | •                                                                 |
| CMV IgG Avidity  |                         |                                      | •                                                                 |
| CMV IgM          |                         |                                      | •                                                                 |
| Rubella IgG      |                         |                                      | •                                                                 |
| Rubella IgM      |                         |                                      | •                                                                 |
| Toxo IgG         |                         |                                      | •                                                                 |
| Toxo IgG Avidity |                         |                                      | •                                                                 |
| Toxo IgM         |                         |                                      | •                                                                 |

<sup>1</sup> Not on cobas e 411<sup>2</sup> Not on cobas c 311<sup>3</sup> Not on cobas c 701 or 702<sup>4</sup> Not on cobas e 801<sup>5</sup> Only on cobas e 801<sup>6</sup> Only on cobas c 501 or 502<sup>7</sup> In development

Please check with your local Roche representative on availability of the assays and tests in your country.

# Elecsys® ECL – unique immunoassay technology

*Still light years ahead*

ECL (ElectroChemiluminescence) is Roche's technology for immunoassay detection. Based on this technology and combined with well-designed, specific and sensitive immunoassays, our Elecsys® tests deliver reliable results. The development of ECL immunoassays is based on the use of a ruthenium complex and tripropylamine. The chemiluminescence reaction for detection of the reaction complex is initiated by applying a voltage to the sample solution resulting in a precisely controlled reaction. ECL technology can accommodate many immunoassay principles while providing excellent performance.

## Your benefit

### Rapid response times

- 93% of assays with 18 min. assay time or less
- 9 min. STAT applications for emergency samples

### Wide measuring range

- Linear signal response over six orders of magnitude

### Low sample volume

- High analytical sensitivity allows low sample volumes
- Patient-friendly 10 – 50 µL per test

### Controlled reaction

- High on-board stability and long shelf-life due to highly stable constituents

### Precision and sensitivity

- Excellent low-end detection limits
- Excellent precision over the entire measuring range



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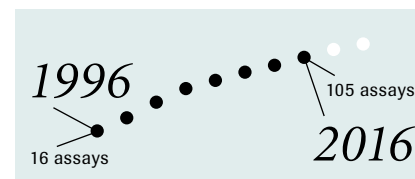
## Elecsys® – 20 years of innovation and experience

With the past in mind and the future in focus we are celebrating 20 years of continuous evolution of Elecsys assays.

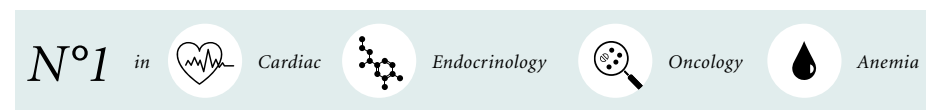
### Product success

|                           |   |                              |   |                   |   |                                                        |
|---------------------------|---|------------------------------|---|-------------------|---|--------------------------------------------------------|
| 35,000                    | : | 105                          | : | 60                | : | 24                                                     |
| cobas e module placements | : | Elecsys parameters available | : | tests/second used | : | Elecsys assay launches and updates in the last 5 years |

### Growing immunochemistry portfolio



### Pioneering with high medical value markers



Source: Roche data on file

# Turbidimetry – highly developed detection technology

*Integrate specific protein testing into your routine*

## Turbidimetry setting new standards:

### Consolidation without compromise

The testing of “specific proteins” continues to be one of the key routines in laboratories due to their wide-ranging clinical utility. In the past, specific proteins were analyzed using a variety of specialized methods, such as radial immunodiffusion, immuno-electrophoresis or using dedicated nephelometers. This incremental investment and the resulting additional costs, handling complexity and reductions in throughput were accepted due to the perceived benefits in performance offered by these methods.

Today, specific protein determinations are frequently carried out on consolidated, random-access clinical chemistry systems using turbidimetric technology. Routine efficiencies such as reduced turnaround times are thereby achieved for these parameters.

## Your benefit

### Efficiency and accelerated result reporting

- High throughput without the associated cost of a dedicated instrument for protein assays
- High sample throughput capability and no sample split
- Most efficient assay usage with high onboard stability and low calibration frequency<sup>1</sup>

### Consolidation without compromise

- Broadest specific protein menu on a fully consolidated platform including open channel offering<sup>1</sup>
- Broad system platform portfolio for every lab size with standardized reagents across the platforms

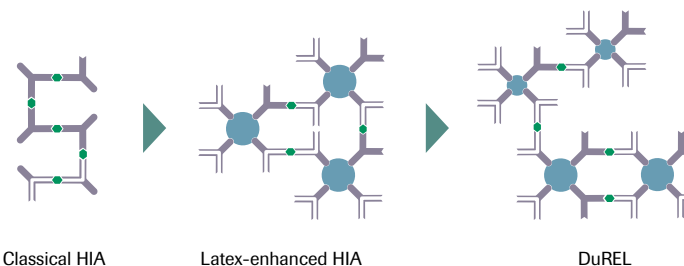
## Product characteristics

Turbidimetry is Roche’s technology for homogeneous immunoassay detection. Continuous development of the classical antigen-antibody assay design to the patented DuREL (Dual-radius enhanced latex) technology forms the basis for high sensitivity and broad dynamic range detection.

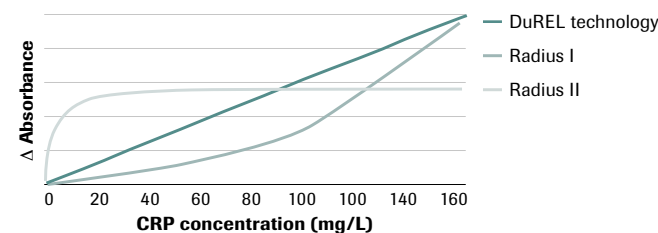
The use of bichromatic wavelengths in spectrophotometry in conjunction with the measurement of a sample blank minimizes interference effects.



## Technological advances and future-oriented assay design



## Differently-sized particles working together



<sup>1</sup> Roche data on file.

# Diagnostic excellence in Infectious Diseases

*One step ahead*

Roche Diagnostics offers a comprehensive portfolio of infectious diseases assays along the continuum of care, thereby enabling laboratories to provide the right information, from screening and diagnosis to patient management and treatment monitoring.

Our complete Infectious Diseases offer includes serology and also molecular testing (please refer to chapter «Molecular Diagnostics» for more information) which, thanks to our Personalized Lab Automation solutions can be configured, connected and integrated to suit the requirements of any laboratory.

Each Roche Diagnostics infectious diseases test is designed with a clinical benefit in mind. A few examples that have been described in scientific publications are:

- The Anti-HCV II and HIV Combi PT tests excel in seroconversion sensitivity allowing earlier intervention<sup>1-3</sup>
- Studies have confirmed the superior capability of the HBsAg and HIV Combi PT tests to detect mutants and rare variants, therefore driving screening effectiveness<sup>4-7</sup>

- The CMV tests allow for a reliable discrimination between an acute and a remote infection, therefore preventing unnecessary repeat testing<sup>8</sup>

Our extensive infectious diseases portfolio is expanding every year. We are not only focusing on launching new parameters but we are also continuously updating our existing portfolio seeking continuous improvement, as well as keeping pace with the evolution of pathogens.



- 1 Combined data from "Study report: Performance evaluation CE: Elecsys Anti-HCV II; 20 Feb.; Version2; Study Number: CIM RD 001230/B10P010" Penzberg, Germany.
- 2 Esteban, et al. (2013). *J Med Virol*.
- 3 Mühlbacher, et al. (2012). *Med Microbiol Immunol*. Miller et al. (2010). (HIV).
- 4 Ly et al. (2012). *J Clin Virol*.
- 5 Mühlbacher, et al. (2008). *Med Microbiol Immunol*. 6. Jia, et al. (2009). *Med Microbiol Immunol*.
- 7 Louisirirothanakul, et al. (2010). *J Med Virol*.
- 8 Revello, M.G. et al. (2012). *Eur J Clin Microbiol Infect Dis*. (CMV)



|                             | S                        | D | P |
|-----------------------------|--------------------------|---|---|
| <b>Elecsys immunoassays</b> |                          |   |   |
| <b>Viral hepatitis</b>      | Anti-HAV total           | • | • |
|                             | Anti-HAV IgM             | • | • |
|                             | HBsAg                    | • | • |
|                             | HBsAg confirmatory       | • | • |
|                             | HBsAg quantitative       | • | • |
|                             | Anti-HBs                 | • | • |
|                             | Anti-HBc                 | • | • |
|                             | Anti-HBc IgM             | • | • |
|                             | Anti-HBe                 | • | • |
|                             | HBeAg                    | • | • |
| <b>STDs</b>                 | Anti-HCV                 | • | • |
|                             | HIV combi PT             | • | • |
|                             | HIV Antigen              | • | • |
|                             | HIV Antigen confirmatory | • | • |
|                             | Syphilis                 | • | • |
|                             | Syphilis TPLA            | • | • |
|                             | Syphilis RPR             | • | • |
|                             | HSV-1 IgG                | • | • |
|                             | HSV-2 IgG                | • | • |
|                             | HTLV-I/II                | • | • |
| <b>TORCH</b>                | CMV IgG                  | • | • |
|                             | CMV IgM                  | • | • |
|                             | CMV IgG Avidity          | • | • |
|                             | HSV-1 IgG                | • | • |
|                             | HSV-2 IgG                | • | • |
|                             | Rubella IgG              | • | • |
|                             | Rubella IgM              | • | • |
|                             | Toxo IgG                 | • | • |
|                             | Toxo IgM                 | • | • |
|                             | Toxo IgG Avidity         | • | • |
| <b>Others</b>               | Syphilis                 | • | • |
|                             | Syphilis TPLA            | • | • |
|                             | Syphilis RPR             | • | • |
|                             | Chagas                   | • | • |

|                         | S                    | D | P |
|-------------------------|----------------------|---|---|
| <b>Molecular assays</b> |                      |   |   |
| <b>Viral hepatitis</b>  | HBV DNA quantitative | • | • |
|                         | HCV RNA qualitative  | • | • |
|                         | HCV RNA quantitative | • | • |
|                         | HCV genotyping       | • | • |
|                         | HEV RNA qualitative  | • | • |
|                         | MPX (HIV/HCV/HBV)    | • | • |
|                         | DPX (B19V/HAV)       | • | • |
| <b>STDs</b>             | CT DNA               | • | • |
|                         | CT/NG DNA            | • | • |
|                         | HSV1 and HSV2 DNA    | • | • |
|                         | HIV RNA quantitative | • | • |
|                         | HIV RNA qualitative  | • | • |
|                         | HPV DNA              | • | • |
|                         | HPV genotyping       | • | • |
| <b>TORCH</b>            | MPX (HIV/HCV/HBV)    | • | • |
|                         | CMV DNA quantitative | • | • |
| <b>Others</b>           | C. Difficile DNA     | • | • |
|                         | MRSA DNA             | • | • |
|                         | MRSA/SA DNA          | • | • |
|                         | MTB DNA              | • | • |
|                         | MAI DNA              | • | • |
|                         | Sepsis               | • | • |
|                         | VRE <sup>1</sup>     | • | • |
|                         | West Nile Virus      | • | • |

• Part of the Roche Blood Safety Solutions panel

<sup>1</sup> For research use only

Please check with your local Roche representative on the availability of the assays and tests in your country.

# The Roche Hepatitis diagnostic portfolio

## A clear direction ahead

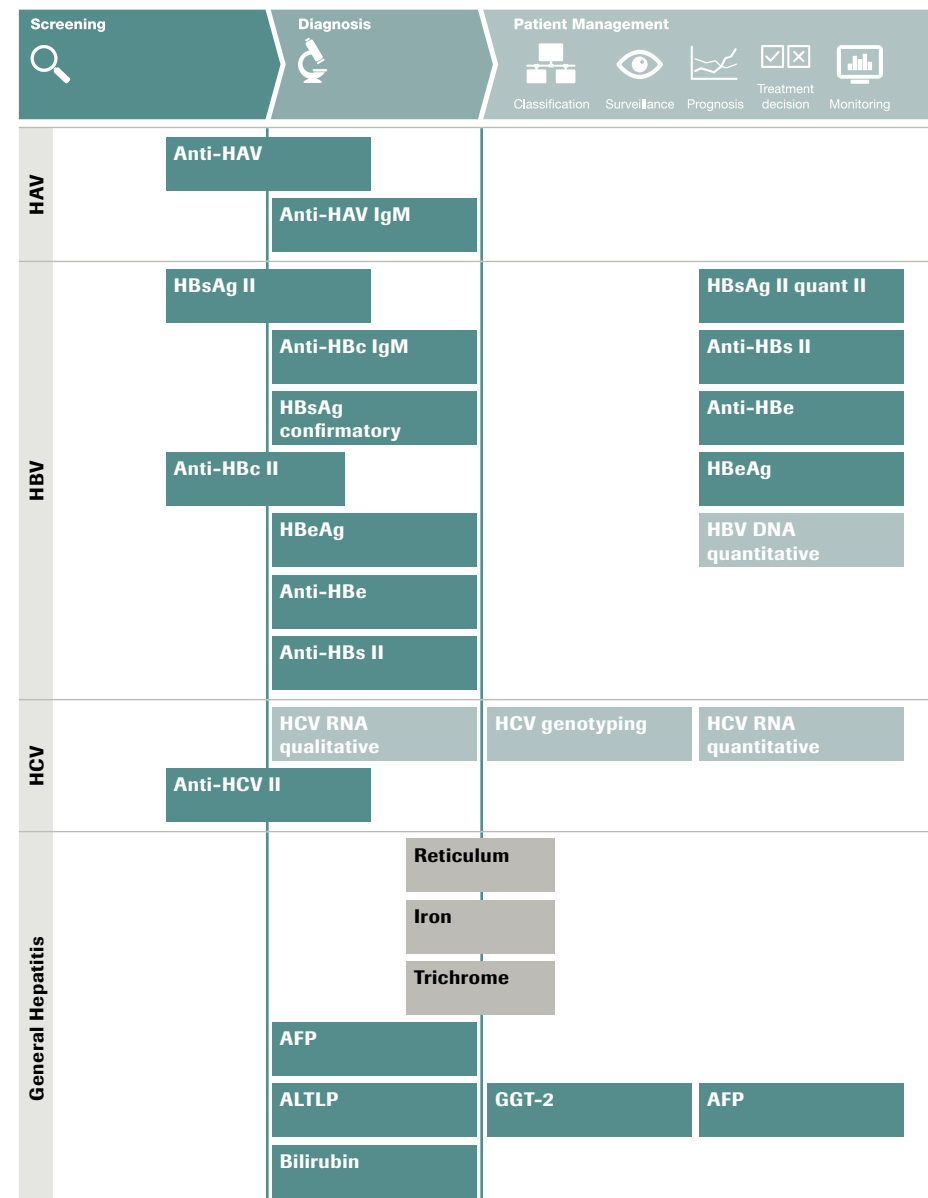
Viral hepatitis is a global burden. In particular, infection with HBV or HCV leads to chronic liver disease including fibrosis, cirrhosis and eventually hepatocellular carcinoma in hundreds of millions of people.<sup>1</sup> According to WHO, HBV and HCV infections cause approximately 80% of all liver cancer related deaths and kill approximately 1.4 million people every year.<sup>2</sup> Most of those infected are undiagnosed, thereby increasing the risk of developing severe liver disease and transmitting the virus to others.



Roche provides integrated and comprehensive solutions consisting of the **cobas®** family of diagnostic platforms combined with workflow and IT solutions for streamlined lab operations, and diagnostic assays that cover the complete hepatitis health-care continuum.

Roche offers a broad portfolio of serology-based and molecular tests required for screening, diagnosis and management of viral hepatitis. With more than 30 years of experience in the area of Infectious Diseases, Roche covers all relevant diagnostic fields to help provide encompassing patient care. Not surprisingly, Roche customers regularly leverage our experience as the provider of excellent performing hepatitis immunoassays and extensively clinically validated hepatitis viral load assays worldwide.

From screening to patient management, Roche's diagnostic excellence and efficiency provides answers today for a healthier tomorrow.



Roche Serum Work Area  
Roche Molecular Diagnostics

Roche Tissue Diagnostics

cobas®

1 Mauss S et al. Hepatology – A Clinical Textbook; 7th Edition, 2016. Medizin Fokus Verlag.  
2 <http://www.who.int/mediacentre/news/releases/2015/world-hepatitis-day/en>

# Elecsys® HIV combi PT

## 4<sup>th</sup> Generation (Ag+Ab test)

*Designed for early detection of HIV infection*



The human immunodeficiency virus (HIV) is the causative agent of the acquired immunodeficiency syndrome (AIDS). It can be transmitted through contaminated blood and blood products, sexual contact or from an HIV infected mother to her child. Reliable screening and diagnosis constitutes a crucial aspect of the global strategy for reducing the human and financial burden of HIV transmission.

With the Elecsys HIV combi PT assay, the HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 can be detected simultaneously in one determination. The assay uses recombinant antigens derived from the Env and Pol-region of HIV-1 (including group O) and HIV-2 to determine HIV-specific antibodies. Specific monoclonal antibodies are used for the detection of HIV-1 p24 antigen. The test includes an automated sample pretreatment step with detergent incubation in order to lyse HIV virions and maximize exposure of the HIV p24 antigen to increase sensitivity.

A new concept of HIV testing will be added to the Roche HIV screening solution in 2017. Available on the **cobas e 801**, the HIV Duo allows separate antigen and antibody detection.

### Your benefit

#### Earlier detection of infection

- Due to improved sensitivity by lysis of the virus using a pre-treatment (PT) step

#### Compliant with recent international guidelines

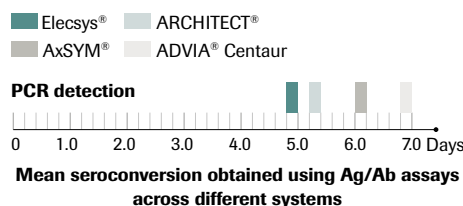
- Analytical sensitivity  $\leq 2.0$  IU/mL

#### Robust to viral change

- Multiple target concept to ensure excellent inclusivity: special detection of HIV-1 subtypes, group O and HIV-2 antibodies

#### Cost efficiency

- High clinical specificity reduces the need for repeat testing<sup>1</sup>



Comparison of the time required until acute infection can be detected using different HIV antigen/antibody combination immunoassays.<sup>1</sup>

### Product characteristics

#### Elecsys® HIV combi PT test characteristics

- Indications: Diagnostic use and for screening of blood donations
- Assay time: 27 min.
- Analytical sensitivity:  $\leq 2.0$  IU/mL Human immunodeficiency virus type 1 (HIV-1 p24 antigen) – 1<sup>st</sup> International Reference Reagent 1992, code 90/636
- Sample material:
  - Serum, standard or separating gel tubes
  - Plasma types: Li-heparin, Na-heparin, K<sub>2</sub>-EDTA, K<sub>3</sub>-EDTA, ACD, CPD, CP2D, CPDA, Na-citrate and Li-heparin plasma tubes containing separating gel
- Sample volume: 40 µL
- Clinical sensitivity: 100 % (n 1,532) HIV-1 group M, O and HIV-2
- Clinical specificity
  - Blood donors: 99.88 % (95 % LCL: 99.77) (n 7,343)
  - Samples from unselected daily routine, dialysis patients and pregnant women: 99.81 % (95 % LCL: 99.62) (n 4,103)



<sup>1</sup> Mühlbacher, A. et al. (2012). Performance evaluation of a new fourth gen. HIV combination antigen-antibody assay. *Med. Microbiol. Immunol.* DOI: 10.1007/s00430-012-0250-5.

# The Syphilis test panel

*Fully automated for complete assessment of the disease syphilis*

Syphilis is caused by the intracellular gram-negative spirochete bacterium *Treponema pallidum* subspecies *pallidum*. It is mainly transmitted sexually, but can also be transmitted from mother to fetus during pregnancy or at birth, resulting in congenital syphilis. Syphilis facilitates the acquisition of HIV.

Roche offers an automated panel of three assays for efficient and reliable assessment of syphilis patients.

## Your benefit

- Reliable and complete solution using your algorithm of choice
- Integrated with other tests in the TORCH and blood safety solutions portfolios
- Treponemal test suitable for screening in the general population, pregnant women and blood donations

| Screening                                                                                   | Diagnosis                                                                                   | Treatment monitoring                                    |
|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Syphilis</li> <li>• TPLA</li> <li>• RPR</li> </ul> | <ul style="list-style-type: none"> <li>• Syphilis</li> <li>• TPLA</li> <li>• RPR</li> </ul> | <ul style="list-style-type: none"> <li>• RPR</li> </ul> |

Panel for the complete assessment of the syphilis patient.

Screening, diagnosis, confirmation and activity monitoring of the disease.

TPLA and RPR are SEKISUI, Japan products distributed by Roche.

TPLA = *T. pallidum* Latex Agglutination

RPR = Rapid Plasma Reagin

# Elecsys® Syphilis immunoassay

*Confidence in all stages of treponemal infection*



[www.cobas.com](http://www.cobas.com)

The Syphilis immunoassay has been designed using the latest recombinant thermostable-antigen technology, to achieve unprecedented high sensitivity and specificity performance across all stages of infection.

## Your benefit

### Designed for high sensitivity

- High sensitivity minimizes the probability of missing new infections

### Cost efficiency

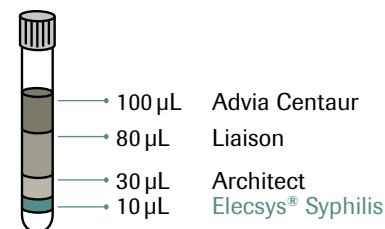
- High specificity reduces the need for re-testing<sup>1</sup>

### Clear results interpretation

- Clear cut-off separation of positive and negative results

### Efficient use of sample volume

- Maximizes the chance to order all the tests required from the same sample



Source: Package insert.



## Product characteristics

- Serum, standard or separating gel tubes
- Plasma types: Li-heparin, Na-heparin, K<sub>2</sub>-EDTA, K<sub>3</sub>-EDTA, Na-citrate, ACD, CPD, CP2D, CPDA and K<sub>2</sub>-EDTA plasma tubes containing separating gel
- Sample volume: 10 µL
- Assay time: 18 min.
- Test format: IgM/IgG (three antigens: TpN15, TpN17, TpN47)
- Clinical sensitivity: 100 % (n = 924)
- Clinical specificity: 99.88 % (n = 8,079)
  - Blood donors: 99.93 % (n = 4,579)
  - Routine samples: 99.80 % (n = 3,500)

<sup>1</sup> Kremastinou J et al. (2016). Evaluation of the Elecsys® Syphilis assay for routine and blood screening and detection of early infection. *Journal of Clinical Microbiology*; doi:10.1128/JCM.02544-15

# Elecsys® TORCH panel

## Reliable screening for early diagnosis



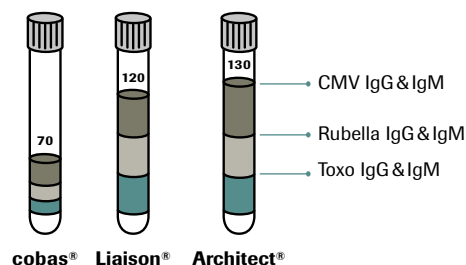
www.cobas.com



Infections with *Toxoplasma gondii*, Rubella virus, Cytomegalovirus (CMV) and Herpes simplex virus (HSV), collectively designated as TORCH, pose a particular risk during pregnancy. Prenatal diagnosis of such infections is important and demands assays of outstanding quality and reliability.

Opportunistic infections with Toxo and CMV can also have severe consequences for immunodeficient patients. A combination of high clinical sensitivity and specificity is therefore essential.

### Sample volume\* in µL



\*Sample volume without dead volumes; Serum/Plasma samples (for all values); information from respective pack inserts.

Source: Product inserts assessed September 2016. For Roche products: current Package Insert.

### Your benefit

#### High efficiency

- Consolidation of TORCH panel on **cobas®** immunology analyzers

#### Early detection

- Allows early management of acute congenital infections

#### Fewer confirmation tests and fewer reruns<sup>1-3</sup>

- Due to highly specific assays

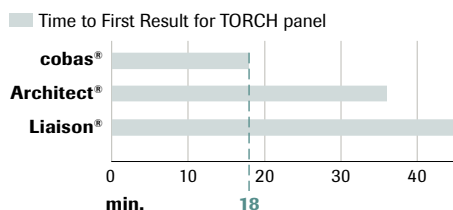
#### Efficient use of sample volume

- Maximizes the chance to order all the tests required from the same sample

#### Fast reporting

- Results in less than 20 min.

#### Increased efficiency by time to first result



### Product characteristics

Roche has been continuously developing innovative TORCH assays. Based on recombinant antigens and specific assay formats such as  $\mu$ -capture and DAGS (double antigen sandwich), these assays combine high clinical sensitivity and specificity.

#### Elecsys® Toxo IgM, IgG and IgG Avidity

- The Elecsys® Toxo IgM assay design and respective cut-off minimize the probability of missing any new infection
- The Toxo IgG assay accurately detects past infections
- The Elecsys® Toxo IgG Avidity assay is a reliable method to rule out infection occurring within the last 4 months
- Combined use of the three assays allows accurate determination of primary infections and rules out non relevant cases

#### Elecsys® Rubella IgM and IgG

Clearly discriminates between an acute and a remote infection

- The ultrasensitive Rubella IgG test detects remote infections
- Complemented with early detection of acute infections by the Rubella IgM test

The combination of these assays provides an excellent tool for identifying and characterizing Rubella infections.

#### Elecsys® CMV IgM, IgG and IgG Avidity

- Designed to detect all suspected primary infections
- Less sensitive to persistent IgM antibodies<sup>1</sup>
- Prevents cross reactivity with other herpes viruses
- CMV IgG avidity testing is the most reliable procedure to identify primary infection or confirm past infection

#### Elecsys® HSV-1 IgG and HSV-2 IgG

- Identification of silent carriers of Herpes simplex virus infection
- Type-specific assays for reliable differentiation between HSV-1 and HSV-2 (two Elecsys HSV IgG assays available) according to the recommendation from CDC or European guidelines\*

\* Workowski et al. *Sexually Transmitted Diseases Treatment Guidelines 2015*. MMWR Recomm Rep 2015;64:27-32.

Patel et al. (2011) *European guideline for the management of genital herpes 2010 Int J STD AIDS 22(1):1-10*.

1 Revello, M.G., Vauloup-Fellous, C., Grangeot-Keros, L. et al. (2012). *Eur J Clin Microbiol Infect Dis* 31: 3331. doi:10.1007/s10096-012-1700-0.

2 Van Helden, J. (2009). *Clin. Lab* 55: 261-273.

3 Meylan, P. (2015). *European Journal of Microbiology and Immunology* 5: 2, pp. 150-158.

**cobas®**

# Elecsys® Troponin T – high sensitive

## *Faster diagnosis of Acute Myocardial Infarction*



www.cobas.com



In a clinical setting consistent with myocardial ischemia, detection of a rise and/or fall in troponin is the cornerstone of myocardial infarction diagnosis.

The joint ESC/ACCF/AHA/WHF task force for the Universal definition of myocardial infarction and the IFCC recommend using a troponin test that can measure the 99<sup>th</sup> percentile upper reference limit (URL) with an analytical precision  $\leq 10\%$  (% CV; coefficient of variation)<sup>1,2</sup>. The Elecsys Troponin T-hs assay achieves less than 10% CV at the 99<sup>th</sup> percentile URL defined at 14 ng/L and complies with this recommendation.

In addition the IFCC defines a high-sensitivity troponin test as one that can measure cTn above the Limit of Detection (LoD) in  $\geq 50\%$  of healthy subjects<sup>2</sup>. For example a multicenter trial reports that 57% of healthy subjects were measured with cTnT-hs levels above 3 ng/L<sup>3</sup>. Studies report LoD of 2.05 – 2.85 ng/L with the **cobas e 601/ e 602/MODULAR ANALYTICS E170**<sup>4</sup>.

This analytical performance results in significant clinical advantages for the diagnosis of acute coronary syndrome (ACS).<sup>5</sup>

### Your benefit

#### Early diagnosis of AMI with cTnT-hs using the T0/1-hour or 3-hour algorithm

- The accelerated algorithm to rule-in/out AMI within 1- or 3-hour using cTnT-hs is endorsed by the 2015 European Society of Cardiology (ESC) guidelines for Acute Coronary Syndrome (ACS) without ST-elevation<sup>6</sup>
- The performance of cTnT-hs 0h/1-h algorithm is validated by three multicenter trials in over 3,038 patients and results demonstrate that  $>75\%$  of patients are triaged within 1 hour<sup>7,8,9</sup>
- The high negative predictive value and the low 30-day-mortality rate confirmed the safety of this approach for early discharge<sup>7,8,9</sup>

#### Improved risk stratification and clinical management of patients with suspected ACS compared with conventional cTn assays

- More at-risk patients are identified without inappropriate increase in hospital resource utilisation<sup>5</sup>

#### Consistent correlation

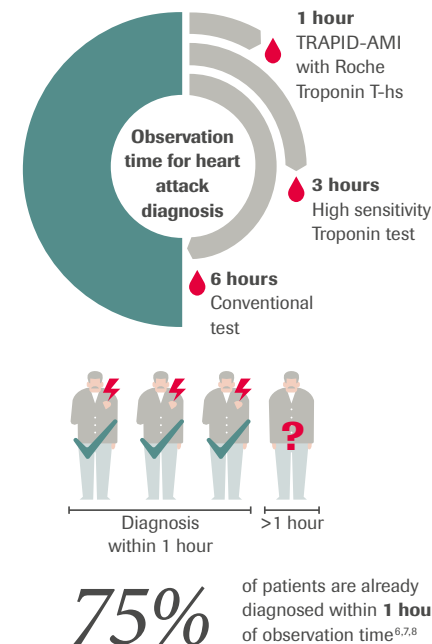
- Between POC devices for emergency testing and all **cobas**® immunoassay analyzers<sup>10</sup>

### Product characteristics

- STAT test: 9 min.
- 99<sup>th</sup> percentile upper reference limit: 14 ng/L (pg/mL)
- 10% CV precision: 13 ng/L (pg/mL)

#### Introduction of cTnT-hs in routine practice helps to:

- Reduce time to diagnosis and improve patient care<sup>9,11</sup>
- Lower the need for cardiac stress testing by more than 30%<sup>11</sup>
- Shorten the length of stay in the emergency department by nearly 80 minutes and has the potential to contribute to cost savings<sup>11</sup>



- 1 Thygesen, K. et al. (2012). *J. Am. Coll Cardiol*; 60:1581-98.
- 2 Apple, F.S. et al. (2015). *Clin. Biochem.*; 48(4-5):201-3.
- 3 Saenger, A.K. et al. (2011). *Clin Chim Acta*; 412(9-10):748-54.
- 4 Elecsys Troponin T-high sensitive package insert, 2016.
- 5 Eggers, K.M. et al. (2016). *Eur Heart J* 2016 Aug 7;37(30):2417-24.
- 6 Roffi, M. et al. (2015). *Eur Heart J* 2016; 37(3):267-315.
- 7 Reichlin, T. et al. (2012). *Arch Intern Med*; 172(16):1211-8.
- 8 Reichlin, T. et al. (2015). *CMAJ*; 187(8):E243-52.
- 9 Mueller, C. et al. (2016). *Ann Emerg Med*; 68(1):76-87.
- 10 Roche CARDIAC POC Troponin T Package insert, 2015.
- 11 Twerenbold, R. et al. (2016). *Eur Heart J*. 2016 Nov 21; 37(44):3324-3332.

# Elecsys® NT-proBNP

## The clear choice for heart failure management



www.cobas.com



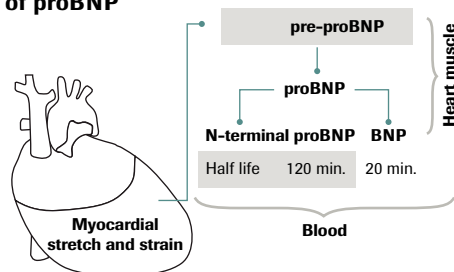
Heart failure (HF) is a global health problem associated with high morbidity and mortality affecting 26 million patients worldwide.<sup>1</sup>

Early stage diagnosis of HF and appropriate treatment are key objectives in improving patients' quality of life.

Patients with HF – especially with mild symptoms – are often not diagnosed. On the other hand, many patients with suspected heart failure are unnecessarily referred to echocardiography.

- NT-proBNP is well-established in international guidelines
- NT-proBNP has shown to improve clinical decision-making in HF management from diagnosis to monitoring

### NT-proBNP is formed by cleavage of proBNP



### Product characteristics

- Fully automated quantitative assay
- Low sample volume: 50 µL
- Fast results: 9 min. with STAT assay
- High test precision (CV 2.9 to 6.1 %) coupled with wide dynamic measuring range (5 – 35,000 pg/mL)
- Sample material: standard serum and heparin/EDTA plasma

### Your benefit

#### Recommended by major Guidelines

- NT-proBNP is recommended by major international guidelines (ACC/AHA, ESC, NICE)

#### Reliable results, regardless of therapy

- Unlike BNP, NT-proBNP is not a neprilysin substrate and is the more suitable biomarker for patients treated with new ARNi drugs (e.g. sacubitril-valsartan)<sup>2,3</sup>

### Consistent correlation between all cobas® immunoassay analyzers and POC devices

- Ability to generalize cut-offs without the need to rebase patients' value when changing instrument

### Simplified testing process and improved efficiency of testing

- NT-proBNP sample stability is 3 days at room temperature and longer at 4 °C
- Test tube requirements allow one tube solution for all cardiac markers

### NT-proBNP: an objective and cost-effective tool from diagnosis to monitoring

#### Diagnosis

- In combination to clinical assessment, NT-proBNP is an essential test improving diagnostic in acute (emergency department) and non-acute onset (outpatient and primary care)<sup>4</sup>
- Associated with more efficient allocation of imaging and faster patient turnover in the emergency department<sup>5,6</sup>



#### Prognosis

- NT-proBNP levels correlate with disease severity

#### Monitoring

- NT-proBNP serial measurements helps to gain information about disease progression or improvement of patients' condition

1 Ambrosy, P.A. et al. (2014). The Global Health and Economic Burden of Hospitalizations for Heart Failure. Lessons Learned From Hospitalized Heart Failure Registries. *J Am Coll Cardiol*, 63: 1123–1133.

2 McKie, P.M. and Burnett, J.C. (2016). NT-proBNP: The Gold Standard Biomarker in Heart Failure. *JACC*, Vol 68, No 22.

3 Januzzi, J.L. Jr. (2016). B-Type Natriuretic Peptide Testing in the Era of Neprilysin Inhibition: Are the Winds of Change Blowing? *Clin Chem*, May, 62(5):663–5.

4 Ponikowski, P. et al. (2016). ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur J Heart Fail*, Aug, 18(8):891–975.

5 Behnes, M. et al. (2009). Diagnostic performance and cost effectiveness of measurements of plasma N-terminal pro brain natriuretic peptide in patients presenting with acute dyspnea or peripheral edema. *Int J Cardiol*, 135(2): 165–174.

6 Moe, G. et al. (2007). N-Terminal Pro-B-Type Natriuretic Peptide Testing Improves the Management of Patients With Suspected Acute Heart Failure. *Circ*, 115: 3103–3110.

# Elecsys® IL-6, PCT and Tina-quant® CRP

*For early and effective sepsis management – because time matters*



www.cobas.com



Sepsis, the systemic inflammatory response to infection, is a leading cause of death. More than 1 in 1,000 people in developed countries develop sepsis each year, representing a major burden on healthcare.<sup>1</sup>

Early recognition is critically important for patient survival, but clinical signs and symptoms are often ambiguous.

Elecsys IL-6, Elecsys BRAHMS PCT, in combination with CRP, deliver rapid, reliable information about the patient's immediate inflammatory status and likelihood of bacterial sepsis, which is important for antimicrobial therapy management.

| Acute inflammatory episode | Clinical indication of sepsis                                                                                                                               | Differential diagnosis                                                                                                               | Severe sepsis/shock |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------|
|                            | Suspicion/treatment                                                                                                                                         | characterization of infection*                                                                                                       | Therapy stewardship |
| • <b>IL-6</b>              | <ul style="list-style-type: none"> <li>• Temperature</li> <li>• Heart rate</li> <li>• Breathing rate</li> <li>• Leukocytes</li> <li>• <b>CRP</b></li> </ul> | <ul style="list-style-type: none"> <li>• Blood culture</li> <li>– <b>PCT</b></li> <li>– <b>IL-6</b></li> <li>– <b>CRP</b></li> </ul> | • <b>PCT</b>        |

\* Rapid identification of sepsis pathogens is possible with LightCycler® SeptiFast Test.

## Your benefit

### Rapid diagnostics

- Short total assay time

### Testing efficiency

- All parameters from one sample tube

### Economical sample handling

- Low sample volumes, especially important for pediatrics

## PCT, IL-6 and CRP: a biomarker panel to support early recognition and management of sepsis

**IL-6:** Early warning sign of (systemic) inflammation and sepsis

**PCT:** Follows IL-6 and indicates high probability of bacterial sepsis

**CRP:** Released from the liver as a later marker of inflammation



## Product characteristics

| Assay                         | Elecsys BRAHMS PCT                                | Elecsys IL-6                                                           | CRP on cobas c analyzers                                               |
|-------------------------------|---------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|
| <b>Sample material</b>        | Serum, Li-heparin and K <sub>3</sub> -EDTA plasma | Serum, Li-heparin and K <sub>2</sub> - and K <sub>3</sub> -EDTA plasma | Serum, Li-heparin and K <sub>2</sub> - and K <sub>3</sub> -EDTA plasma |
| <b>Sample volume</b>          | 30 µL                                             | 30 µL                                                                  | 2 µL                                                                   |
| <b>Assay time</b>             | 18 min.                                           | 18 min.                                                                | 10 min.                                                                |
| <b>Measuring range</b>        | 0.02 – 100 ng/mL                                  | 1.5 – 5,000 pg/mL                                                      | 0.3 – 350 mg/L                                                         |
| <b>Analytical sensitivity</b> | <0.02 ng/mL                                       | 1.5 pg/mL                                                              | 0.3 mg/L                                                               |
| <b>Functional sensitivity</b> | <0.06 ng/mL                                       | 5 pg/mL                                                                | 0.6 mg/L                                                               |
| <b>Traceability</b>           | Standardized against BRAHMS PCT LIA               | WHO Standard NIBSC 1 <sup>st</sup> IS 89/548                           | IRMM reference preparation CRM470 (RPPHS)                              |

<sup>1</sup> Issrah Jawad, et al (2012). "Assessing available information on the burden of sepsis: global estimates of incidence, prevalence and mortality." *J Glob Health. Jun; 2(1)*: 010404. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3484761/>

# Elecsys® tumor marker portfolio

## Supporting improvements in cancer diagnosis and monitoring



In the last decade, the sensible use of tumor markers and the careful interpretation of their results have led to the continuous enhancement of their clinical significance. The inclusion of tumor markers in clinical management can help to provide more information for improved clinical decision-making and therefore maximize the quality of care. Nowadays, therapy management of cancer patients is guided by tumor marker measurements based on the individual base line levels before and after primary treatment. An excellent long-term assay accuracy, lot-to-lot stability and precision is crucial for the reliable evaluation of significant differences in tumor marker levels in cancer patients during therapy monitoring and follow up.

### Your benefit

#### Longitudinal accuracy for reliable long-term patient monitoring

- High reproducibility and analytical precision over the entire measuring range, especially in lower concentration ranges
- High lot-to-lot consistency across all cobas® platforms

#### Reliable results

- Robustness against interference (e.g. HAMA) by blocking proteins, fragmented catcher or tracer antibodies or chimeric antibodies<sup>1</sup>
- Standardized to international standards or, if no standard available, traceable to a commonly accepted methodology

#### Operational efficiency

- High degree of system automation
- Less retesting due to high precision and wide measuring ranges
- Broad tumor marker menu with specialties such as CA72-4, S100, NSE, CYFRA 21-1, HE4, and ProGRP
- Outstanding degree of SWA consolidation with > 230 parameters for clinical chemistry and immunochemistry

#### Complete diagnostic picture with Personalized Healthcare

- Coverage of the whole chain from diagnostics, therapy decision and monitoring by Roche's broad oncology menu in tissue diagnostics, Elecsys tumor markers and molecular solutions

#### Roche reagent and application portfolio for consolidated tumor marker testing

| Test             | Cancer indications                    | Roche/<br>Hitachi<br>systems | COBAS<br>INTEGRA | cobas e<br>systems | MODULAR<br>ANALYTICS<br>EVO | cobas c<br>systems |
|------------------|---------------------------------------|------------------------------|------------------|--------------------|-----------------------------|--------------------|
| AFP              | Liver, testicles                      |                              |                  | •                  | •                           |                    |
| Calcitonin       | Medullary, thyroid carcinoma          |                              |                  | •                  | •                           |                    |
| CA 125           | Ovary                                 |                              |                  | •                  | •                           |                    |
| HE4              | Ovary                                 |                              |                  | •                  | •                           |                    |
| CA 15-3          | Breast                                |                              |                  | •                  | •                           |                    |
| CA 19-9          | Pancreatic, colorectal                |                              |                  | •                  | •                           |                    |
| CA 72-4          | Gastric, colorectal, mucinous ovarian |                              |                  | •                  | •                           |                    |
| CEA              | Colorectal- and lung adenocarcinoma   |                              |                  | •                  | •                           |                    |
| CYFRA 21-1       | Non small cell lung                   |                              |                  | •                  | •                           |                    |
| Ferritin         | Tumor related anemia                  | •                            | •                | •                  | •                           | •                  |
| HCG              | Chorion                               |                              |                  | •                  | •                           |                    |
| β2 Microglobulin | Multiple myeloma (non-Hodgkin)        | •                            | •                |                    | •                           | •                  |
| NSE              | Small cell lung                       |                              |                  | •                  | •                           |                    |
| ProGRP           | Small cell lung                       |                              |                  | •                  | •                           |                    |
| SCC              | Squamous cell lung, cervix            |                              |                  | •                  | •                           |                    |
| Free PSA         | Prostate                              |                              |                  | •                  | •                           |                    |
| Total PSA        | Prostate                              |                              |                  | •                  | •                           |                    |
| S100             | Malignant melanoma                    |                              |                  | •                  | •                           |                    |
| Anti-TG          | Medullary, thyroid carcinoma          |                              |                  | •                  | •                           |                    |
| Tg II (hs)       | Medullary, thyroid carcinoma          |                              |                  | •                  | •                           |                    |

<sup>1</sup> Bolstad, N. et al (2011). Heterophilic antibody interference in commercial immunoassays. *Clin Chem Lab Med* 49(12), 2001-2006.

# Elecsys® HE4

## An oncological biomarker improving ovarian cancer care

Worldwide, ovarian cancer is a gynecological disease with one of the highest mortality rates. As survival rate and stage at diagnosis are correlated, it is important to detect this cancer early. Especially in early stages symptoms are unspecific and cause little, if any, discomfort. For detecting the disease earlier, the biomarkers HE4 (human epididymal protein 4) and CA125 can play a very important role here.

### Your benefits

#### Early marker with increased sensitivity for supporting the diagnosis of epithelial ovarian cancer (EOC)

- As a single tumor marker, HE4 had the highest sensitivity (specificity 95%) in detecting of EOC, especially in the early non-symptomatic stage<sup>1</sup>

#### High discrimination between benign ovarian masses/cysts and ovarian cancer

- The combination of HE4 and CA 125 shows the greatest accuracy in differentiating between patients with EOC vs. those with benign pelvic masses<sup>1</sup>

#### Improved monitoring of ovarian cancer recurrence and progression

HE4 in combination with CA125 performed better than CA125 and HE4 alone in pre-

dicting recurrence within 12 months after first-line chemotherapy.<sup>2</sup>

#### Reliable results with efficiency

- Excellent precision and lot-to-lot consistency
- Comprehensive tumor marker menu available on all **cobas®** platforms

#### ROMA increases the diagnostic value of the dual marker combination HE4 and CA 125

Measured values of HE4 and CA 125 can be combined in an algorithm called ROMA – which takes into account the menopausal status of the woman. Several published studies show that ROMA helps in the triage of pre- and postmenopausal women suspected of having ovarian cancer. Moore et al. (2009) found that the algorithm correctly classified 94 % of women with epithelial ovarian cancer.<sup>3</sup> ROMA can therefore help triaging patients to be fastly transferred to an expert medical center. ROMA combines the diagnostic power of the complementary biomarkers HE4 and CA 125 with menopausal status, to stratify women into low- and high-risk groups, thus increasing diagnostic accuracy.<sup>3-5</sup>



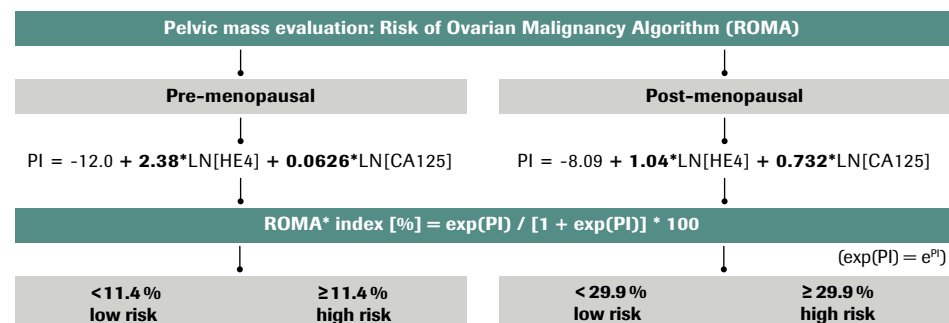
www.cobas.com



### Product characteristics

- Assay time: 18 min.
- Sample material: Serum collected using standard sampling tubes or tubes containing separating gel Li-heparin plasma, K2-EDTA and K3-EDTA plasma
- Sample volume: 10 µL
- Limit of detection: 15 pmol/L
- Measuring range: 15 – 1,500 pmol/L
- Intermediate imprecision **cobas e 411** analyzer, Elecsys 2010 analyzer: 2.7 – 4.3 %  
**cobas e 601/e 602** modules, E170: 2.6 – 3.4 %
- Repeatability **cobas e 411** analyzer, Elecsys 2010 analyzer: 1.3 – 1.8 %  
**cobas e 601/e 602** modules, E170: 1.5 – 1.9 %

- 1 Moore, R.G., Brown, A.K., Miller, M.C., Skates, S., Allard, W.J., Verch, T., Steinhoff, M., Messerlian, G., DiSilvestro, P., Granai, C.O., Bast, R.C. Jr. (2008). The use of multiple novel tumor biomarkers for the detection of ovarian carcinoma in patients with a pelvic mass. *Gynecologic Oncology*, Volume 108, Issue 2, February, 402-408, ISSN 0090-8258, <http://dx.doi.org/10.1016/j.ygyno.2007.10.017>. (<http://www.sciencedirect.com/science/article/pii/S0090825807008542>).
- 2 Nassir, M., Guan, J., Luketina, H. et al. (2016). *Tumor Biol.* 37: 3009. doi:10.1007/s13277-015-4031-9.
- 3 Moore, R.G. et al. (2009). A novel multiple marker bioassay utilizing HE4 and CA125 for the prediction of ovarian cancer in patients with a pelvic mass. *Gynecologic Oncology*, 112, 40-46.
- 4 Dayyani, F., et al. (2006). Diagnostic performance of Risk of Ovarian Malignancy Algorithm against CA 125 and HE4 in connection with ovarian cancer. *Int J Gynecol Cancer*, 26, 1586-93.
- 5 Ortiz-Munoz, B., et al. (2014). HE4, Ca125 and ROMA algorithm for differential diagnosis between benign gynaecological diseases and ovarian cancer. *Tumour Biol*, 35, 7249-58.



\*ROMA is a registered trademark of Fujirebio Diagnostics, Inc.

Calculation of the ROMA-values for pre- and postmenopausal women and individual cut-points for the Elecsys assays to separate between low and high risk patients.

# Elecsys® ProGRP

## Crucial information for differential diagnosis in lung cancer and monitoring of small-cell lung cancer patients

Progastrin-releasing peptide (ProGRP) is a tumor marker with benefits for the management of small-cell lung cancer patients.

Lung cancer is one of the most common cancers in the world with 1.35 million new cases diagnosed every year. The two main histological types of the disease are small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). It is important to distinguish between these two subtypes as they have different treatments and prognoses. NSCLC (approx. 80% of cases), when in the early stages, is curable with surgery. SCLC, however, is an aggressively spreading neoplasm of rapid growth that is usually only treatable with chemo and radiotherapy.<sup>1</sup>

ProGRP is the tumor marker of choice for SCLC as it aids in quick and decisive discrimination between SCLC and NSCLC for faster decisions on patient treatment. ProGRP is also a tumor marker that can be used to assess response to therapy as well as to monitor recurrence of the disease.<sup>2</sup>

In future, lung cancer biomarkers such as ProGRP can also play an important role in assessing therapy resistance of patients receiving targeted EGFR-tyrosine kinase inhibitor (TKI) therapies. It has been demonstrated that a subset of NSCLCs with mutated EGFR return as SCLC when resistance to EGFR-TKIs develops and that this is caused by a transformation from NSCLC to SCLC.<sup>2</sup>

### Your benefit

- High sensitivity and discrimination aiding the accurate differential diagnosis of SCLC
- Excellent precision across the entire measuring range for reliable results

### Lung cancer differential diagnosis

ProGRP serum/plasma level

SCLC  
>80.1 pg/mL

NSCLC  
<80.1 pg/mL

The 80.1 pg/mL cut-off value is based on the 95% specificity of the NSCLC collective.

- 1 Ferlay, J., Soerjomataram, I., Ervik, M., Dikshit, R., Eser, S., Mathers, C., Rebelo, M., Parkin, D.M., Forman, D., Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>, accessed on day/month/year.
- 2 Oser, M.G. et al. (2015). Transformation from non-small cell lung cancer to small-cell lung cancer: molecular drivers and cells of origin. *Lancet Oncol.*; 16: e165-172.
- 3 Korse, C. et al (2015). Multicenter evaluation of a new progastrin-releasing peptide (ProGRP) immunoassay across Europe and China. *Clinica Chimica Acta* 438, 388-395.



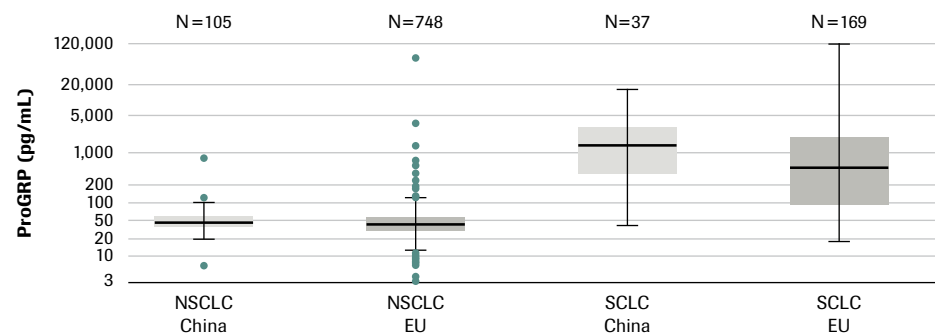
[www.cobas.com](http://www.cobas.com)



- Lung cancer biomarkers available on a single automated platform – CEA, CYFRA 21-1, NSE, ProGRP and SCC
- Equivalent performance between plasma and serum for flexibility and convenience, thus offering advantages over existing assays<sup>3</sup>

### Product characteristics

- Assay time: 18 min.
- Sample material:
  - Serum collected using standard sampling tubes or tubes containing separating gel
  - Li-heparin plasma, K<sub>2</sub>-EDTA and K<sub>3</sub>-EDTA plasma
- Sample volume: 30 µL
- Limit of detection (LoD): 3 pg/mL
- Measuring range (lower end defined by LoD): 3 – 5,000 pg/mL



Use of ProGRP for the primary differential diagnosis in lung cancer. The ability of ProGRP to distinguish SCLC from NSCLC was investigated in a study on 1059 patients in 5 centers in Europe and China (206 SCLCs and 853 NSCLCs), and ProGRP levels were correlated with biopsy proven histology. (Source: Elecsys ProGRP Method Sheet)

**cobas**®

# Elecsys® SCC

*An important part of Roche's portfolio  
in tumor markers for managing patients  
with squamous cell cancers*

The SCC assay is used as an aid in the management of patients with squamous cell carcinoma in conjunction with other methods that align to the standard clinical management guidelines.

SCC antigen (SCCA) has been studied in its involvement in squamous cell malignancies including lung, uterine cervix, esophagus, head & neck, anal canal and skin for many years.<sup>1-3</sup> SCCA levels can be elevated in squamous cell cancers and it has been reported that more advanced cancer stages are associated with higher SCCA levels especially in lung and cervical cancer.<sup>4,5</sup> It was reported that measurement of the antigen, in serial determinations, aids in the assessment of disease recurrence, residual disease following treatment, and response to therapy.<sup>6,7</sup>

## SCC antigen in different types of squamous cell cancers:

- SCCA has been reported as a biomarker for **non-small cell lung cancer (NSCLC)**, mainly of the squamous cell carcinoma type. SCC in lung is closely correlated with a history of tobacco smoking, more than other

types of lung cancer.<sup>8</sup> Based on literature, SCCA elevated serum levels were found to be indicative of NSCLC if renal failure and dermatological diseases were excluded.<sup>9</sup> Utility of SCCA in lung cancer has been also reported to indicate disease recurrence and residual disease following treatment and response to therapy.<sup>10</sup>

- The most common histology in **cervical cancer** is SCC, with SCCA being the biomarker of choice for this histology. Serum levels of SCCA have been found to correlate with tumor stage, tumor size and residual tumor after treatment, recurrent or progressive disease, and survival in patients with squamous cell cervical cancer.<sup>11,12</sup>
- 90 % of **head & neck cancers** are SCCs, in patients with primary tumors, SCCA serum levels were related to nodal involvement with significantly higher levels in node-positive patients. Multivariate analyses showed that SCCA is a significant independent predictor of disease-free survival and pretreatment levels are an independent prognostic indicator in patients with head and neck malignancies.<sup>13</sup>

## Your benefit

- Combining SCC antigen with other **lung cancer** biomarkers (ProGRP, CYFRA 21-1, NSE and CEA) gives a clearer picture on the patient's status
- SCC antigen as biomarker for **cervical cancer** is another tool in patient management together with other markers for gynecological malignancies (i.e. CA 125, HE4, CA 15-3, HPV, CINtec® PLUS Cytology)
- High assay precision for accurate and sustainable results for patient monitoring

- One blood sample for all lung cancer biomarkers for time and cost efficiency
- High reagent on-board stability
- Short turn around time for fast results

## Product characteristics

- Assay time: 18 min.
- Sample material: Serum, plasma
- Sample volume: 15 µL
- Measuring range: 0.1 – 70 ng/mL
- LoQ: 0.24 ng/mL
- Precision: 5 % CV
- Detection of SCC antigen 1 and 2
- Standardization: Abbott Architect

- 1 Kato, H., Torigoe, T. (1977). Radioimmunoassay for Tumor Antigen of Human Cervical Squamous Cell Carcinoma. *Cancer*; 40: 1621-1628.
- 2 Cataltepe, S., Gornstein, E.R., Schick, C., et al. (2000). Co-expression of the Squamous Cell Carcinoma Antigens 1 and 2 in Normal Adult Human Tissues and Squamous Cell Carcinomas. *J Histochem Cytochem*; 48(1): 113-122.
- 3 Torre, G.C. (1998). SCC antigen in malignant and nonmalignant squamous lesions. *Tumor Biol* 1998;19: 517-526.
- 4 Einarsson, R. (2005). Squamous Cell Carcinoma Antigen (SCCA) Isomers- Markers for squamous cell carcinoma. *Adv. Clin. Exp. Med.*; 14: 643-648.
- 5 Henry, R.J., Dodd, J.K., Tyler, J.P., and Houghton, C.R. (1987). SCC Tumor Marker and Its Relationship to Clinical Stage in Squamous Cervical Cancer. *Aust. NZJ. Obstet. Gynaecol.*; 27: 338-340.
- 6 Kenter, G., Bonfrer, J.M.G. and Heintz, A.P.M. (1987). Pretreatment Tumor-Antigen TA-4 in Serum of Patients With Squamous Cell Carcinoma of the Uterine Cervix. *Br. J. Cancer*; 56: 157-158.
- 7 Barak, V., Holdenrieder, S., Nisman, B., et al. (2009/2010). Relevance of circulating biomarkers for the therapy monitoring and follow-up investigations in patients with non-small cell lung cancer. *Cancer Biomarkers*; 6: 191-196.
- 8 Kenfield, S.A., Wei, E.K., Stampfer, M.J., Rosner, B.A., Colditz, G.A. (2008). Comparison of aspects of smoking among the four histological types of lung cancer. *Tobacco Control*; 17: 198-204.

- 9 Molina, R., Auge, J.A., Escudero, J.M., et al. (2008). Mucins CA 125, CA 19.9, CA 15.3 and TAG-72.4 as Tumor Markers in Patients with Lung Cancer: Comparison with CYFRA 21-1, CEA, SCC and NSE. *Tumor. Biol.*; 29: 371-380.
- 10 Ebert, W., Muley, T., Drings, P. (1996). Does the assessment of serum markers in patients with lung cancer aid in the clinical decision making process? *Anticancer Res.*; 16: 2161-2168.
- 11 Lozza, L., Merola, M., Fontanelli, R., et al. (1997). Cancer of the uterine cervix: clinical value of squamous cell carcinoma antigen (SCC) measurements. *Anticancer Research*; 17: 525-530.
- 12 Kato, H. et al. (1983). Prognostic significance of the tumor antigen T4-A in squamous cell carcinoma of the uterine cervix. *Am. J. Obstet. Gynecol.*; 145: 350-354.
- 13 Molina, R., Torres, M.D., Moragas, M., Perez-Villa, J., Filella, X., Jo, J., Farrus, B., Giménez, N., Traserra, J., Ballesta, A.M. (1996). Prognostic significance of SCC antigen in the serum of patients with head and neck cancer. *Tumor Biol.*; 17: 81-90.

# The Roche lung cancer diagnostics portfolio

Strengthen our diagnostics position in Oncology using the potential of Roche's full lung cancer portfolio for patient management across all business areas utilizing all available technologies.

## Background

- Enhanced medical value with a comprehensive tumor marker panel
- This requires a common vision and strategy for oncology, a coordinated portfolio view across technologies and a consolidated commercialization focus

## Hematoxylin & Eosin Stain (H&E)/Immunohistochemistry (IHC)



VENTANA  
HE 600 system



VENTANA  
BenchMark ULTRA  
system



VENTANA  
BenchMark XT  
system



VENTANA  
BenchMark GX  
system



VENTANA iScan HT

## Immunochemistry (IC)

cobas e 801

cobas c 501

cobas e 601



cobas® 8000 modular  
analyzer series



cobas® 6000 analyzer series



cobas e 411  
analyzer



cobas z 480  
analyzer

## Polymerase Chain Reaction (PCR)

## Initial Assessment



### Imaging

**CEA, CYFRA21-1, SCC, ProGRP**  
Diagnostic aid in addition to imaging and histology



**Cancer Center**

CT Biopsy

## Differential Diagnosis and Staging



### H&E

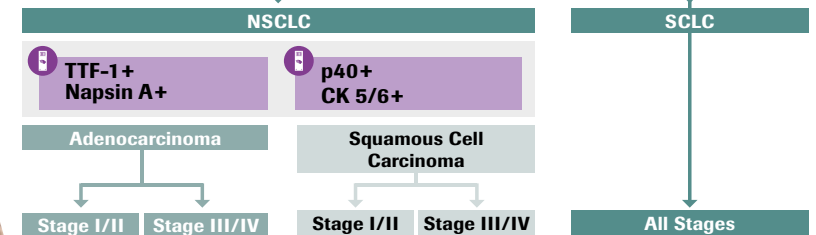
Histological classification  
About 70 % of NSCLC cases can be diagnosed based on morphological evaluation alone

### IHC

Sub-typing  
About 30 % of cases require IHC to subclassify poorly differentiated non-small cell lung carcinomas

**ProGRP for differential diagnosis in case of histological discrepancies**

## Prediction



## Therapy Decision



**Surgery**

In case of recurrence

**Targeted Therapy**  
Tarceva® and TAGRISSO™ (T790M) for EGFR+, XALKORI® for ALK+

In case of resistance

**Chemotherapy**  
**Radiotherapy**

## Monitoring



### EGFR

Therapy monitoring of EGFR+ patients

### CEA, CYFRA21-1

Recurrence Detection

### CEA, CYFRA21-1, NSE, ProGRP

Therapy monitoring with serum panel depending on leading biomarker initially elevated

## Imaging

Immunochemistry (IC)

Polymerase Chain Reaction (PCR)

Hematoxylin & Eosin Stain (H&E)/Immunohistochemistry (IHC)

# Elecsys® Calcitonin

*A powerful tool for the diagnosis and monitoring of medullary thyroid carcinoma (MTC)*



www.cobas.com



Thyroid carcinoma is the most common malignancy of the endocrine system. In up to 10 % of all thyroid carcinoma patients a medullary thyroid carcinoma (MTC) is identified. These carcinoma produce elevated serum concentrations of calcitonin and therefore can be diagnosed with an exceptional degree of accuracy and specificity by immunoassays measuring serum calcitonin. The diagnostic marker calcitonin is a sensitive and specific tumor marker for the diagnosis as well as for the life-long monitoring of MTC patients after thyroid surgery.<sup>1</sup>

## Elecsys® Calcitonin – excellent precision at low concentrations

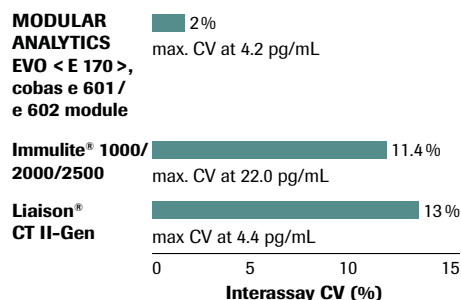


Figure 2: Comparison of interassay CVs (coefficient of variation) at the lowest concentrations tested. Source: package inserts; March 2013.

## Your benefit

### A marker with high specificity for MTC (Figure 1)

- Sensitive tool for diagnosis and follow-up of MTC
- High correlation with tumor burden, supporting early detection of new or residual disease

### Elecsys® Calcitonin with high precision

- High sensitivity and precision at low end concentrations ensure improved follow-up and monitoring (figure 2)
- Excellent precision across the entire measuring range support accurate results

## Workflow efficiency with the most complete automated thyroid portfolio

- All tests required for differential diagnosis of thyroid diseases are consolidated on one platform, including routine thyroid assays and specialties such as Elecsys TgII, Elecsys Calcitonin, Elecsys Anti-Tg, Elecsys Anti-TPO and Elecsys Anti-TSHR

<sup>1</sup> Bories, P.N., et al. (2016). Comparison of the Elecsys calcitonin assay with the Immulite 1000 assay. Describing one case with heterophilic antibody interference. *Clin Chem Lab Med*, 54:e45–7.

## Product characteristics

- Assay time: 18 min.
- Sample material: Serum, Li-heparin plasma, K<sub>2</sub>-EDTA plasma, K<sub>3</sub>-EDTA plasma
- Sample volume: 50 µL
- LoB, LoD, LoQ\*: 0.3 pg/mL, 0.5 pg/mL, 1 pg/mL
- Measuring range: 0.5 – 2,000 pg/mL
- Traceability: IRP WHO 89/620
- Total imprecision:
  - **cobas e 411** analyzer, E2010: 2.6 – 5.2 %
  - **cobas e 601/cobas e 602** modules, E170: 1.6 – 2.3 %



\* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation with a total allowable error of ≤30 %

## Elecsys® Calcitonin – high specificity for MTC

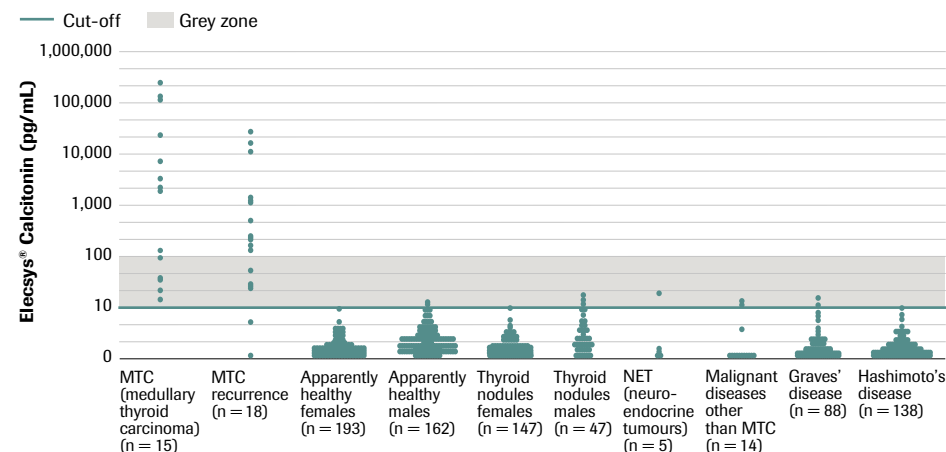


Figure 1: Calcitonin is a highly specific marker for MTC, allowing early and specific diagnosis and reliable monitoring. Source: Performance Evaluation Study 2013, data available upon request.

# Elecsys® Tg II

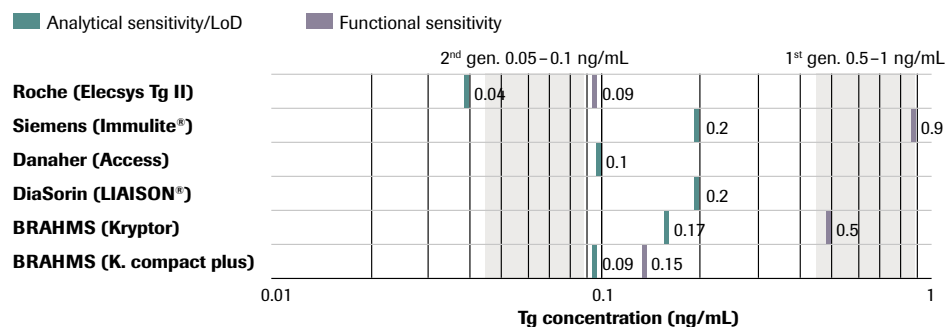
## The power to offer more for differentiated thyroid cancer (DTC) management

The main application for Thyroglobulin (Tg) testing is the post-operative follow-up of patients with differentiated thyroid carcinoma (DTC). Detectable levels of serum Tg after total thyroidectomy are indicative of persistent or recurrent DTC.<sup>1</sup>

### Your benefit

#### Excellent functional sensitivity and precision

- Improved sensitivity comes with better precision in the range around the clinical cut-off and improved negative predictive value
- Sensitive Tg assays can avoid TSH-stimulated Tg testing during follow-up in low-risk patients<sup>1</sup>
- Patients with a basal Tg below the functional sensitivity of a sensitive Tg assay have a high chance of being free of disease<sup>2</sup>



Sensitivity of current automated Tg assays: Elecsys Tg II with best-in-class sensitivity.

Source: Package inserts, Feb. 2013.

### High quality patient results and accurate long-term monitoring

- Excellent precision across the entire measuring range supports accurate results
- Lot-to-lot consistency across all **cobas**® platforms allows a reliable long-term patient monitoring
- Elecsys Tg II shows lower TgAb interference compared to other assays

### Higher sensitivity allows for potentially earlier detection of persistence or recurrence

- Increasing concentrations of Tg (even at low concentrations) are an early and reliable indicator of recurrent disease
- Treatment is usually more successful with early detection as the tumor burden is lower



### Product characteristics

- Assay time: 18 min.
- Sample material: Serum, K<sub>2</sub>-EDTA plasma, K<sub>3</sub>-EDTA plasma
- Sample volume: 35 µL
- LoB, LoD, LoQ\*: 0.02 ng/mL, 0.04 ng/mL, 0.1 ng/mL
- Measuring range: 0.04 – 500 ng/mL
- Traceability: BCR-CRM 457
- Total imprecision:
  - **cobas e 411** analyzer, E2010: 2.6 – 9.2 %
  - **cobas e 601/cobas e 602** modules: 4.0 – 5.9 %

<sup>1</sup> Haugen, B.R., et al. (2015). American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. *Thyroid*, 26:1-133.

<sup>2</sup> Giovanella, L., et al. (2014). Thyroglobulin measurement using highly sensitive assays in patients with differentiated thyroid cancer: a clinical position paper. *Eur J Endocrinol*, 171: R33-46.

\* LoB = Limit of Blank; LoD = Limit of Detection;

LoQ = Limit of Quantitation with a total allowable error of ≤20 %.

# Elecsys® Anti-TSHR

## Complex testing simplified and automated



www.cobas.com



Elecsys Anti-TSHR (TRAK) is a fully automated test for detection of autoantibodies to the TSH receptor.

### Clinical utility:

- Detection or exclusion of Graves' autoimmune hyperthyroidism and differentiation from disseminated autonomy of the thyroid gland (figure 1)
- Monitoring therapy and prediction of relapse<sup>1</sup>
- Assessing the risk of developing fetal hyperthyroidism in the last trimester of pregnancy<sup>2</sup>

### Your benefit

#### Improved efficiency

- Fully automated test for more workflow efficiency, allows for consolidation of tests required for differential diagnosis of thyroid diseases
- Rapid availability of Anti-TSHR results supports cost- and time-efficient differential diagnosis of thyroid diseases and early treatment

#### High quality results

- Advanced assay quality based on proven and leading ECL technology
- Excellent precision across the entire measuring range (figure 2)
- High diagnostic value based on high sensitivity paired with high specificity (figure 1<sup>3</sup>)

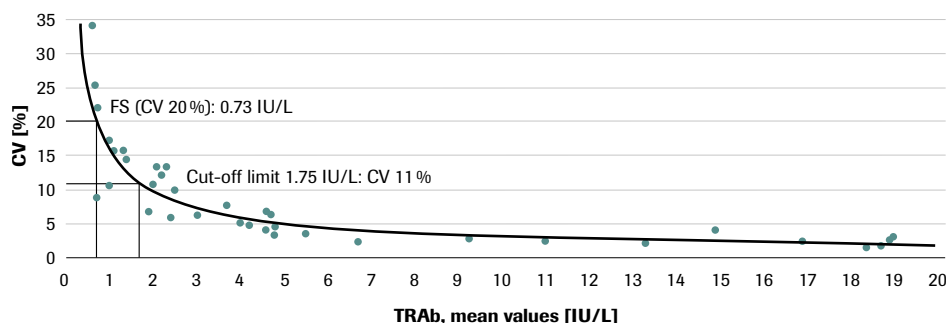


Figure 2: The functional sensitivity of Elecsys Anti-TSHR at approx. 0.9 IU/L is significantly below the cut-off ( $\geq 1.75$  IU/L), allowing clear differentiation of pathological results.

### Product characteristics

- Assay time: 27 min.
- Sample volume: 50  $\mu$ L
- Measuring range: 0.3–40 IU/L
- Functional sensitivity: 0.9 IU/L
- Cut-off: 1.75 IU/L
- Precision: < 6 %
- Strong discrimination between positive and negative results
- Standardization: NIBSC 1<sup>st</sup> IS 90/672



### High clinical accuracy of Elecsys® Anti-TSHR

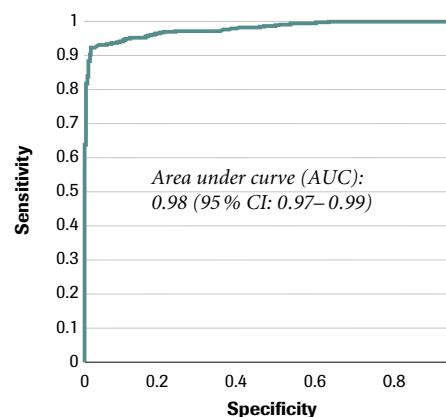


Figure 1: Clinical accuracy of Elecsys Anti-TSHR.<sup>3</sup>

The clinical study comprised:

- 436 samples from apparently healthy individuals
- 210 patients with thyroid diseases excluding Grave's disease
- 102 patients with untreated Grave's disease

Using a cutoff of 1.75 IU/L a clinical sensitivity of 97 % and a specificity of 99 % was obtained.

- 1 Barbesino, G. and Tomer, Y. (2013). Clinical review: Clinical utility of TSH receptor antibodies. *J Clin Endocrinol Metab*, 98(6):2247–55.
- 2 Erik, K.A. et al. (2017). Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease during Pregnancy and the Postpartum. *Thyroid*. DOI: 10.1089/thy.2016.0457.
- 3 Hermesen, D. et al. (2009). Technical evaluation of the first fully automated assay for the detection of TSH receptor autoantibodies. *Clin Chim Acta*, 401(1–2):84–89.

# Elecsys® Vitamin D total II

Allowing better patient care with results you can trust



www.cobas.com



Vitamin D has a proven impact on bone mineral density and bone quality. Desirable levels of 30 ng/mL have been shown to reduce the risk of falls and fractures.

There is also growing scientific evidence linking the level of vitamin D (25-OH) to an increased risk of other indications such as diabetes, cardiovascular disease, autoimmune diseases, and different forms of cancer. The Elecsys Vitamin D total II assay aids in the assessment of vitamin D sufficiency.



## Your benefit

- Direct traceability to the official reference measurement procedure (Ghent University ID-LC-MS/MS) for confidence in patient results
- High lot-to-lot consistency for optimal therapy monitoring
- Excellent functional sensitivity and superior precision over the clinically relevant range
- Efficiency due to consolidation of Vitamin D total,  $\beta$ -CrossLaps, P1NP, Osteocalcin and PTH testing on one fully automated platform

## Traceability and standardization

### National Institute of Standards and Technology (NIST)

#### Standard Reference Material (SRM) 2972

Ethanol solutions of vitamin D2 (25-OH) and vitamin D3 (25-OH) prepared gravimetrically

#### SRM 972a

Four levels of serum with different concentration levels of vitamin D (25 OH), value assigned by LC-MS/MS

### Reference method ID-LC-MS/MS Ghent

Calibration: Reference Method Procedure (RMP) calibrated with NIST standards

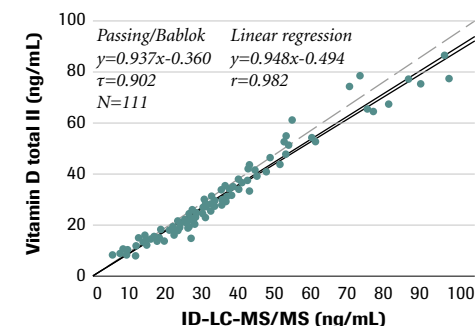
### Elecsys Vitamin D total II assay

Calibrators based on human serum matrix standardised against ID-LC-MS/MS

## Product characteristics

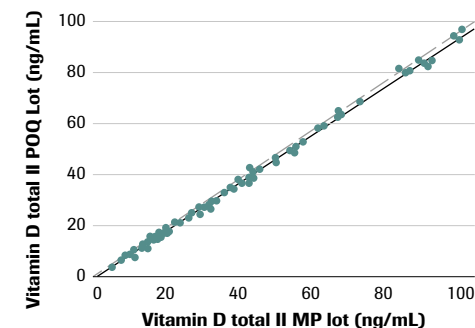
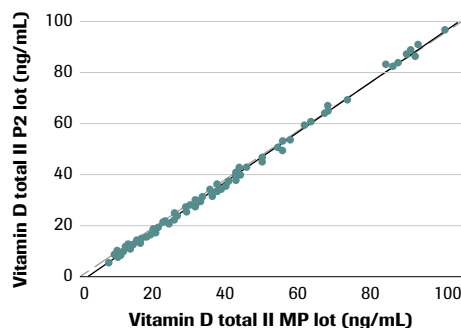
- Assay time: 27 min.
- Sample material: Serum and plasma
- Sample volume: 12  $\mu$ L
- Limit of Quantitation:  
 $\leq 5$  ng/mL ( $\leq 12.5$  nmol/L)
- Repeatability:  $< 20$  ng/mL SD  $\leq 1.1$  ng/mL;  
 $> 20$  ng/mL CV  $\leq 5.5$  %
- Intermediate Precision:  $< 20$  ng/mL  
SD  $\leq 1.4$  ng/mL;  $> 20$  ng/mL CV  $\leq 7.0$  %

## Proven accuracy with CDC reference samples



ID-LC-MS/MS vs Vitamin D total II CDC reference samples (MP lot, cobas e 411 analyzer)

## Consistent results from lot to lot



| N=123     | Slope | Intercept | Kendall |
|-----------|-------|-----------|---------|
| P2 vs MP  | 1.03  | -1.76     | 0.959   |
| POQ vs MP | 0.983 | -0.888    | 0.962   |

# Fully automated Elecsys® Anti-Müllerian Hormone (AMH) assay

*Providing clinical confidence in reliable  
assessment of ovarian reserve and prediction of  
response to controlled ovarian stimulation*

Mean female age at first birth has increased steadily over the past few decades in many developed countries. This postponement leads to couples attempting to have children during a period where female fertility is already in decline. 30 % of infertility problems among women arise from diminished ovarian reserve.

**Anti-Müllerian hormone (AMH)** is a direct serum marker of functional ovarian reserve and plays an important role in assessing ovarian reserve levels and therefore the capacity to provide eggs for fertilization.

Serum AMH levels have been shown to remain relatively stable during the menstrual cycle and may be measured on any day of the cycle.

AMH is a reliable marker for prediction of response to controlled ovarian stimulation and can therefore add prognostic information to the counseling and planning process for infertile couples seeking treatment.

## Your benefit

- Fully automated, fast, sensitive and robust measurement of AMH
- High precision over entire measuring range for reliable results
- Clinical agreement with Antral-Follicle-Count (AFC)
- Age specific reference ranges and PCOS (polycystic ovary syndrome) information

Anti-Müllerian Hormone. Elecsys and cobas e analyzers package insert 2016.

La Marca, A., Broekmans, F.J. (2009). *Hum Reprod*; 24(9):2264–75.

Visser, J.A., Themmen, A.P. (2005). *Mol Cell Endocrinol*; 234(1–2):81–6.

La Marca, A., Volpe, A. (2007). *Hum Reprod Update*; 13(3):265–73.

Anderson, R.A. et al. (2012). *Maturitas*; 71:28–33.

Van Disseldorp, J. et al. (2010). *Hum Reprod*; 25:221–227.

Tsepelidis, S. et al. (2007). *Hum Reprod*; 22:1837–1840.

The Practice Committee of the American Society for Reproductive Medicine. (2011). *Fertil Steril*; 98:1407–1415.

Deeks, E.D. (2015). *Mol Diagn Ther*; 19(4):245–249.

Nelson, S.M., Pautuszek, E., Kloss, G. et al. (2015). *Fertil Steril*; 104(4):1016–1021.e6.

Anckaert, E., Oktem, M. et al. (2015). *Clin Biochem*; <http://dx.doi.org/10.1016/j.clinbiochem.2015.10.008>.

Anderson, R.A., Anckaert, E., Bosch, E. et al. (2015). *Fertil Steril*; 103(4):1074–1080.e4.

Rotterdam ESHRE/ASRM-Sponsored PCOS consensus workshop group (2004). *Hum Reprod*; 19:41–47.



[www.cobas.com](http://www.cobas.com)

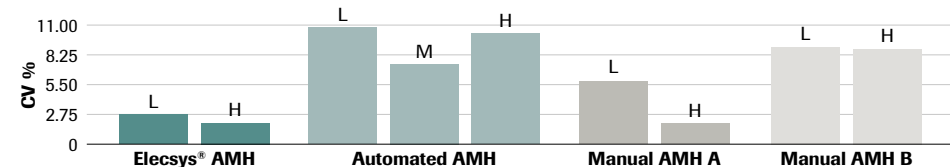


## Fully automated, fast, sensitive and robust measurement of AMH

|                        |                                                                                  |
|------------------------|----------------------------------------------------------------------------------|
| Testing time           | 18 min.                                                                          |
| Measuring range        | 0.07 – 164 pmol/L (0.01 – 23 ng/mL)                                              |
| LoB, LoD, LoQ*         | 0.049 pmol/L (0.007 ng/mL), 0.07 pmol/L (0.010 ng/mL), 0.21 pmol/L (0.030 ng/mL) |
| Repeatability          | 1.0 – 1.8% CV (1.6 – 140 pmol/L; 0.232 – 19.6 ng/mL)                             |
| Intermediate Precision | 2.7 – 4.4% CV (1.6 – 140 pmol/L; 0.232 – 19.6 ng/mL)                             |

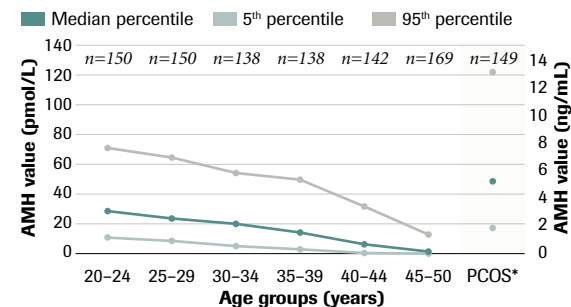
\* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation (20 % total error)

## High precision over entire measuring range for reliable results



Results of an independent study demonstrates Elecsys AMH provides superior precision at clinically relevant levels  
L: low level control; M: medium level control; H: high level control

## Age specific reference ranges and Polycystic ovary syndrome (PCOS) information



Elecsys® AMH values of apparently healthy women per 5 years age groups and Elecsys AMH of women with diagnosed PCOS  
\* According to the revised diagnostic criteria of PCOS defined by the Rotterdam ESHRE/ASRM-sponsored PCOS consensus workshop group

# Elecsys® sFlt-1/PIGF

## Short term prediction and diagnosis of preeclampsia

Preeclampsia is a serious multi-system complication of pregnancy, occurring in 3–5% of pregnancies, and it is one of the leading causes of maternal and perinatal morbidity and mortality worldwide.

Preeclampsia is defined as new-onset of hypertension and proteinuria after 20 weeks of gestation. The clinical presentation of preeclampsia and subsequent clinical course of the disease can vary tremendously, making prediction, diagnosis and assessment of disease progression difficult.

Angiogenic factors (sFlt-1 and PIGF) are proven to play an important role in the pathogenesis of preeclampsia and their concentrations in maternal serum are altered even before the onset of the disease making them a tool for prediction and diagnosis of preeclampsia.



### Your benefit

In a recent multicentre, prospective study – PROGNOSIS (Prediction of short-term outcome in pregnant women with suspected preeclampsia study) – the Elecsys sFlt-1/PIGF ratio proved to be a helpful tool in enabling clinicians to exclude preeclampsia for 1 week with very high confidence, reassuring women suspected of having the disease that is safe to go home.

- Elecsys sFlt-1 and PIGF immunoassays for preeclampsia are the first available and approved automated diagnostic tests for fast and easy assessment in a clinical context
- The measurement of the Elecsys sFlt-1/PIGF ratio is a reliable tool to identify the patients that are at high risk to develop preeclampsia requiring a closer monitoring and to confidently send home patients that are not going to develop the disease
- Early and precise diagnosis of preeclampsia can lead to effective clinical management and improved outcome for both mother and child



www.cobas.com



### Product characteristics

#### Technical assay features of Elecsys® sFlt-1 and PIGF

|                 | sFlt-1          | PIGF           |
|-----------------|-----------------|----------------|
| Assay time      |                 | 18 min.        |
| Sample material |                 | Serum          |
| Sample volume   | 20 µL           | 50 µL          |
| Measuring range | 10–85,000 pg/mL | 3–10,000 pg/mL |

The PROGNOSIS study collected samples and clinical data from 1,273 pregnant women with clinical suspicion of PE, between 24 + 0 and 36 + 6 weeks of gestation, at 30 study sites in different global locations.

A cut-off of <38 for the sFlt-1/PIGF ratio was identified for the rule out of preeclampsia and is approved by NICE for use in clinical practice. In addition cut-offs that aid in diagnosis (i.e. rule-in of PE) have also been validated, though these are not currently recommended by NICE.

### Elecsys® sFlt-1/PIGF ratio cut-offs

#### Early onset preeclampsia – gestational week 20 – 33 + 6 days

|                             |                                            |                                                                                            |
|-----------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------|
| sFlt-1/PIGF<br>≥ 85         | Diagnosis                                  | 99.4 % specificity<br>the woman has preeclampsia<br>Sensitivity: 88.0%                     |
| sFlt-1/PIGF<br>< 85<br>> 38 | Prediction<br>rule-in in the next 4 weeks  | 36.7 % PPV<br>the woman is at high risk to develop<br>preeclampsia within the next 4 weeks |
| sFlt-1/PIGF<br>≤ 38         | Prediction<br>rule-out for the next 1 week | 99.3 % NPV<br>the woman will not develop<br>preeclampsia for the next 1 week               |

Verlohren, S., Herraiz, I., Lapaire, O., Schlembach, D., Zeisler, H., et al. (2014). *Hypertension*; 63(2),346–352.

Verlohren, S., Galindo, A., Schlembach, D., et al. (2010). *Am J Obstet Gynecol*; 202(161).e1–11

Zeisler, H., Llorba, E., Chantraine, F., et al (2016). *N Engl J Med*; 374:13–22

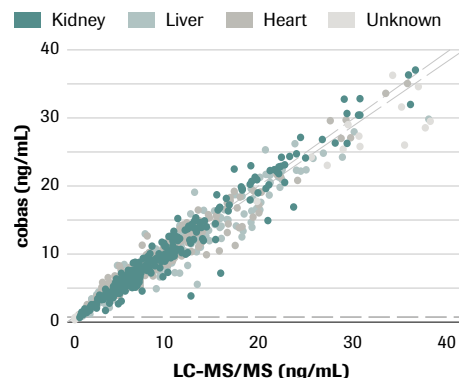
National Institute for Health and Care Excellence (2016). NICE guideline DG23.

# The full SWA immunosuppressive drug assay panel

*Trusted and consistent results for organ transplant patients*

Optimal immunosuppressive therapy, defined clinically and by therapeutic drug monitoring (TDM), is essential to prevent acute rejection and ensure long-term survival of both the patient and the allograft. Characterized by a narrow therapeutic window, the use of immunosuppressive drugs (ISDs) requires both precise and consistent measurement of their concentration in whole blood during life-long monitoring.<sup>1</sup>

*N = 1029 samples, Weighted Deming Regression  
y = 1,07 x - 0,269, r = 0,97*



*Elecsys® Tacrolimus: excellent correlation with a well evaluated LC-MS/MS. (Source: Multicenter evaluation study 2013)*

## Your benefit

### Consolidation for optimized workflow

The recently launched Elecsys Sirolimus and Everolimus assay complete the ISD menu and are an important addition to the **cobas** TDM menu making it the most complete ISD product offering.

- The full ISD menu now available on one automated and integrated Roche SWA platform:
  - Best-in-class automated MPA available on **cobas c** modules<sup>2</sup>
  - Elecsys Cyclosporine and Tacolimus now completed with Sirolimus and Everolimus on **cobas e** modules

- One universal pre-treatment procedure for all ISD assays increase efficiency, ensure high quality results for every product and reduce handling errors in the lab
- Outstanding possibilities for consolidation with >230 parameters on one **cobas**® platform

### High precision for confidence in results

- High precision at low drug concentrations and across a wide measuring range
- Excellent performance confirmed in routine customer laboratories<sup>3</sup>



www.cobas.com



## Consistent results for life-long monitoring

- Excellent lot-to-lot comparability and traceability
- Consistent patient results across all **cobas**® platforms due to universal reagent concept
- Low variability across different customer labs proven in external quality schemes<sup>3</sup>
- High comparability to well established and validated LC-MS/MS



## Product characteristics

|                                               | Tacrolimus                    | Cyclosporine     | Sirolimus      | Everolimus     |
|-----------------------------------------------|-------------------------------|------------------|----------------|----------------|
| <b>Assay time</b>                             | 18 min.                       |                  |                |                |
| <b>Sample material</b>                        | EDTA whole blood              |                  |                |                |
| <b>Sample volume</b>                          | 300 µL                        |                  |                |                |
| <b>Sample pretreatment</b>                    | Identical sample pretreatment |                  |                |                |
| <b>Sensitivity LoB*</b>                       | 0.3 ng/mL                     | 20 ng/mL         | 0.4 ng/mL      | 0.4 ng/mL      |
| <b>LoD*</b>                                   | 0.5 ng/mL                     | 30 ng/mL         | 0.5 ng/mL      | 0.5 ng/mL      |
| <b>LoQ*</b>                                   | 1.0 ng/mL                     | 50 ng/mL         | 1.5 ng/mL      | 1.0 ng/mL      |
| <b>Measuring range</b>                        | 0.5 – 40 ng/mL                | 30 – 2,000 ng/mL | 0.5 – 30 ng/mL | 0.5 – 30 ng/mL |
| <b>Total imprecision cobas e 411 analyzer</b> | 2.1–14.2%                     | 4.2–9.2%         | 2.8–10.9%      | 2.7–8.1%       |
| <b>cobas e 601/e 602 modules</b>              | 2.4–10.4%                     | 3.1–6.4%         | 3.4–9.5%       | 3.9–6.7%       |

\* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation

1 De Jonge, H., Naesens, M., Kuypers, D.R. (2009). New insights into the pharmacokinetics and pharmacodynamics of the calcineurin inhibitors and mycophenolic acid: possible consequences for therapeutic drug monitoring in solid organ transplantation. *Ther Drug Monit*: 31, 416–435.

2 Method sheets as of 2015.

3 IPT (International Proficiency Testing) scheme, Analytical Services International Ltd, UK (including data reports from June 2014 to August 2015).

**cobas**®



# Platelet function testing

## *Hemostasis*

# Coagulation

## *Laboratories*

# Multiplate

## Hemostasis testing

Roche is moving towards a comprehensive new hemostasis testing portfolio with a number of industry firsts and innovative applications for early disease detection and monitoring. From easy-to-use, low-volume analyzers for self- and professional monitoring, to systems meeting the high efficiency requirements of the laboratory, Roche's products provide the highest quality results, offering outstanding productivity while reducing complexity.

Like Roche's current instruments, the new generation of testing solutions is driven by a commitment to deliver high-quality, cost-effective solutions capable of addressing the current and future testing needs of a wide range of customers.

The **cobas t 411** coagulation analyzer is the recent addition to Roche's Hemostasis portfolio. It serves low- to medium-volume central coagulation laboratories. Featuring innovative sample and reagent management concepts, It enables increased operator convenience and productivity.

The coagulation portfolio will be expanded by instruments that will serve the medium- to high-volume laboratories and for which connectivity to Roche's automation line will be available.

The new coagulation analyzers, combined with the point-of-care meters, the Multiplate® analyzer and the LightCycler® for genetic hemostasis testing will allow Roche to provide a full portfolio of solutions for primary and secondary hemostasis testing.

For more information please visit [www.cobas.com](http://www.cobas.com) and [www.roche-multiplate.com](http://www.roche-multiplate.com)

# cobas t 411 coagulation analyzer

## *For maximum efficiency*



[www.cobas.com](http://www.cobas.com)



The **cobas t 411** coagulation analyzer is the powerful first member of the new coagulation family of products designed for the low to medium throughput laboratory.

The **cobas t 411** analyzer is ideally suited for maximum efficiency and flexibility supported by innovative features like automated, multi-vendor cap-piercing and integrated barcode scanning for samples and reagents.

Featuring continuous loading of reagents, samples and cuvettes, the **cobas t 411** analyzer ensures maximum productivity and dynamic workflow.



*cobas t 411 coagulation analyzer*

### Your benefit

#### Ease-of-use

- High reagent, sample and cuvette storage capacity requires minimal interaction during daily use
- Start mechanism via one button start system

#### Dynamic workflow

- Continuous loading
- Large onboard storage capacity, walk-away time is maximized and hands-on time minimized
- Dedicated STAT port

### Premium safety

- Automated multi-vendor cap-piercing
- Positive sample management via the integrated automatic barcode scanner
- Patient results are fully traceable

### Product characteristics\*

#### Throughput

- Up to 140 tests/hour (PT)
- Up to 100 tests/hour (mixed mode)

#### Samples

- Up to 100 samples on-board
- Cap-piercing
- Dedicated STAT port
- Continuous loading via 5 position racks

#### Reagents

- Continuous rack-based loading
- Up to 70 vials on-board capacity
- Extended Routine Menu including PT, APTT, FIB, TT, AT and DD

#### Test principle

- Unique opto-mechanical measuring principle
- Clotting, chromogenic, immuno-turbidimetric assays



### Software

- Comprehensive QC program including Levey-Jennings
- User-definable protocols
- LIS connectivity

*\* based on Product Specification Sheet*

# Multiplate® analyzer

## Platelet function testing with excellent predictivity



www.roche-multiplate.com



Blood platelets play a pivotal role in physiological hemostasis, but also in the development of arterial thrombosis (myocardial infarction and stroke). Platelet function testing is utilized in the analysis of inherited and acquired platelet function disorders that may cause a transient or permanent bleeding tendency. The Multiplate analyzer can detect platelet dysfunction and thus aid in the therapeutic management of such patients.

It can also be used for monitoring of anti-platelet drugs where both compliance and drug effectiveness are key issues. It was shown with Multiplate analyzer results<sup>1</sup> that up to 20% of patients do not respond adequately to clopidogrel treatment. These

patients have a 5–10 fold increased risk of stent thrombosis, stroke and myocardial infarction<sup>1–4</sup> following percutaneous coronary interventions. Multiplate analyzer delivers excellent predictivity<sup>5</sup> and evidence is available demonstrating that Multiplate guided anti-platelet therapy has the potential to improve patient outcome.<sup>6–8</sup>

The Multiplate analyzer also plays a role in the analysis of platelet function in anesthesia and intensive care, where platelet dysfunction can lead to severe bleeding complications. The detection or exclusion of platelet dysfunction before invasive procedures or in bleeding patients can aid the risk stratification and management in these situations.<sup>9–11</sup>

- 1 Sibbing, D. et al. (2009). *J Am Coll Cardiol*. Mar 10; 53(10):849–56.
- 2 Sibbing, D. et al. (2010). *Thromb Haemost. Jan*; 103(1):151–9.
- 3 Schulz, S. et al. (2010). *Am Heart J. Aug*; 160(2):355–61.
- 4 Siller-Matula, J.M. et al. (2010). *J Thromb Haemost. Feb*; 8(2):351–9.
- 5 Tantry, U. et al. (2013). *J Am Coll Cardiol*. 62:2261–73.
- 6 Siller-Matula, J.M. et al. (2013). *Int J Cardiol. Sep 1*; 167(5): 2018–2023.
- 7 Sibbing, D. et al. (2012). *J Am Coll Cardiol*. 59; E265.
- 8 Aradi et al. (2013). *J Am Coll Cardiol*. 61(10): E1922.
- 9 Ranucci, M. et al. (2011). *Ann Thorac Surg. Jan*; 91(1):123–9.
- 10 Weber, C.F. et al. (2012). *Anesthesiology, Sep*; 117(3):531–47.
- 11 Rafiq, S. et al. (2016). *J Card Surg*. 31(9):565–71.
- 12 Straub, N. et al. (2013). *Thromb Haemost*, 111(2):290–299.

Not for use in the US.



### Your benefit

#### Cost-effective therapies

- in cardiac surgery<sup>10,11</sup>
- in coronary interventions<sup>12</sup>

#### Fast and easy assessment

- of platelet function from small volumes of whole blood

#### Excellent predictivity

- for stratification of bleeding risk in surgical procedures
- for tailored anti-platelet therapy

### Consistent results

- using standardized reagents and procedures

### Medical momentum

- More than 600 Medline publications, consensus papers with Multiplate and published guidelines for PFT

### Product characteristics

- High throughput: 30 tests/hour
- Sample volume: only 300 µL per analysis
- Fast turn-around time: 10 min./test

### Comprehensive reagent menu of CE marked tests and controls

| Products                      | Description                                                                                                                                 |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| ADPtest                       | ADP induced platelet activation sensitive to clopidogrel, prasugrel and other ADP receptor antagonists                                      |
| ASPItest                      | Cyclooxygenase dependent aggregation (using arachidonic acid) sensitive to Aspirin®, NSAIDs and other inhibitors of platelet cyclooxygenase |
| COLtest                       | Collagen induced aggregation                                                                                                                |
| RISTOtest                     | vWF and GpIb dependent aggregation (using ristocetin)                                                                                       |
| TRAPtest                      | Platelet stimulation via the thrombin receptor (using TRAP-6), sensitive to IIb/IIIa receptor antagonists                                   |
| Prostaglandin E1 reagent      | For the assessment of ADPtest HS (high sensitivity). For the assessment of positive (i.e. abnormal) controls of the ADPtest                 |
| ASA reagent                   | Inhibitor of cyclooxygenase. Addition of ASA reagent to the blood sample leads to reduced aggregation responses in ASPItest and COLtest     |
| GpIIb/IIIa antagonist reagent | Inhibitor of the platelet GpIIb/IIIa receptor. Addition to a blood sample leads to strongly reduced aggregation in the TRAPtest             |
| Hirudin blood tubes           | Anticoagulant for platelet function analysis with physiological calcium concentrations                                                      |
| Liquid control set            | Quality control for electrical signal in impedance aggregometry based on the analysis of an artificial liquid control material              |



# Hematology Reinvented

*Bloodhound® technology*

## Full automation

*Innovation –  
Information – Integration*

## Digital differential

*Monolayer*

# cobas m 511

## Hematology

Hematology is the study of blood including the blood forming organs, their pathologies and the study of the diseases. Hematology testing is used in a variety of settings, from initial screening up to most complicated hematological diseases, providing an overview about cell count, Differentiation and maturation status of blood cells.

Hematology laboratory assay results help predict, diagnose, establish the prognosis for, and monitor the treatment for a variety of medical disorders (Rodak, 4<sup>th</sup> edition Hematology Clinical Principles and Applications).

The most common test is the Complete Blood Count (CBC), used for general screening and includes at least the following parameter: RBC count, HGB concentration, RBC indices, PLT and WBC count.

CBC is used in conjunction with the WBC Differential which provides more detailed information about the WBC distribution in peripheral blood. When it comes to diagnosis, cell morphology is a key contributor, as cell size or cell appearance may represent a characteristic pattern for certain diseases (such as sickle cell anemia, Chronic Lymphatic Leukemia, assessment of anemia types).

Hematology samples represent a 34 % of the total workload of the laboratory, after the SWA samples.

Roche committed to the diagnostic market and as the beginning of a long-term engagement, has developed **cobas m 511** integrated hematology analyzer; combining innovative technology with high quality standards.

*Not for use in the US.*

**cobas**®

# cobas m 511

## Hematology Reinvented



Addressing needs and desires of consolidating the workflow, **cobas m 511** provides analysis of the blood sample, slide making and staining and digital morphology results in just 6 minutes.

With the combination of integration, innovation, and information, **cobas m 511** will deliver real benefits to the laboratories and their customers, bringing:

1. Smart innovation, through the Bloodhound® technology, combining convenience with efficiency.
2. Meaningful information, from images and data available for reviewing especially abnormal results.
3. Efficient workflow innovation, by integrating the process.



### Your benefit

#### Reduction of TAT

- 6 min. to complete result, no additional preparation to review an abnormal sample
- Unclassified cells conveniently presented for review
- Only 2 touch-points reducing manual steps, providing efficient utilization of laboratory personnel

#### Do more with less

- Low sample volume of 30 µL to provide a complete/full blood count
- Compact footprint in less than 1 square meter
- Fewer consumables for easy handling

#### One standardized process

- An innovative, unique and standardized slide printing technology<sup>1</sup>
- A consistent, standardized and patented staining process
- Easy and convenient patient tracking and digital archiving

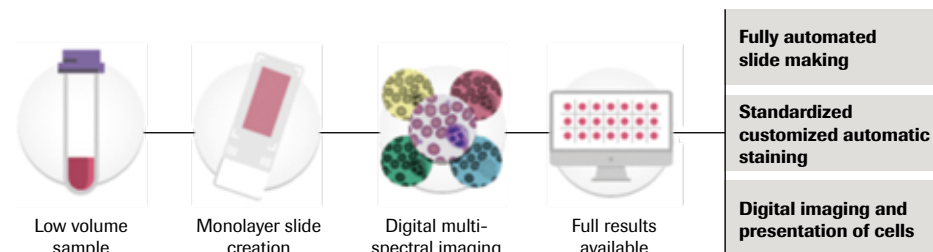
#### Expanding expertise network

- Remote access review to allow specialists to easily access samples results
- Additional expertise included in the slide review
- Best use of expert knowledge

### Product characteristics

- Bloodhound® technology: provides CBC, WBC differential, reticulocyte, and morphologic results, in a monolayer printed slide
- Throughput: 60 samples/hour
- Sample volume: 30 µL
- Reportable parameters: 26
- Small footprint: 1 square meter
- Reagents: stain pack (2 stains, rinse and a fixative), reticulocyte stain and wash solution
- Test principle: Digital multi-spectral imaging
- Intuitive software provides easy access to WBC, RBC and platelet image galleries for patient review
- Remote functionality of the viewing station, providing real-time image access
- Digital archiving of results and images

### Principle of Bloodhound® technology



<sup>1</sup> Rodak, B.F., Fritsma, G.A. & Keonhane, E.M. (2007). Hematology clinical principles and applications. 3<sup>rd</sup> Hrsg. St. Louis, Missouri: Elsevier Saunders. pp. 194-199.



**Combur**  
*Laboratories*  
**Sediment**  
*Urine work area solution*  
**Point of Care**  
*Physician's office*  
**50 years experience**

## Urinalysis

Urinalysis has always been an important diagnostic tool in medicine. Even today, urine is still a key health barometer for many diseases, mainly urinary tract infections, kidney disease and diabetes. The analysis of urine can reveal serious diseases that show no symptoms in their early stages but are treatable. These diseases can cause severe damage if they remain undetected. Urine test strips are a crucial diagnostic tool and easy to use, yielding quick and reliable information on pathological changes in the urine. Their diagnostic significance lies primarily in first-line diagnosis, screening during routine or preventive examinations, and treatment monitoring.<sup>1</sup>

Today Roche offers a broad portfolio of urinalysis solutions for different customer needs. Drawing on our 50 years of experience in urinalysis, starting with the launch of the first Combur-Test® strip, we have continuously improved strip technology for clinical and general practice. In response to customer needs for increased efficiency and safety, we have developed a range of analyzers with differing degrees of automation and throughput capabilities. By combining the proven Combur-Test strip technology with Roche automation, we offer customized urinalysis solutions for physician office laboratories, hospital point-of-care and central laboratory settings.

For more information please  
visit [www.cobas.com](http://www.cobas.com)

<sup>1</sup> NKF, 2016. Prevention. [Online]  
Available at: <https://www.kidney.org/prevention>  
[Accessed 6 February 2017].

## Urinalysis from Roche

*Expertise coming from a long tradition  
of more than 50 years*



www.cobas.com



Micral-Test®



Combur-Test®



cobas u pack



Urisys 1100®



cobas u 411 urine analyzer



cobas® 6500 urine analyzer series

### Urine diagnostics portfolio

|                             | Micral-Test®                             | Combur-Test®                               | Urisys 1100®                                                                               | cobas u 411<br>urine analyzer                                                       | cobas 6500 urine<br>analyzer series                                             |
|-----------------------------|------------------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>Automation<br/>grade</b> | Visual reading strip<br>for microalbumin | Visual reading and<br>for all UA platforms | Instrument<br>intended for single<br>measurements<br>in wards or in<br>physicians' offices | Semi-automated<br>urinalysis system<br>for small to<br>medium sized<br>laboratories | Fully automated<br>urine work area<br>solution for large-<br>scale laboratories |
| <b>Workloads</b>            | Manual                                   | Manual                                     | 10 – 50 samples<br>per day                                                                 | 30 – 100 samples<br>per day                                                         | 100 – 1,000 samples<br>per day                                                  |
| <b>Test strips</b>          | Micral-Test                              | Combur <sup>2,3,4,5,6,7,9,10</sup><br>Test | Combur <sup>10</sup> Test UX<br>Combur <sup>5</sup> Test<br>Combur <sup>7</sup> Test       | Combur <sup>10</sup> Test M                                                         | <b>cobas u pack</b>                                                             |
| <b>Consumables</b>          |                                          |                                            |                                                                                            |                                                                                     | <b>cobas u cuvette</b>                                                          |

## Micral-Test® strip for albumin in urine

*Quick and secure results of albumin  
in urine*



The Micral-Test strip is an easy to use test designed to deliver quick and secure results, specific for human albumin and sensitive across the diagnostic range. Using one test for all patient groups, the Micral-Test strip is a cost efficient way to gain actionable health information.

### Your benefit

#### Specific for human albumin

The Micral-Test strip is based on an immunological test principle using gold-labelled monoclonal antibodies with a chromo-genic color indicator ensuring confidence in results.

#### Sensitive across the diagnostic range

The cutoff for positive results is 20 mg/L with an excellent sensitivity of 97 %. The Micral-Test strip does not show a “hook-effect” because it uses a chromogenic color reaction instead of an agglutination reaction.<sup>1</sup>

#### Fast and easy

After 60 seconds, result is ready for visual reading with a convenient color comparison on the strip box. The Micral-Test strip is easy to handle and improves testing workflow.

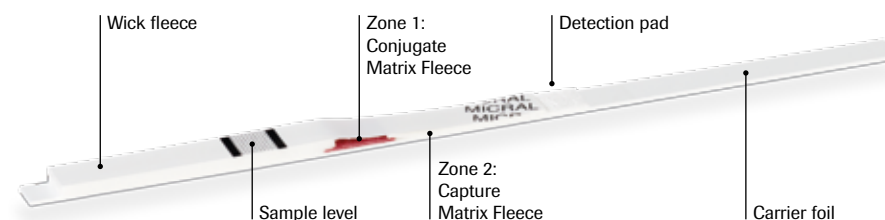
Unique design of the Micral-Test strip delivers secure results

- The Immunological test principle with monoclonal antibodies is highly specific for human albumin
- The urine sample is absorbed by the test strip and transferred through the following two zones before reaching the detection pad:

Zone 1 – Conjugate Fleece contains free gold-labelled antibodies

Zone 2 – Capture Matrix Fleece with fixed human serum albumin (HSA)

<sup>1</sup> Micral Test, M. S., 2016. eLabDoc. [Online]  
Available at: <https://dialog1.roche.com>  
[Accessed 13 February 2017].



**cobas®**

# Combur-Test® strip

## Established quality – proven to perform

Urine reagent strips are a useful tool for investigating, diagnosing and screening diseases immediately. Reliable and precise results are important, since adulterated results can lead to false negative results or re-testing of patients. Roche's unique test strip technology is used for visual test strips and for all instrument test strips.

### Your benefit

#### Accuracy

- Combur-Test® strip\* detects even low concentrations of glucose and erythrocytes/hemoglobin (5–10 Ery/mL) in the presence of vitamin C<sup>1</sup>

#### Efficiency

- Avoidance of retesting and false-negative results in glucose and blood even with high levels of ascorbic acid (up to 400 mg/L) with the application of an iodate impregnated mesh layer<sup>1</sup>



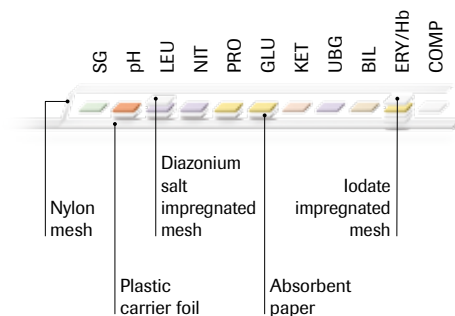
<sup>1</sup> Combur10 Test M, M. S., 2017. eLabDoc. [Online] Available at: <https://dialog1.roche.com> [Accessed 4 January 2017].

#### Safety

- Independence interference from of glued components as a result of a unique sealing technology
- Test area colors prevented from flowing with an absorbent paper
- Reduction of the risk of false results through compensation of strong intrinsic urine coloration with the availability of a color compensation pad\*

#### Easy strip handling

- Facilitation of analysis with a consistent reading time of 60 seconds for all parameters
- Advanced and hygienic strip handling with possibility of reading tip down



Combur-Test urine test strips from Roche have iodate impregnated mesh layers and are uninfluenced by ascorbic acid.<sup>1</sup>

\*For instrument tests only.

# Urisys 1100® analyzer

## Small and easy



The Urisys 1100 analyzer is a small semi-automated benchtop instrument for a workload of 10 to 50 samples per day. It is optimal for small labs, doctor's offices or in decentralized settings.

The high quality Combur-Test® strips provide accurate results in one minute which can be optionally printed out for your convenient documentation.



<sup>1</sup> Urisys 1100, O. M., 2016. eLabDoc. [Online] Available at: <https://dialog1.roche.com> [Accessed 13 February 2017].

### Your benefit

#### Compact

- Semi-automated urine analyzer for the small lab, ward or doctor's office

#### Easy handling

- Automatic printing of results

#### Simplify your life

- Eliminate manual documentation through the export of data via host connection

#### Safety

- Prevent unauthorized access and comply with accreditation requirements via an operator lock-out feature

### Product characteristics

- Workloads: 10–50 samples per day<sup>1</sup>
- Throughput: approx. 50 test strips/hour
- Combur-Test® is resistant to ascorbic acid interference
- Control-Test M for weekly calibration
- Test strips\*: Combur<sup>10</sup> Test® UX
- Memory capacity: 100 results
- Printer: Thermal printer
- Connectivity to the **cobas** POC IT solution

\* Combur<sup>7</sup> Test®, Combur<sup>5</sup> Test® are not available in all countries.

# cobas u 411 urine analyzer

## Consolidated result management



www.cobas.com



The **cobas u 411** semi-automated urine analyzer is designed for workloads of approximately 30–100 samples per day.

When connected to the optional barcode reader and sediment terminal, this analyzer designed optimized work and data flow.



cobas u 411 urine analyzer

### Your benefit

#### Fast and efficient workflow

- By connecting analyzer to sediment terminal and consolidating the results

#### Ensure reliable results

- Ascorbic acid does not interfere with test strips<sup>1</sup>

#### Safe and hygienic handling of strips

- Due to netsealing technology

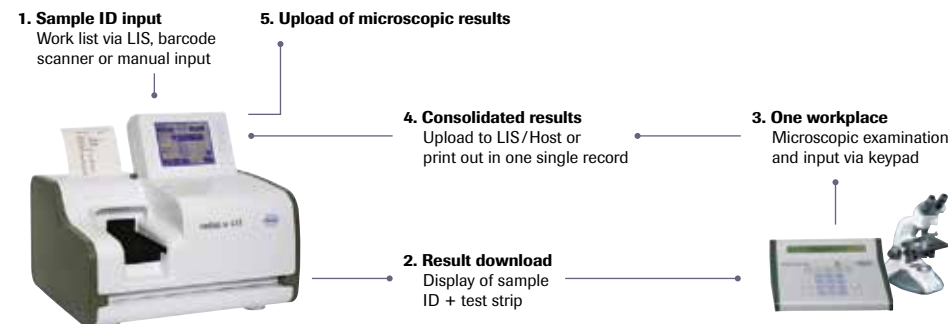
### Product characteristics

- Workloads: 30 – 100 samples per day<sup>2</sup>
- Throughput: 600 tests/hour
- Continuous loading of test strips without requiring a measurement cycle
  - optional barcode reader simplifies manual work steps
- Entry of tracking information including user identification and lot numbers for test strips, calibration strips and control material



### Consolidated analysis

Parallel working on the **cobas u 411** analyzer and its connected sediment terminal as a result of a consolidated work and data flow for strip analysis and microscopy. Easier documentation and improved overview of patient records with single print-out for strip and microscopic information.



Semi-automated urine work area solution.

<sup>1</sup> Combur10 Test M, M. S., 2017. eLabDoc. [Online] Available at: <https://dialog1.roche.com> [Accessed 4 January 2017].

<sup>2</sup> cobas u 411 system, O. M., 2014. eLabDoc. [Online] Available at: <https://dialog1.roche.com> [Accessed 13 February 2017].

# cobas<sup>®</sup> 6500 urine analyzer series

## *One tube, one touch – fully automated urine workflow*



www.cobas.com



The **cobas** 6500 urine analyzer series is a fully automated urine work area solution for laboratories processing 100–1,000 urine samples per day.

Due to its modular design **cobas** 6500 urine analyzer series can be installed as a stand-alone urine analyzer or as a stand-alone microscopy analyzer or together as a fully automated urine work area.

### Your benefit

#### Automation of the gold standard

- Taking real microscopy images – eliminating operator variability and the need for manual review, improving TAT

#### Precise and safe strip results

- High quality results by proven unique strip construction based on 50 years experience
- Accurate, safe results by new technology

#### Consolidation of urine work area

- Convenient validation – all results on one screen
- Full menu covers urine strip testing and urine sedimentation

#### Workflow optimization

- Full integration into lab automation



*cobas<sup>®</sup> connection module (CCM) connected to 2 cobas 8000, cobas p 501 post-analytical unit, cobas 6500 and cobas u 601*

*Not for use in the US.*

### Product characteristics<sup>1</sup>

#### **cobas u 601 urine analyzer**

- Fully automated urine strip new generation
- 12 on-board parameters
- Throughput: 240 samples/hour
- **cobas u** pack;
  - cassette with 400 test strips
  - Combur-Test<sup>®</sup> strips technology
  - two weeks on-board stability (humidity protected)
- New photometer technology for the strip result reading
- Detecting the intact and lysed erythrocytes



*cobas u 601 urine analyzer*



*cobas u 701 microscopy analyzer*

#### **cobas u 701 microscopy analyzer**

- Fully automated urine microscopy system
- 11 on-board parameters
- Reagent-free system
- Throughput: 116 samples/hour
- 400 cuvettes in one package (**cobas u** cuvette)
- Excellent counting performance
- Storage of real images



*cobas 6500 urine analyzer series*

<sup>1</sup> cobas 6500 urine analyzer series, O. M., 2016. eLabDoc. [Online] Available at: <https://dialog1.roche.com> [Accessed 13 February 2017].



**Real-time PCR**  
*Virology*  
**Women's health**  
*Genomics/Oncology*  
**Full automation**  
*Blood screening*  
**Microbiology**  
*Companion diagnostics*  
**Molecular Point of Care**

## Molecular diagnostics

Roche is a pioneer in molecular diagnostics. Since 1992 we have been providing innovative tests based on the Nobel Prize-winning polymerase chain reaction (PCR) technology.

Thanks to our wide range of products, services and solutions we are able to cover the needs of different types of hospitals and laboratories worldwide.

Roche provides solutions for indication areas such as hepatitis, HIV, transplantation, women's health, oncology, genomics and microbiology. We have recently expanded into the molecular point of care testing segment to better serve customer needs within the lab for after hours and STAT testing, and in the primary care segment with rapid diagnostics. These solutions are

designed to provide information that allows healthcare professionals to diagnose diseases. In addition we offer a range of products to identify the molecular characteristics of patients and diseases, thus enabling Personalized Healthcare.

Roche products also help to ensure the safety of blood and blood products by using Roche Molecular Diagnostics approved systems to screen donations.

Besides molecular diagnostic solutions, we also provide a range of innovative products for nucleic acid purification and PCR in the field of molecular biology.

For more information please  
visit [www.molecular.roche.com](http://www.molecular.roche.com)

# Molecular diagnostics solutions

*Innovative, reliable and efficient*



www.molecular.roche.com



Meeting the requirements for confidence in PCR results and comprehensive high-quality solutions, Roche offers a wide range of systems including full lab automation

for unrivalled efficiency, integrated IVD and LDT processing for greater consolidation, and connectivity to pre- and post-analytics.

## Workflow solutions for molecular diagnostics

| Laboratory needs                                                                                                                                                                                       |                                                                                                                                                                                                                                                                |                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| IVD Systems                                                                                                                                                                                            |                                                                                                                                                                                                                                                                |                                                                                                                          |
| <ul style="list-style-type: none"> <li>• Very high throughput</li> <li>• Absolute automation</li> <li>• Unmatched flexibility</li> </ul>                                                               | <b>cobas® 8800 System</b><br>                                                                                                                                                 |                                                                                                                          |
| <ul style="list-style-type: none"> <li>• Mid-high throughput</li> <li>• Absolute automation</li> <li>• Unmatched flexibility</li> </ul>                                                                | <b>cobas® 6800 System</b><br>                                                                                                                                                 |                                                                                                                          |
| <ul style="list-style-type: none"> <li>• Mid to low throughput</li> <li>• Full automation</li> </ul> <b>cobas z 480 Analyzer</b> available as standalone solution with manual sample prep for oncology | <b>cobas® 4800 System</b><br> <i>cobas x 480 Instrument</i>  <i>cobas z 480 Analyzer</i> |                                                                                                                          |
| <ul style="list-style-type: none"> <li>• Mid to low throughput</li> <li>• Full automation</li> </ul>                                                                                                   | <b>COBAS® AmpliPrep/COBAS® TaqMan® System</b><br>                                                                                                                           |                                                                                                                          |
| <ul style="list-style-type: none"> <li>• Medium throughput</li> </ul> Manual low throughput solution available with COBAS® TaqMan® 48 Analyzer                                                         | <b>Manual or COBAS® AmpliPrep Instrument</b><br>                                                                                                                            | <b>COBAS® TaqMan® 48 Analyzer</b><br> |
| <ul style="list-style-type: none"> <li>• Very low throughput</li> </ul> On-demand testing for the Point of Care as well as out-of-hours & STAT testing.                                                | <b>cobas® Liat® System</b><br>                                                           |                                                                                                                          |

## Your benefit

- Flexible, efficient workflow
- Innovative real-time PCR technology meets international guidelines for sensitivity and linear measurement range
- Confidence in results due to integrated quality controls and physical and biochemical contamination control

| Laboratory needs                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Blood and Donor Screening Systems                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <ul style="list-style-type: none"> <li>• Very high throughput</li> <li>• Absolute automation</li> <li>• Unmatched flexibility</li> </ul> | <b>cobas® 6800/8800 Systems and cobas p 680 Instrument</b><br>                                                                                                                                                                                                                                                                                                                                          |
| <ul style="list-style-type: none"> <li>• High throughput</li> </ul>                                                                      | <b>cobas s 201 System</b><br>                                                                                                                                                                                                                                                                                                                                                                           |
| LDT Solutions                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <ul style="list-style-type: none"> <li>• High throughput</li> <li>• Complete Workflow</li> </ul>                                         | <b>FLOW Solution</b><br> <i>Roche Primary Sample Handling</i>  <i>MagNA Pure 96</i>  <i>Roche PCR Set-up</i>  <i>Roche qPCR System</i> |
| <ul style="list-style-type: none"> <li>• Medium and low throughput</li> </ul>                                                            | <b>MagNA Pure 24 System or High Pure Kits</b> <b>LightCycler® 96 or 480 Systems</b><br>                                                                                                                                                                                                                          |

# Test Overview



|                                             | Detection     | cobas® 6800/8800 | cobas s 201 | cobas® 4800,<br>cobas x 480/z 480 | COBAS®<br>AMPLICOR | COBAS® TaqMan® | cobas®<br>Liat® System<br>LightCycler® 2.0<br>Instrument |
|---------------------------------------------|---------------|------------------|-------------|-----------------------------------|--------------------|----------------|----------------------------------------------------------|
| <b>Viruses</b>                              |               |                  |             |                                   |                    |                |                                                          |
| Cytomegalovirus                             | Quant.        | •                |             | •*                                |                    | •              |                                                          |
| Hepatitis B                                 | Quant.        | •                |             | •                                 |                    | •              |                                                          |
| Hepatitis C quant                           | Quant.        | •                |             | •                                 |                    | •              |                                                          |
| Hepatitis C qual                            | Qual.         |                  |             |                                   |                    | •              |                                                          |
| Hepatitis C GT                              | Genot.        |                  |             | •                                 | •                  |                |                                                          |
| Herpes                                      | Qual., Diff.  |                  |             | •                                 |                    |                | •                                                        |
| Human Immunodeficiency                      | Quant.        | •                |             | •                                 |                    | •              |                                                          |
| Human Immunodeficiency                      | Qual.         | •*               |             |                                   |                    | •              |                                                          |
| Human Immunodeficiency RUO                  | Qual.         |                  |             |                                   |                    | •              |                                                          |
| Human Papillomavirus                        | Qual., Genot. | •*               |             | •                                 |                    |                |                                                          |
| Influenza A/B                               | Qual., Diff.  |                  |             |                                   |                    |                | •                                                        |
| Influenza A/B+RSV                           | Qual., Diff.  |                  |             |                                   |                    |                | •                                                        |
| Parvo B 19 (RUO)                            | Quant.        |                  |             |                                   |                    |                | •                                                        |
| Varicella-Zoster                            | Qual.         |                  |             |                                   |                    |                | •                                                        |
| <b>Other pathogens</b>                      |               |                  |             |                                   |                    |                |                                                          |
| Chlamydia trachomatis/Neisseria gonorrhoeae | Qual.         | •                |             | •                                 | •                  |                |                                                          |
| Chlamydia trachomatis                       | Qual.         |                  |             |                                   |                    | •              |                                                          |
| Clostridium difficile                       | Qual.         |                  |             | •                                 |                    |                | •*                                                       |
| Methicillin-resistant Staphylococcus aureus | Qual., Diff.  |                  |             | •                                 |                    |                | •*                                                       |
| Mycobacteria Tuberculosis                   | Qual.         | •*               |             |                                   |                    | •              |                                                          |
| Trichomonas vaginalis/Mycoplasma genitalis  | Qual.         | •*               |             |                                   |                    |                |                                                          |
| Vancomycin resistant enterococcus           | Qual.         |                  |             |                                   |                    |                | •                                                        |

Please check with your local Roche representative on availability of the assays and tests in your country.

|                               | Detection           | cobas® 6800/8800 | cobas s 201 | cobas® 4800,<br>cobas x 480/z 480 | COBAS®<br>AMPLICOR | COBAS® TaqMan® | cobas®<br>Liat® System<br>LightCycler® 2.0<br>Instrument |
|-------------------------------|---------------------|------------------|-------------|-----------------------------------|--------------------|----------------|----------------------------------------------------------|
| <b>Sepsis pathogens</b>       |                     |                  |             |                                   |                    |                |                                                          |
| Bacteria/Fungi                | Qual., Diff.        |                  |             |                                   |                    |                | •                                                        |
| Bacteria/Fungi                | Qual., Ident.       |                  |             |                                   |                    |                | •                                                        |
| <b>Blood screening</b>        |                     |                  |             |                                   |                    |                |                                                          |
| MPX: HIV-1**, HIV-2, HCV, HBV | Qual., Diff.        | •                | •           |                                   |                    |                |                                                          |
| DPX: B19V/HAV                 | Qual., Diff.        | •                | •           |                                   |                    |                |                                                          |
| West Nile virus               | Qual.               | •                | •           |                                   |                    |                |                                                          |
| Hepatitis E                   | Qual.               | •                |             |                                   |                    |                |                                                          |
| <b>Bacteria</b>               |                     |                  |             |                                   |                    |                |                                                          |
| Strep A                       | Qual.               |                  |             |                                   |                    |                | •                                                        |
| <b>Oncology</b>               |                     |                  |             |                                   |                    |                |                                                          |
| BRAF                          | Qual., Mut. Detect. |                  |             | •                                 |                    |                |                                                          |
| BRAF/NRAS (LSR)               | Qual., Mut. Detect. |                  |             | •                                 |                    |                |                                                          |
| KRAS                          | Qual., Mut. Detect. |                  |             | •                                 |                    |                |                                                          |
| KRAS V2 (LSR)                 | Qual., Mut. Detect. |                  |             | •                                 |                    |                |                                                          |
| EGFR V2                       | Qual., Mut. Detect. |                  |             | •                                 |                    |                |                                                          |
| PIK3CA (RUO)                  | Qual., Ident.       |                  |             | •                                 |                    |                |                                                          |
| <b>Genetics</b>               |                     |                  |             |                                   |                    |                |                                                          |
| Factor V Leiden               | Qual., Mut. Detect. |                  |             | •*                                |                    |                | •                                                        |
| Factor II                     | Qual., Mut. Detect. |                  |             | •*                                |                    |                | •                                                        |

Qual. = Qualitative; Quant. = Quantitative; Genot. = Genotyping;  
 Diff. = Differentiation; Ident. = identification; Mut. Detect. = Mutation Detection  
 \*In development. \*\*Groups M and O.  
 RUO = For research use only. Not for use in diagnostic procedures.  
 LSR = Life Science Research. Not for use in diagnostic procedures.

# cobas® HPV Test

## Know the risk

Almost all cervical cancer is attributable to HPV, so knowing a woman's HPV status is important to ascertain her risk of cervical cancer and to determine clinical management.

The **cobas** 4800 HPV Test is the only clinically validated CE-marked, and FDA-approved assay for first-line, primary screening of cervical cancer, that simultaneously provides results on a pool of "high-risk" genotypes, including individual results on the highest-risk genotypes, HPV 16 and HPV 18, giving three results in just one test. HPV genotypes 16 and 18 are known to be responsible for more than 70 percent of all cervical cancer cases.

This test enables physicians to focus on the few patients who need more aggressive treatment or careful management, and reassures the vast majority of women they are at very low risk, protecting them from potentially unnecessary interventions.



### Your benefit

#### Evidence based

- Clinically validated in Roche's landmark ATHENA trial, the largest U.S.-based registration study for cervical cancer screening, including more than 47,000 women
- One in 10 women in the landmark ATHENA study who tested positive for either HPV genotype 16 or 18 had evidence of cervical pre-cancer, even though their Pap cytology test was normal
- Expanded U.S. indication to include screening of women ages 25–29 years

#### Clinically relevant results

- Knowing the patients HPV 16/18 status may impact patient management and allow better risk stratification for patients at the highest risk

#### Report with confidence

- Cellular internal control for assurance of sample integrity
- No cross reactivity with low risk HPV genotypes, helping to ensure positive results are clinically meaningful

#### Efficiency

- Suited for high volume screening programs
- By fully automated sample preparation workflow process, and unique efficiency feature



[www.hpv16and18.com](http://www.hpv16and18.com)



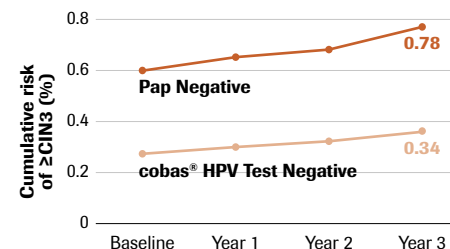
### Product characteristics

- The test utilizes amplification of target DNA by PCR and nucleic acid hybridization for the detection of 14 high-risk HPV types in a single analysis. The test specifically identifies genotypes HPV 16 and HPV 18, while simultaneously detecting the rest of the hrHPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

#### Sample material:

- Cervical cells collected in **cobas**® PCR cell collection media (Roche Molecular Systems, Inc.), PreservCyt® solution (Hologic) and SurePath® preservative fluid (BD Diagnostics-TriPath)
- Sample volume of 1 mL is sufficient

**A negative cobas® HPV Test provides the confidence that ≥CIN3 will not develop within 3 years vs. a negative pap.**



See also CINtec® PLUS Cytology and CINtec® Histology.

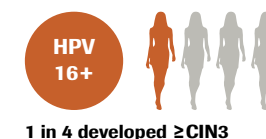
### Primary Screening with cobas® HPV Test:

- Multiplex assay to detect 12 pooled high risk genotypes, with simultaneous individual genotyping for highest risk HPV 16 and 18
- Beta-globin internal control helps prevent false negative results

#### Throughput:

- Up to 282 HPV samples in a day with <1.5 hours total hands-on time

### Risk of developing ≥CIN3 within 3 years



# cobas® Oncology Portfolio

*Seven to ten days is a long time to wait when every day counts*



The **cobas®** Oncology Portfolio exemplifies Roche's commitment to Personalized Healthcare. The tests detect mutations in key biomarkers which helps identify patients who are most likely to respond to certain drug treatments. These extensively validated diagnostic tests can help our physicians make important treatment decisions and allow investigators to assess clinical relevance. When every day counts, the **cobas®** Oncology Portfolio provides answers in hours instead of days or weeks.

## Key features and shared benefits

- Complete and controlled IVD system optimized for use with the **cobas®** DNA Sample Preparation Kit, the **cobas®** cfDNA Sample Preparation Kit (only for **cobas®** EGFR Mutation Test v2), the **cobas®** BRAF, KRAS, EGFR v2 and PIK3CA (RUO) Mutation Tests, as well as the **cobas®** 4800 System, v2.1 or higher
- Automated result interpretation and test reporting provide from laboratory to laboratory
- Delivering patient results in one work shift
- 24 reportable results from a single test kit
- Only requires one 5 µm tissue section



See page 84 for additional information on the Roche lung cancer diagnostics portfolio.

## Portfolio menu\*

### cobas® EGFR Mutation Test v2

- Identifies patients with non-small cell lung cancer who benefit from anti-EGFR TKI therapy, e.g. Tarceva® in first-line therapy or TAGRISSO™ in subsequent-lines of therapy
- Detects 42 mutations in exons 18, 19, 20 and 21 of the EGFR gene
- One test, two sample types (tissue and plasma)

### cobas® 4800 BRAF V600 Mutation Test

- Identifies which metastatic melanoma patients can be considered for BRAF inhibitor therapy, e.g. Zelboraf®
- Detects V600E mutations of the BRAF gene; also sensitive to V600K and V600D

### cobas® KRAS Mutation Test

- Identifies which metastatic colorectal cancer patients can be considered for anti-EGFR mAb therapies e.g. Vectibix®, Erbitux®
- Detects all of the reported mutations in exons 2 and 3\*\* of the KRAS gene

### cobas® DNA Sample Preparation Kit

- Validated with FFPET samples
- Isolation time: 3 – 4 hours only

### cobas® cfDNA Sample Preparation Kit

- Validated with plasma samples
- Isolation time: ~2 hours

### cobas® PIK3CA Mutation Test (RUO)

- Broad detection of 17 PIK3CA mutations in exons 1, 4, 7, 9 and 20

### BRAF/NRAS Mutation Test (LSR)

- Broad detection of 11 BRAF mutations in exons 11 and 15 plus 25 NRAS mutations in exons 2, 3 and 4

### KRAS Mutation Test v2 (LSR)

- Broad detection of 28 KRAS mutations in exons 2, 3 and 4

\* Data on file

\*\*Not available in all markets.

RUO = For research use only. Not for use in diagnostic procedures.

LSR = Life Science Research. Not for use in diagnostic procedures.

## cobas® CT/NG

*Proven efficiency, giving you the freedom to do more*

*Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) are among the most common sexually transmitted infections (STIs). **cobas®** CT/NG for use on the **cobas®** 6800/8800 Systems is an automated, qualitative in vitro nucleic diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of CT and NG, simultaneously from the same sample. **cobas®** CT/NG is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.



### Your benefit

#### Exceptional Assay Performance

- Validated for CE-IVD use with extragenital samples
- Extensive contamination control solution
- Proven, performance in urogenital samples

#### Most Efficient Workflow

- Highest volume molecular test for CT/NG
- Onboard capacity of up to 5,670 tests with onboard stability of 90 days
- Continuous loading with no pre-sorting required for mixed test request

#### Most Flexible Solution

- Simultaneous processing of multiple tests from the same patient sample (e.g. CT/NG plus HPV)
- Full automation and process control of all STI tests on a single platform including LDTs
- Consolidation of menu beyond STIs with onboard capacity of up to 12 different tests

## cobas® HSV 1 and 2 Test

*Bring more to your sexually transmitted infections menu*



Due to extremely different outcomes regarding recurrence, it is essential to determine whether a patient has type 1 or type 2 herpes simplex virus. The **cobas** HSV 1 and 2 Test, which runs on the **cobas** 4800 System, offers exceptional sensitivity while delivering reliable answers that result in optimal patient treatment and management decisions.



### Your benefit

#### Amplified reliability

- Robust, dual-target detection amplifies two separate regions on each of the HSV-1 and HSV-2 genomes
- Optimizes sensitivity and specificity
- Ensures reliable results as new HSV strains emerge

#### Reduced hands-on time

- Just load your primary sample vials on the **cobas®** 4800 System and you're ready to go

#### Unmatched flexibility

- Run as few as 6 or as many as 94 samples
- Process different tests and sample types simultaneously



# COBAS® TaqMan® MTB Test

## Rapid MTB detection

Tuberculosis is the world's most common infectious disease, with two million deaths annually. Due to the risk and severity of the disease, rapid diagnosis of the *M. tuberculosis*-complex is extremely important. Routine cultures are time-consuming and can take up to eight weeks. Microscopic examination of acid-fast smears is insensitive and nonspecific. The COBAS TaqMan MTB test has further improved the rapid diagnosis of tuberculosis by allowing direct detection of mycobacteria in clinical specimens.

### Your benefit\*

- Fast results in only 3.5 hours including sample preparation
- Reliability of test results
  - high sensitivity and specificity
  - clear differentiation of the pathogen from atypical mycobacteria (MOTT)
  - contamination protection through AmpErase System
- Efficient workflow, no manual steps required after sample preparation
- Proven and safe sample preparation with the COBAS® AMPLICOR® respiratory specimen preparation kit

### Product characteristics\*

- Detects pathogens of the *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*)
- Test is performed on the IVD CE-marked COBAS TaqMan 48 Analyzer that allows variable batch sizes – between 1 and 48 tests per run
- Internal controls included in the same reaction batch
- Specificity: 99 %
- Sensitivity: 0.46 CFU/PCR, corresponding to a calculated concentration of 18 CFU/mL sputum



COBAS TaqMan 48 Analyzer and MTB kits

\* Data on file

# cobas® Cdiff Test

## The right result the first time



*Clostridium difficile* (*C. difficile*) infection is a major cause of diarrhea in healthcare facilities. By rapidly detecting Cdiff in patient stool samples, the **cobas®** Cdiff Test, which is performed on the **cobas** 4800 System, provides accurate information for timely treatment and prevention.



### Your benefit\*

#### Exceptional performance

- Selectively detects a specific Cdiff toxin gene directly from unformed stool samples using real-time PCR
- Generates robust results automatically, using patented, state-of-the art algorithms
- Detects the presence of 31 Cdiff toxinotypes and 20 ribotypes

#### Confidence in results

- Lower inhibition rate minimizes invalids and need for repeat testing resulting in cost efficiency
- Reduces possibilities for errors

#### Unmatched flexibility

- Run as few as 6 or as many as 94 samples
- Process different tests and sample types simultaneously



\* Data on file

# cobas® MRSA/SA Test

*Faster than a spreading infection*

*Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) infections represent a critical threat to public health. The **cobas** MRSA/SA Test, performed on the **cobas**® 4800 System, provides innovative solutions for detecting both organism variances from a single nasal swab specimen, providing timesaving efficiencies and lifesaving answers.



## Your benefit

### Exceptional performance

- Quickly identify colonized patients and take decisive action
- Get the sensitivity and specificity that only PCR technology can deliver

### Greater workflow efficiencies

- Save time with first-of-its-kind primary sample vial loading
- Run MRSA/SA, Cdiff, and HSV 1 and 2 samples at the same time, on the same system
- Simplify data interpretation with patented, state-of-the-art software algorithms

### Automated efficiency

- Run 6 to 94 specimens using the fastest, most advanced real-time PCR amplification and detection available today



# cobas® HCV test

*Own the future*



The **cobas**® HCV test quantitative nucleic acid test for use on the **cobas**® 6800/8800 Systems delivers robust, clinically relevant assay performance based on Roche's proprietary dual-probe assay design. **cobas**® HCV test provides built-in redundancy with broad genotype coverage and incorporates mismatch tolerance to ensure confidence in viral load monitoring. **cobas**® HCV test is designed to deliver high sensitivity to meet the requirements of current and future chronic hepatitis C therapies.

### cobas® HCV test delivers:

- Tight precision at medically-relevant decision points
- Accurate detection and quantification of HCV genotypes 1 through 6
- High sensitivity suitable for use with new HCV therapies
- Excellent correlation with the COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0

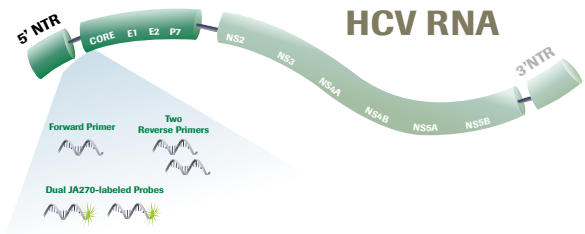


## cobas® HCV test performance summary\*

| Parameter                                         | Performance                                                                              |
|---------------------------------------------------|------------------------------------------------------------------------------------------|
| Sample type                                       | EDTA plasma, serum                                                                       |
| Minimum amount of sample required                 | 650 µL or 350 µL                                                                         |
| Sample processing volume                          | 500 µL or 200 µL                                                                         |
| Analytical sensitivity (LoD by hit rate of ≥ 95%) | 15 IU/mL (500 µL)<br>40 IU/mL (200 µL)                                                   |
| Linear range                                      | 500 µL: 15 IU/mL – 1×10 <sup>8</sup> IU/mL<br>200 µL: 40 IU/mL – 1×10 <sup>8</sup> IU/mL |
| Specificity                                       | 100% (one-sided 95% confidence interval: 99.5%)                                          |
| Genotypes detected                                | HCV genotypes 1–6                                                                        |

Not commercially available in all countries.

\* Data on file



# cobas® HCV test

See what truly matters

**cobas® HCV test** quantitative nucleic acid test for use on the **cobas® 4800 System**, delivers robust, clinically relevant assay performance based on the proprietary dual-probe assay design from Roche with built-in redundancy for broad genotype coverage and improved mismatch tolerance to ensure confidence in viral load monitoring.

## cobas® HCV test accurately detects and quantifies all HCV genotypes 1 through 6

- **Two non-overlapping detection probes**, when combined with two staggered primers, ensure assay performance
- **Mismatch tolerance** to accurately quantify with high specificity despite changes in the viral genome

## cobas® HCV test delivers:

- Tight precision at medically-relevant decision points

- Accurate detection and quantification of HCV genotypes 1 through 6
- High sensitivity suitable for use with new HCV therapies
- Excellent correlation with the COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0

## cobas® HCV test performance

| Parameter                                    | Performance                                                                                                                   |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Sample types                                 | Serum, plasma                                                                                                                 |
| Sample processing volume                     | 400 µL and 200 µL                                                                                                             |
| Sensitivity (LoD by PROBIT at ≥95% hit rate) | plasma: 9.2 IU/mL (400 µL); 15.2 IU/mL (200 µL)<br>serum: 7.6 IU/mL (400 µL); 15.3 IU/mL (200 µL)                             |
| Linear range                                 | 400 µL: 15 – 1×10 <sup>8</sup> IU/mL<br>200 µL: 25 – 1×10 <sup>8</sup> IU/mL                                                  |
| Precision                                    | 0.06 to 0.10 log <sub>10</sub> S.D. across an HCV RNA concentration range of 1×10 <sup>3</sup> – 1×10 <sup>7</sup> IU/mL      |
| Accuracy (across the linear range)           | plasma: ±0.20 log <sub>10</sub> (400 and 200 µL)<br>serum: ±0.23 log <sub>10</sub> (400 µL); ±0.25 log <sub>10</sub> (200 µL) |
| Specificity                                  | plasma: 99.5% (95% confidence limit: 98.7%)<br>serum: 100% (95% confidence limit: 99.5%)                                      |

Not commercially available in all countries. Data on file.

# cobas® HCV Genotyping test

See what truly matters



Identification of the infecting genotype is required before a patient is prescribed antiviral therapy as response to treatment correlates to the HCV genotype. Determination of HCV genotype prior to treatment initiation has been implemented in international HCV treatment guidelines.

**cobas® HCV GT test** for use on the **cobas® 4800 System** is a highly sensitive real-time PCR based test for the qualitative identification of HCV genotypes 1 to 6 and genotype 1 subtypes a and b in human plasma or serum from individuals with chronic HCV infection.

**cobas® HCV GT test** uses three different target regions in the HCV genome (5'-UTR, Core, NS5B) to achieve excellent genotyping and subtyping accuracy compared to sequencing and the capability to detect both genotypes in mixed infections down to a ratio of 1:100.

## Automated assay providing workflow efficiencies

- Time to first result: <4 hrs
- Generates up to 90 reportable results in 8 hours
- Mixed testing capability with HIV-1 and HCV viral load tests on the **cobas® 4800 System**
- Small sample processing volume: 400 µL

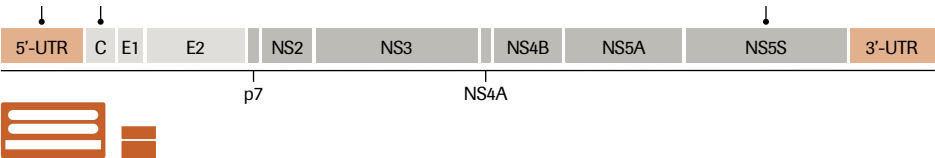
## Sensitivity to meet clinical needs

| Genotype | Limit of detection (LoD)* |                |
|----------|---------------------------|----------------|
|          | Serum (IU/mL)             | Plasma (IU/mL) |
| 1a       | 125                       | 125            |
| 1b       | 125                       | 250            |
| 2        | 50                        | 125            |
| 3        | 125                       | 125            |
| 4        | 125                       | 125            |
| 5        | 500                       | 1,000          |
| 6        | 125                       | 125            |

\*Lowest tested concentration with correct genotype results in at least 95 % of tests

Not commercially available in all countries. Data on file.

## HCV genome organization and targets of cobas® HCV GT test



# COBAS® AmpliPrep/ COBAS® TaqMan® HCV qualitative and quantitative Tests, v2.0

*Empowering change in HCV*

## COBAS® AmpliPrep/COBAS® TaqMan® HCV quantitative Test, v2.0

assess the probability of a sustained viral response early in a course of antiviral therapy and viral response to antiviral treatment.

## COBAS® AmpliPrep/COBAS® TaqMan® HCV qualitative Test, v2.0 and quantitative Test, v2.0

developed with a lower input volume, and innovative dual-probe design to provide improved sensitivity and precise detection across all genotypes for the new era of direct acting antiviral agents (DAAs).

## The COBAS® AmpliPrep/COBAS® TaqMan® HCV qualitative Test, v2.0

a qualitative molecular diagnostic tool in HCV diagnosis patients who have evidence of liver disease and antibody evidence of HCV infection.

## Your benefit

- Precisely distinguish true signals from background noise for more accurate viral load results
- Perfect tool to aid in response-guided therapy with excellent sensitivity and specificity
- Economic sample provides laboratory with enough left over sample for other laboratory testing

## Product characteristics

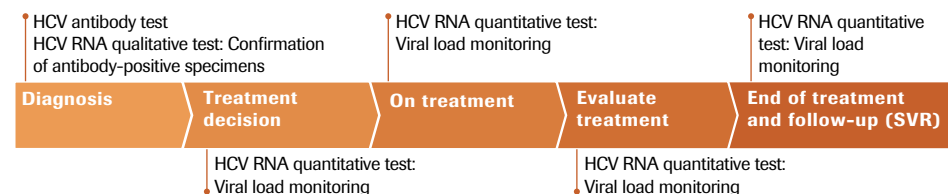
- Kit configuration 72 tests/kit
- Sample types EDTA plasma and serum
- Sample input volume 650 µL
- Limit of detection 15 IU/mL
- Genotype inclusivity genotypes 1 through 6

## Workflow

- Flexible batch size with continuous loading
- Interleave with other COBAS® TaqMan® Tests (HIV, HBV, HCV, CMV)

*Not commercially available in all countries. Data on file.*

## Roche offers a complete continuum of care to run the key tests for the diagnosis and management of HCV



*Key steps in the diagnosis and management of HCV*

# cobas® HIV-1

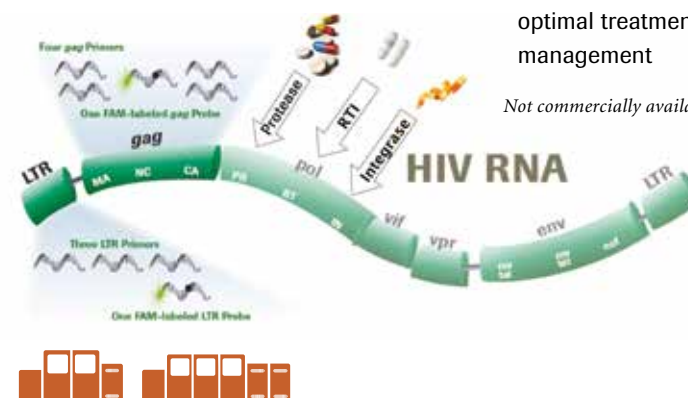
*Stay one step ahead*



## It takes more than just a single target.

As the challenges you face evolve, stay one step ahead with the **cobas®** HIV-1 quantitative test with a dual target approach.

Rapidly mutating HIV-1 virus can evade quantification with a single target viral load assay. **cobas®** HIV-1 quantitative nucleic acid test for use on the **cobas®** 6800/8800 Systems targets two unique regions of the HIV-1 genome, gag and LTR, which are not subject to selective drug pressure. This approach improves test sensitivity, coverage and security in the event of mutation in one primer/probe region.



## cobas® HIV-1 performance summary

| Parameter              | Performance                                                          |
|------------------------|----------------------------------------------------------------------|
| Sample type            | EDTA plasma, serum                                                   |
| Sample process volume  | 500 µL or 200 µL                                                     |
| Analytical sensitivity | 13.2 cp/mL (500 µL)<br>35.5 cp/mL (200 µL)                           |
| Linear range           | 500 µL: 20 cp/mL – 1.0E+07 cp/mL<br>200 µL: 50 cp/mL – 1.0E+07 cp/mL |
| Specificity            | 100% (one-sided 95% confidence interval: 99.5%)                      |
| Genotypes detected     | HIV-1M (A-D, F-H, CRF01_AE, CRF02_AG), HIV-1O, HIV-1N                |

## Drive better decisions for a positive impact on patients' lives

- Targeting two regions improves genotype inclusivity, detects HIV-1 variants and potentially avoids under quantification
- Accurate quantification of HIV-1 RNA with a dual target assay contributes to optimal treatment decisions for patient management

*Not commercially available in all countries. Data on file.*

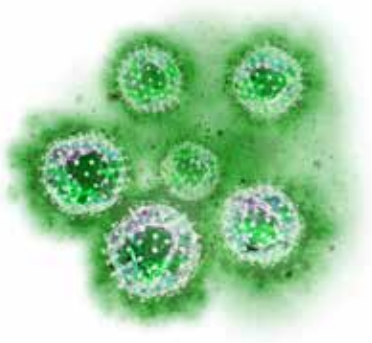
# cobas® HIV-1

Stay one step ahead

**It takes more than just a single target.**

As the challenges you face evolve, stay one step ahead with the **cobas®** HIV-1 quantitative test with a dual target approach.

Rapidly mutating HIV-1 virus can evade quantification with a single target viral load assay. **cobas®** HIV-1 quantitative nucleic acid test for use on the **cobas®** 4800 System targets two unique regions of the HIV-1 genome, gag and LTR, which are not subject to selective drug pressure. This approach improves test sensitivity, coverage and security in the event of mutation in one primer/probe region.



- Drive better decisions for a positive impact on patients' lives**
- Targeting two regions improves genotype inclusivity, detects HIV-1 variants and potentially avoids under quantification
  - Accurate quantification of HIV-1 RNA with a dual target assay contributes to optimal treatment decisions for patient management

| Parameter              | Performance                                                          |
|------------------------|----------------------------------------------------------------------|
| Sample types           | EDTA plasma                                                          |
| Sample process volume  | 400 µL or 200 µL                                                     |
| Analytical sensitivity | 14.2 cp/mL (400 µL)<br>43.9 cp/mL (200 µL)                           |
| Linear range           | 400 µL: 20 cp/mL – 1.0E+07 cp/mL<br>200 µL: 60 cp/mL – 1.0E+07 cp/mL |
| Specificity            | 100 % (one-sided 95 % confidence interval: 99.5 %)                   |
| Genotypes detected     | HIV-1M (A-D, F-H, CRF01_AE, CRF02_AG), HIV-1O, HIV-1N                |

Not commercially available in all countries. Data on file.



# COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test, v2.0

A dual-target approach for greater security against the unexpected



An in vitro nucleic acid amplification test for the quantitation of HIV-1 RNA in human plasma.

This test enhances the reliability of test results and provides great confidence in assessing viral loads. It also increases the probability of detection and expands coverage by targeting two highly conserved regions of the HIV-1 genome to compensate for the possibility of mutations or mismatches.

- Product characteristics**
- Offers primers and probes that are used to amplify the gag and LTR regions
  - Provides LTR primers that have broad genotype inclusivity and are well conserved phylogenetically
  - Quantifies the clinically significant HIV-1 groups and subtypes with full subtype coverage and quantification of HIV-1 groups O and M
  - Quantitates HIV-1 RNA from 20 – 10,000,000 copies/mL
  - Has a lower limit of detection (LOD) and 100 % specificity at 20 copies/mL than previously available HIV-1 tests
  - Is fully traceable to WHO international standards

Not commercially available in all countries. Data on file.



# COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test, v2.0

*The trusted choice for Hepatitis B  
viral load testing*



Improve patient management and treatment success.

Fully automated viral load quantitative hepatitis B test used in the management of patients with chronic hepatitis B infection undergoing antiviral therapy.

The test provides clinically relevant assay performance, and high sensitivity to deliver optimal results throughout critical medical decision points and across all genotypes, all combined with fully automated sample extraction and real-time PCR amplification and detection for a highly efficient laboratory workflow.

## Your benefit

- Confidence in assay design with optimized primer-probe selection targeting highly conserved pre-core and core regions. The amplified region of the genome will not be affected by mutations that arise due to drug resistance
- Confidence in detection with multiple layers of contamination control including built-in AmpErase enzyme, optimized pipetting and workflow settings and verified low rates of cross contamination
- Confidence in measuring HBV DNA with high precision at medical decisions points translates into confidence in each result regardless of HBV DNA level
- Confidence through clinical validation – Roche HBV viral load tests have been the most widely used tests in pharmaceutical trials worldwide providing a link between clinical practice and clinical trials

## Roche HBV Tests in clinical trials for approved HBV drugs on the market

| Generic Name          | Trade Name   | Date FDA Approved |
|-----------------------|--------------|-------------------|
| Interferon alfa-2b    | INTRON® A    | 1991              |
| Lamivudine            | EPIVIR-HBV®  | 1998              |
| Adefovir dipivoxil    | HEPSERA™     | 2002              |
| Entecavir             | BARACLUDE™   | 2005              |
| Peginterferon alfa-2a | PEGASYS®     | 2005              |
| Telbivudine           | TYZEKA™      | 2006              |
| Tenofovir             | VIREAD (HIV) | 2008              |

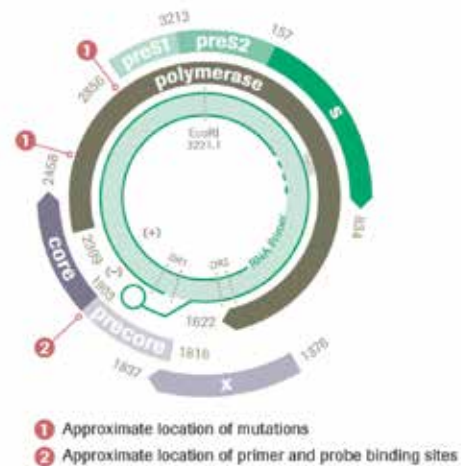
*Not commercially available in all countries.*



The **cobas®** HBV Test for use on the **cobas®** 6800 and 8800 Systems provides robust, clinically relevant assay performance, and high sensitivity to deliver optimal results throughout critical medical decision points and across all genotypes, for an improved patient care, all combined with a highly efficient laboratory workflow.

Roche primers and probes target the highly conserved pre-core and core regions of the HBV genome.

The amplified region of the genome will not be affected by mutations that arise due to drug resistance.<sup>1</sup>



#### The **cobas®** HBV Test offers

- Broad coverage of all known HBV genotypes (A – H) including pre-core mutations
- Tight precision at medically relevant decision points
- Excellent performance and flexibility with serum and plasma specimens
- Built-in contamination control with AmpErase enzyme to prevent carryover contamination
- Excellent correlation to Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0

#### **cobas®** HBV performance summary

| Parameter                                        | Performance                                              |        |
|--------------------------------------------------|----------------------------------------------------------|--------|
| Sample types                                     | EDTA plasma, serum                                       |        |
| Minimum amount of sample required                | 650 µL or 350 µL                                         |        |
| Sample process volume                            | 500 µL or 200 µL                                         |        |
| Analytical sensitivity (LoD by hit rate of ≥95%) | 400 µL                                                   | 200 µL |
| EDTA plasma (IU/mL)                              | 2.7                                                      | 15.5   |
| Serum (IU/mL)                                    | 1.45                                                     | 12.5   |
| Linear range (IU/mL)                             | 500 µL: 10 – 1.0E+09 IU/mL<br>200 µL: 25 – 1.0E+09 IU/mL |        |
| Specificity                                      | 100% (one-sided 95% confidence interval: 99.5%)          |        |
| Genotypes detected                               | HBV Genotype A – H, and predominant precore mutant       |        |



The **cobas®** HBV Test for use on the **cobas®** 4800 Systems provides robust, clinically relevant assay performance, and high sensitivity. **cobas®** HBV delivers optimal results throughout critical medical decision points and across all genotypes combined with a highly efficient laboratory workflow.

Roche primers and probes target the highly conserved pre-core and core regions of the HBV genome.

The amplified region of the genome will not be affected by mutations that arise due to drug resistance.<sup>1</sup>

#### **cobas®** HBV performance summary

| Parameter                         | Performance                                                                            |        |
|-----------------------------------|----------------------------------------------------------------------------------------|--------|
| Sample types                      | EDTA plasma, serum                                                                     |        |
| Minimum amount of sample required | Please refer to the <b>cobas®</b> 4800 Systems Operator's Manual for <b>cobas®</b> HBV |        |
| Sample process volume             | 400 µL or 200 µL                                                                       |        |
| Analytical sensitivity            | 400 µL                                                                                 | 200 µL |
| EDTA plasma (IU/mL)               | 4.4                                                                                    | 7.6    |
| Serum (IU/mL)                     | 2.8                                                                                    | 5.5    |
| Linear range (IU/mL)              | 400 µL: 10 – 1.0E+09 IU/mL<br>200 µL: 25 – 1.0E+09 IU/mL                               |        |
| Specificity                       | 100% (one-sided 95% confidence interval: 99.5%)                                        |        |
| Genotypes detected                | HBV Genotype A – H, precore mutant                                                     |        |
| Cross Contamination               | 0.0% (one-sided 95% confidence interval of 1.3%)                                       |        |

Data on file.



<sup>1</sup> Hunt, C.M., et al., (2000). Clinical relevance of hepatitis B viral mutations. *Hepatology*, 31(5): p. 1037-44.

# COBAS® AmpliPrep/ COBAS® TaqMan® CMV Test

*Setting the standard in assessing virological response in CMV infection*

Improve disease management and patient care with a Roche real-time, fully automated PCR test.

Cytomegalovirus (CMV) is a leading cause of morbidity and mortality in transplant recipients. Severe CMV infection in high risk patients may develop soon after transplantation and without effective treatment, may lead to CMV syndrome, tissue invasive disease, and potential rejection or loss of the graft. Roche's CMV Test reliably monitors Cytomegalovirus (CMV) infection in patients receiving anti-viral therapy.



## Your benefit

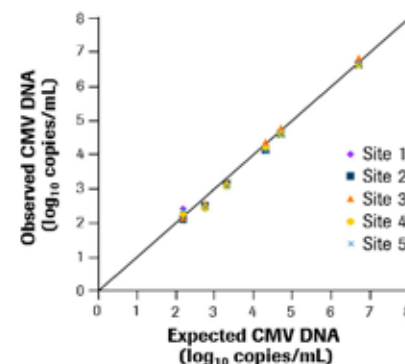
With the COBAS® AmpliPrep/COBAS® TaqMan® CMV Test, you can be reassured that you are requesting:

- A test that fulfils international guideline recommendations – demonstrating co-linearity to the WHO international standard and reports results in IU/mL, as recommended by the international consensus guidelines for CMV management in solid organ transplant patients<sup>1,8</sup>
- A test that is clinically validated – Used in key clinical studies, demonstrating clinical utility of CMV viral load monitoring<sup>3,9</sup>
- A test that provides reproducible and reliable results – proven to provide reliable, comparable and reproducible viral load results across different institutions, over several orders of magnitude.<sup>6</sup> The first standardized CMV viral load test with CE and FDA approval<sup>8</sup>

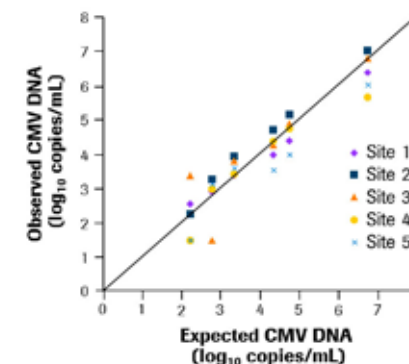
*Not commercially available in all countries.*

## CMV viral load test standardization enables improvement in CMV infection management<sup>4,5</sup>

### Comparability of the Roche CMV Test results across five laboratory testing sites



### Comparability of LTD results across five laboratory testing sites



- 1 Asberg, A., Caliendo, A. M., Chou, S., Kotton, C. N., Kumar, D. et al. (2013). Updated international consensus guidelines on the management of cytomegalovirus in solid-organ transplantation. *Transplantation* 96, 333-360.
- 3 Åsberg, A., Boisvert, D., Caliendo, A.M., Do, T.D., Rollag, H., Duncan, J., Humar, A., Razonable RR, Yao, J.D. (2013). Virologic suppression measured by a cytomegalovirus (CMV) DNA test calibrated to the world health organization international standard is predictive of CMV disease resolution in transplant recipients. *Clin Infect Dis.* ;56:1546–1553.
- 4 Caliendo, A. M., Fenton, J. M., Fox, J. D., Miller, G. G., Pang, X. L. et al. (2009). Interlaboratory comparison of cytomegalovirus viral load assays. *Am J Transplant* 9, 258-268.
- 5 Abdul-Ali, D., Caliendo, A. M., Ingersoll, J., Schaper, C., Shahbazian, M. D. et al. (2009). A commutable cytomegalovirus calibrator is required to improve the agreement of viral load values between laboratories. *Clin Chem* 55, 1701-1710.
- 8 COBAS® AmpliPrep/COBAS® TaqMan® CMV Test package insert data
- 9 Åsberg, A., Hartmann, A., Humar, A., Jardine, A. G., Mouas, H., Noronha, I.L., Pescovitz, M. D., Rollag, H., Sgarabotto, D., Tuncer, M., and on behalf of the VICTOR Study Group (2007). Oral Valganciclovir Is Noninferior to Intravenous Ganciclovir for the Treatment of Cytomegalovirus Disease in Solid Organ Transplant Recipients. *Am J of Transplant*, 7:2106–2113

## cobas® CMV

*Enhance the picture of CMV control*

Consistency in test results is vital for successful CMV management, helping transplant patients enjoy long, healthy lives. The **cobas®** CMV quantitative nucleic acid test for use on the **cobas®** 6800/8800 Systems reliably monitors infection in patients receiving antiviral therapy.



- 1 Kotton, C.N. et al. (2013). Updated international consensus guidelines on the management of cytomegalovirus in solid-organ transplantation. *Transplantation*; 96:333–360.
- 2 Razonable, R.R., Hayden, R.T. (2013). Clinical utility of viral load in management of cytomegalovirus infection after solid organ transplantation. *Clin Microbiol Rev*; 26:703–727.
- 3 Wolff, D.J. et al. (2009). Multisite PCRbased CMV viral load assessment assays demonstrate linearity and precision, but lack numeric standardization. A report of the Association for Molecular Pathology. *J Mol Diagn*; 11:87–92.
- 4 Pang, X.L., Fox, J.D., Fenton, J.M., Miller, G.G., Caliendo, A.M., Preiksaitis, J.K. (2009). Interlaboratory comparison of cytomegalovirus viral load assays. *Am J Transplant*; 9:258–268.
- 5 Hirsch, H.H. et al. (2013). An international multicenter performance analysis of cytomegalovirus load tests. *Clin Infect Dis*; 56:367–373.

### Your benefit

- Traceability to the first WHO Standard (NIBSC 09/162) providing consistent, reliable results across the dynamic range of the assay and across institutions
- Proven advantages over Lab Developed Tests<sup>1-5</sup> – providing quality control and quality assurance of reagents and validated results
- Reassurance in clinical decision making – **cobas®** CMV standardized viral load testing enables a common strategy to be developed in the management of CMV infection in transplant patients

### cobas® HBV performance summary

| Parameter                             | Performance                                                                          |
|---------------------------------------|--------------------------------------------------------------------------------------|
| Sample types                          | EDTA plasma                                                                          |
| Minimum amount of sample required     | 500 µL                                                                               |
| Sample process volume                 | 350 µL                                                                               |
| Analytical sensitivity                | 34.5 IU/mL                                                                           |
| Linear range                          | 34.5 IU/mL – 1E+07 IU/mL                                                             |
| Specificity                           | 100%                                                                                 |
| Genotypes detected                    | CMV Glycoprotein B Genotype 1–4                                                      |
| Drug resistant CMV specimens detected | CMV specimens resistant against Ganciclovir, Valganciclovir, Cidofovir and Foscarnet |



## COBAS® AmpliPrep/ COBAS® TaqMan® System

*Easy begins here*



The COBAS® AmpliPrep/COBAS® TaqMan® System, a real-time PCR system, unites primary tube handling with fully automated sample preparation, amplification and detection of RNA or DNA. The system provides high throughput processing for a menu includes HIV, HCV, HBV, and CMV.

The system improves workflow efficiencies with the COBAS® AmpliPrep Instrument for automated extraction of DNA and RNA using magnetic bead technology and the COBAS® TaqMan® or COBAS® TaqMan® 48 Analyzers for automated real-time amplification and detection of DNA or RNA for up to 96 samples and four assays at the same time.



Data on file.

### Your benefit

#### Safety and reliability

- Closed tubes for samples and purified nucleic acids minimize contamination
- Sample tracking with barcoded tubes prevents sample mix-ups

#### Efficiency

- Handles up to four tests simultaneously; continuous reloading during the run
- Ready to use reagents – no aliquotting or mixing required
- Overnight runs

#### Reliability for routine PCR

- Reliable results within two to three hours
- Sensitive, highly linear tests can handle both low titer and high titer samples in the same run
- Greater safety due to AmpErase enzyme contamination prevention and internal controls for detecting possible PCR inhibitors

# cobas® 6800/8800 Systems

## Own the future



[www.cobas68008800.com](http://www.cobas68008800.com)



The **cobas** 6800/8800 Systems are new molecular testing platforms, available in medium and high throughput models, designed for donor screening, viral load monitoring, women's health, and micro-biology testing.

The **cobas** 6800 System and the higher throughput **cobas** 8800 System are designed to be readily integrated into laboratory workflow from pre-analytic to post-analytic solutions.

For more information visit [www.cobas68008800.com](http://www.cobas68008800.com)

### Your benefit

#### Unparalleled Performance

Rapidly complete daily testing requirements with trusted and reproducible results.

#### Absolute Automation

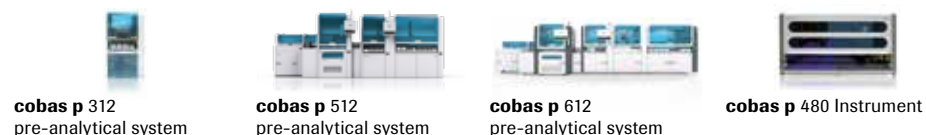
Allows you to focus on more complex testing demands while increasing productivity within the lab.

#### Unmatched Flexibility

Run the tests you want when you want with minimal user interactions.

### Automated pre-analytic sample handling

#### cobas® connection modules



|                 |                          |                          |                         |                                   |
|-----------------|--------------------------|--------------------------|-------------------------|-----------------------------------|
| Sorting         | Decapping                | Tube type ID             | Sample volume detection | Aliquoting with barcode labelling |
| Archiving       | Recursive workflows      | Sample quality           | Recapping               |                                   |
|                 |                          | Centrifugation           | Bulk loading            |                                   |
| 450 sample/hour | Up to 1,400 samples/hour | Up to 1,400 samples/hour |                         |                                   |

Learn more on pages 40–42, 48 and 168 (for cobas p 480)

### Product characteristics



Ready-to-use reagents do not require thawing, mixing or pouring



Uni- and bi-directional LIS interface



Automated onboard storage and refrigeration of consumables and reagents



System connectivity: up to six systems managed by a single instrument gateway



RFID and barcodes ensure full traceability from sample in to results out



Consolidate LDTs with routine IVD tests with the **cobas omni** Utility Channel

### Consolidated menu

Offers a broad and expanding menu to meet your needs today and in the future.

| Blood Screening | Infectious Diseases | Women's Health |        |
|-----------------|---------------------|----------------|--------|
| MPX**           | HIV-1†              | MTB*           | HPV*   |
| WNV             | HBV                 | MAI*           | CT/NG* |
| DPX             | HCV††               | RIF/INH*       | TV/MG* |
| HEV*            | CMV*                |                |        |
| Zika (IND)      | HIV-1/2 Qual*       |                |        |
| chikV/DenV*     |                     |                |        |



**cobas omni** Utility Channel\*

*cobas® assays are not available in all markets.*



\*may vary based on workflow demands



Data on file.

# cobas® 4800 System

*Works the way you do*



The **cobas® 4800** System offers state-of-the-art, fully automated sample preparation, real-time PCR amplification/detection and easy-to-use software for multiple sample types and an expanding menu of assays.

It consists of the **cobas x 480** Instrument for the nucleic acid extraction sample preparation and PCR pipetting and the **cobas z 480** real-time PCR analyzer.

The **cobas z 480** analyzer is also available as single system and can be used for parameters in the oncology field like BRAF, KRAS and EGFR.

## Your benefit

### Workflow efficiency

- Flexible and efficient sample loading of primary and secondary vials
- Run up to 3 tests simultaneously for faster turnaround of results
- Scalability on each and every test through flexible run sizes

### Consolidated menu

- Broad and expanding assay menu for IVD and LDT testing on a single instrument

### Confidence in results

- Physical and chemical measures ensure confidence in results
- Certainty of results through validation of every test run
- Automated interpretation of PCR results eliminates subjectivity

## Test menu

| Virology | Microbiology & Women's Health | G&O             |                            |
|----------|-------------------------------|-----------------|----------------------------|
| HIV-1†   | HPV                           | BRAF            | * Currently in development |
| HBV      | CT/NG                         | KRAS            | † Dual-target              |
| HCV††    | HSV 1/2                       | KRAS v2* (LSR)  | †† Dual-probe              |
| HCV GT   | Cdiff                         | EGFR v2         | RUO Research Use Only      |
| CMV*     | MRSA/SA                       | PIK3CA (RUO)    | LSR Life Science Research  |
|          |                               | BRAF/NRAS (LSR) |                            |
|          |                               | Factor II/V*    |                            |

- Virus
- Bacteria
- Variant
- For Lab Developed Tests



USER DEFINED FUNCTIONALITY

*cobas® assays are not available in all markets.*



cobas x 480 Instrument



cobas z 480 analyzer

# cobas® 4800 System

*Works the way you do*



## Product characteristics

- Processes up to 376 samples in 10 h
- Bidirectional connectivity to LIS
- Easy to use software
- Automated result interpretation

## cobas p 480 Instrument

Primary & secondary automated pre-analytical sample handling

Decapping

Recapping

Aliquoting

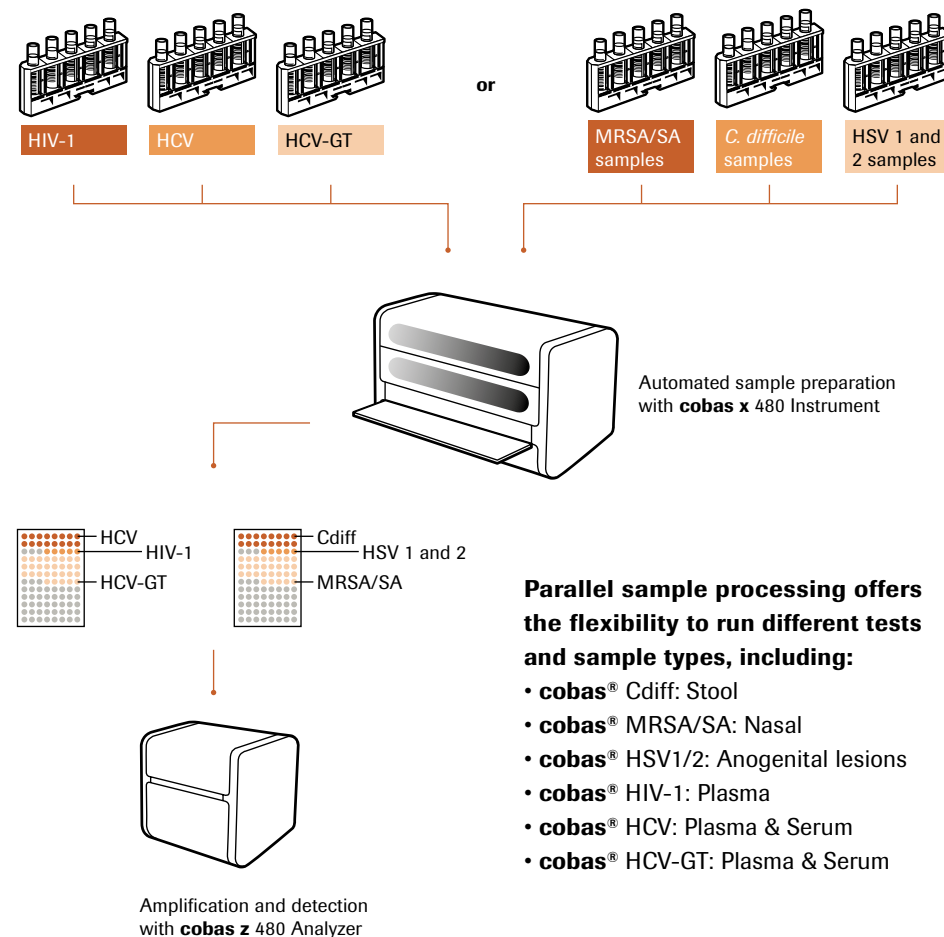
Reagent addition & heating

Four customizable workflows



cobas p 480 Instrument

## Mixed testing on cobas® 4800 System



# cobas® Liat® System

*We put a lab in a tube, because they put their trust in you*

The **cobas® Liat®** System incorporates Roche real-time PCR technology in a compact, fully automated bench top analyzer.

The self-contained **cobas® Liat®** Analyzer and its uniquely segmented assay tubes allow the efficient use of Roche PCR in the time-sensitive analysis of individual patient samples – with definitive results generated in 30 minutes or less.

Closed-system design and multiple process controls make it ideal for adoption by satellite labs, physician offices and pharmacies.



Data on file.

## Your benefit

### Accuracy

- Roche PCR technology
- Definitive, reproducible, objective

### Speed

- Analysis in 30 minutes or less, to expedite diagnosis and treatment
- Single-sample testing, to enable immediate response

### Ease-of-use

- No technical training required
- Touchscreen-guided operation, minimizes potential for human error

### Safety

- Multiple process controls
- Completely closed system
- Minimal risk of contamination

### Space-Efficiency

- Small bench top footprint



Sample

Scan

Start



[www.cobasliat.com](http://www.cobasliat.com)



## Product characteristics

- No complex set up
- Pre-packed reagents in a single assay tube – no direct operator contact with reagents or other solutions
- Easy, 3-step process
- Definitive, objective results
- Over 20 process controls including comprehensive real-time monitoring
- Printer connectivity for report outputs

### Analyzer dimensions and weight

24.1 × 11.4 cm × 19.0 cm, 3.76 kg

### cobas® Liat® Assay Menu

**cobas®** Influenza A/B

**cobas®** Influenza A/B + RSV

**cobas®** Strep A

**cobas®** MRSA/SA\*

**cobas®** Cdiff\*

Additional assays in development



\*in development

The **cobas® Liat®** System is not commercially available in all markets and some associated assays are currently in development.

**cobas®**

# cobas s 201 System

## *The first multi-dye nucleic acid testing (NAT) screening system*



The **cobas s 201** system is a complete NAT solution able to meet both current and future needs of blood screening labs.

This system provides the efficiency and reliability of real-time polymerase chain reaction (RT-PCR) technology, modular automation, convenient ready-to-use reagents and a robust menu selection. New assays utilize multi-channel capabilities to provide real-time discrimination of major viruses.

The system is backed by world-class service and strong local support in over 140 countries.



*Pooling and data management server*



*Hamilton MICROLAB STAR  
Pipettor instrument for automated pooling*



*COBAS® AmpliPrep Instrument and  
COBAS® TaqMan® Analyzer combined  
with a docking station*

### Your benefit

- Full automation including optional pooling and archiving with minimal hands-on time for the entire testing process
- Confidence in the test results through full process control
- Comprehensive assay menu with ready-to-use reagents
- Built-in viral target resolution through multi-dye technology makes confirmation testing obsolete

### Product characteristics

#### Scalable, modular system

- Flexible, mix-and-match scalability helps NAT labs work more efficiently
- Supports simultaneous multiple assay processing
- Accommodates integrated backup to maximize lab productivity

#### Pooling and data management server

- Single server, accommodating multiple instrument configurations and providing the added security of built-in redundancy

### Test menu

- Reagents are ready-to-use with built-in contamination control
- No freezers required, reagents are stored at 2 – 8° C
- Stabilized reagents obsoletes calibrations

#### cobas® TaqScreen MPX Test, v2.0

- Cover 5 critical viral targets (HIV-1 Group M, HIV-1 group O, HIV-2, HCV and HBV) in one easy-to-use assay
- Immediate virus discrimination in a single assay, no need for virus discriminatory testing

#### cobas® TaqScreen DPX Test

- Simultaneous quantitative detection of parvovirus B19V DNA and qualitative detection of HAV
- B19V target values are traceable to the WHO B19V International standard

#### cobas® TaqScreen WNV Test

- Qualitative in vitro test for the direct detection of West Nile virus (WNV) RNA in human plasma
- Screening test for donations of whole blood and blood components
- Capable of detecting other members of flavivirus that have been implicated in fusion transmitted infectious disease



*Data on file.*

# FLOW Solution

## Unleash your potential



[idsolutions.roche.com/flow](https://idsolutions.roche.com/flow)



The Roche FLOW Solution delivers ultimate flexibility based on your instrument configuration. It offers complete workflow standardization and data automation for your entire lab developed testing process. By moving your sample information from your lab information system through all instruments with complete data safety and sample tracking, the FLOW Solution enables you to generate accurate results with less effort than ever before.

### FLOW Flex

- Offers medium-throughput capabilities
- Uses one pipetting instrument for improved cost effectiveness

### FLOW Classic

- Offers high-throughput capabilities
- Uses two pipetting instruments for higher throughput capabilities



### Your benefit

#### Stay Flexible

The FLOW Solution helps you stay ahead of a quickly shifting market:

- React quickly and effectively to changing environments
- Make use of self-developed assays or solutions supplied by Roche
- Adapt a highly modular instrument setup to your needs

#### Increase Productivity

The FLOW Solution delivers automation and increased throughput:

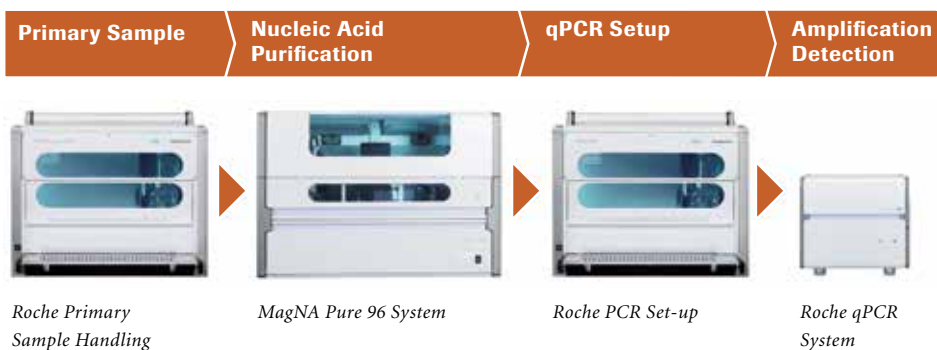
- Process more samples with less effort
- Minimize hands-on time
- Capable of reporting more than 2,000 results in less than 8 hours

*The FLOW Solution is for General Laboratory Use.  
The FLOW Solution is not available in all territories due to different national regulations.*

#### Ensure Result Safety

The FLOW Solution delivers increased accuracy:

- Utilize a completely paperless data transfer process
- Enables software connectivity between the lab LIS and FLOW Solution
- Use the Roche process control to monitor the workflow



# LightCycler® Systems

## Excellence in real-time PCR



Whether your interest is in gene expression profiling or in detecting genetic variations, there is a member of the LightCycler® System family offering the analytical performance and throughput you need for your research.

Supported by a broad range of software tools, real-time PCR based analysis can be performed in 32 capillaries or plastic tubes, interchangeable 96-/384-well plates, or using the unique 1536-well formats.

For additional information, visit [lifescience.roche.com](http://lifescience.roche.com) or [www.lightcycler.com](http://www.lightcycler.com)

### Your benefit

#### High precision

- Reproducible results independent of the sample position

#### High flexibility

- Suitable for all common assay formats and dyes

#### High sensitivity

- Even single copies can be detected

#### High operator convenience

- Data analysis according to your needs

#### Versatility

- Absolute or relative quantification, melting curve analysis or genotyping – the software offers all options

### Available reagents

- Generic kits for qPCR and RT-qPCR
- Parameter-specific kits including assays from TIB MOLBIOL
- Ready to use custom assays and panels for all available LightCycler® Systems (e.g., Universal ProbeLibrary and RealTime Ready)
- Optimized line of LightCycler® consumables



### Product characteristics

|                 | LightCycler® 2.0 System                                                                                                                                                                                                                                                                                       | LightCycler® 96 System                                                                                                                                                                                                                                   | LightCycler® 480 System (96/384)                                                                                                                                                                                                                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Throughput      | 32 reactions                                                                                                                                                                                                                                                                                                  | 96 reactions                                                                                                                                                                                                                                             | 96 or 384 reactions                                                                                                                                                                                                                                                                                                          |
| Hardware        | 6 detection channels                                                                                                                                                                                                                                                                                          | 4 excitation and 4 detection filters                                                                                                                                                                                                                     | 5 excitation and 6 detection filters                                                                                                                                                                                                                                                                                         |
| Disposable      | Capillaries                                                                                                                                                                                                                                                                                                   | 96 multiwell plates or tube strips                                                                                                                                                                                                                       | 96 or 384 multiwell plates or tube strips                                                                                                                                                                                                                                                                                    |
| System features | <ul style="list-style-type: none"> <li>• Excellent temperature homogeneity in all wells/vessels</li> <li>• No need for passive reference dyes</li> <li>• 40 cycles are possible in 40 minutes</li> <li>• Freely programmable protocols, data import and export, creation of macros, and templates.</li> </ul> |                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                              |
| Assay formats   | SYBR Green I, hydrolysis and hybridization probes                                                                                                                                                                                                                                                             | SYBR Green I, hydrolysis probes                                                                                                                                                                                                                          | SYBR Green I, hydrolysis and hybridization probes                                                                                                                                                                                                                                                                            |
| Applications    | <ul style="list-style-type: none"> <li>• Absolute Quantification</li> <li>• Relative Quantification</li> <li>• T<sub>m</sub> Calling</li> <li>• Melt-Curve Genotyping</li> <li>• Endpoint Genotyping</li> <li>• Qualitative Detection</li> </ul>                                                              | <ul style="list-style-type: none"> <li>• Absolute Quantification</li> <li>• Relative Quantification</li> <li>• T<sub>m</sub> Calling</li> <li>• Endpoint Genotyping</li> <li>• Qualitative Detection</li> <li>• High-Resolution Melting (HRM)</li> </ul> | <ul style="list-style-type: none"> <li>• Absolute Quantification</li> <li>• Relative Quantification</li> <li>• T<sub>m</sub> Calling</li> <li>• Melt-Curve Genotyping</li> <li>• Endpoint Genotyping</li> <li>• Qualitative Detection</li> <li>• High-Resolution Melting (HRM)</li> <li>• Multiple Plate Analysis</li> </ul> |

The LightCycler® 2.0 System (IVD) is not available in all countries.  
 Information about the high-throughput LightCycler® 1536 System is available on request.  
 For life science research only.  
 Not for use in diagnostic procedures unless otherwise noted.



# LightCycler® 2.0 Instrument

## For medical research



The LightCycler® 2.0 System is a proven standard of excellence with its high precision thermocycling, state-of-the-art quantification software, and numerous high-quality kits for a wide range of applications in in vitro diagnostics and in medical research.

It generates fast and reliable results through its innovative features, including the single air-driven chamber, which ensures ultra-precise temperature regulation for the high accuracy and reproducibility.



LightCycler® 2.0  
System (IVD)

### Your benefit

- Safety and ease of use in the IVD mode, including test-specific reagent kits, and PCR macros that can automate instrument programming, test analysis and result reporting
- The research mode offers flexible programming, editing and user evaluation
  - Versatility in application options e.g., qualitative and quantitative detection, mutation detection by melting curve analysis and SNP genotyping
  - Broad choice of detection formats

### Product characteristics

- Compact benchtop model
- Fast run of 35 cycles in 40 minutes
- Reaction batch of 1–32 samples 20 µL or 100 µL capillaries
- 6 detection channels for 530, 560, 610, 640, 670, and 710 nm
- Versatile detection formats: SYBR Green, hybridization probes, hydrolysis probes, SimpleProbe probes, Scorpion primers, and other FRET-based detection formats

### Test kits, validated for IVD

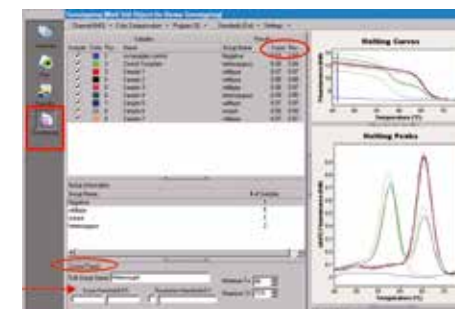
- CMV quantification
- EBV quantification
- HSV 1/2 detection and differentiation
- VZV detection
- MRSA advanced detection
- SeptiFast identification of bacteria and fungi
- SeptiFast mec A resistance screening
- Factor V mutation detection
- Factor II mutation detection

### For medical research

- HAV quantification
- Parvo B19 quantification
- VRE resistance screening
- Translocation (9;22) quantification

| Samples                             |       |     |                     | Calls    |          |         |
|-------------------------------------|-------|-----|---------------------|----------|----------|---------|
| Include                             | Color | Pos | Name                | Combined | Target   | Control |
| <input checked="" type="checkbox"/> | Blue  | 1   | no template control | Success  | Negative | Success |
| <input checked="" type="checkbox"/> | Green | 2   | Negative Control    | Success  | Negative | Success |
| <input checked="" type="checkbox"/> | Red   | 3   | Positive Control    | Success  | Positive | Success |
| <input checked="" type="checkbox"/> | Black | 4   | Sample 1            | Positive | Positive | Success |
| <input checked="" type="checkbox"/> | Pink  | 5   | Sample 2            | Positive | Positive | Success |
| <input checked="" type="checkbox"/> | Green | 6   | Sample 3            | Negative | Negative | Success |
| <input checked="" type="checkbox"/> | Blue  | 7   | Sample 4            | Positive | Positive | Success |
| <input checked="" type="checkbox"/> | Grey  | 8   | Sample 5            | Positive | Positive | Success |

Data display for a qualitative detection analysis



Genotyping analysis

\* More details on following page.

The LightCycler® 2.0 System (IVD) is not available in all countries.

# MagNA Pure Systems

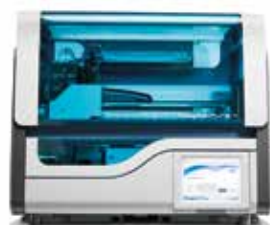
## Breakthroughs have a beginning



Your genomic workflow begins with nucleic acid purification. Roche Molecular Diagnostics has revolutionized automated sample preparation with nearly 2 decades of expertise. Enhancing your laboratory workflow, the MagNA Pure Systems offer automated, flexible, and consistent solutions.

### Your benefit

- Extract a wide range of starting materials
- Simplified sample preparation for dramatic reduction of handling errors
- Preloaded protocols for a broad range of sample types
- Pre-filled and barcoded reagent kits
- Intuitive software and guidance



MagNA Pure 24 System  
(Currently in development,  
available March 2017)



MagNA Pure 96 System



### Discover the right solution for you

Start confidently and increase your workflow efficiency with Roche manual and automated solutions. Use the table below to guide your next nucleic acid extraction.

### Product characteristics

|                      | MagNA Pure 24 System #                                                                                            | MagNA Pure 96 System |
|----------------------|-------------------------------------------------------------------------------------------------------------------|----------------------|
| # of Samples         | 1-24 samples per run                                                                                              | 1-96 samples per run |
| Run Time             | 1 hour                                                                                                            | ~1 hour              |
| Starting Samples     | Whole Blood, Plasma, Serum, Cell Culture, Tissue, Body Fluids, Fresh Frozen and FFPE* Tissue, Swab, Stool, Sputum |                      |
| Nucleic Acid Targets | Genomic and Bacterial DNA, Viral DNA/RNA, Plasmid DNA and Total RNA                                               |                      |

MagNA Pure 24 and MagNA Pure 96 Systems are for in vitro diagnostic use.

\*only on MagNA Pure 96 Systems

# cobas p 480 instrument

## Automating your primary vial preprocessing steps



The **cobas p 480** instrument improves laboratory efficiency by allowing valuable technician time to be used more productively, eliminating repetitive, manual sample handling, improving workflow and reducing risk of contamination, human error and workplace injury.

### Your benefit

#### Improving laboratory efficiency

- Accepts PreservCyt®, SurePath™ liquid based cytology vials as well as **cobas**® PCR Media and **cobas**® PCR Cell Collection Media primary vials
- Processes four vials simultaneously
- Intuitive interface requires minimal training
- High throughput automation

### Workflow Volumes



**Decapping/Recapping**



**Aliquoting**



**Reagent Addition & Heating**

*\*Up to the stated sample volume processed by workflow in an 8-hour shift*

### Product characteristics

#### Improves sample reproducibility and process reliability

- Sample chain of custody is assured with primary and secondary vial barcode matching
- All vials are spun prior to opening to remove potentially contaminating droplets from sample caps
- Precision pipetting using CO-RE tip, Total Aspirate and Dispense Monitoring and Anti-Droplet Control technologies reduce opportunities for contamination and ensure sample integrity
- No LIS or data connection required
- Printable reports capture all sample ID's, sample error and reagent lot and expiration information



### Reduces hands on time and repetitive motions with four unique workflows



#### Decapping

Removes caps from primary tubes for testing on the **cobas**® 4800/6800/8800 Systems.



#### Recapping

Recaps sample vials with new caps to avoid contamination.



#### Aliquoting

Aliquots configurable volumes from PreservCyt®, SurePath™ and **cobas**® PCR Cell Collection Media primary vials into barcode matched secondary tubes Compatible with SurePath™ vials with plastic inserts.



#### Reagent addition and heating\*

Addition of **cobas**® Sample Prep Buffer and incubation of specimens collected in SurePath™ medium to reverse cross-linking and free nucleic acids for testing<sup>1</sup>.

<sup>1</sup> Kiernan, J.A. Preservation and retrieval of antigens for immunohistochemistry – methods and mechanisms Part 2. Retrieving masked antigens Department of Anatomy and Cell Biology. *The Cutting Edge*, 5-11.

# cobas p 680 instrument

*Supports the creation of sample pools for use with the cobas® 6800/8800 Systems*



The **cobas p 680** instrument automates the creation of pools in secondary tubes and pipetting of samples into aliquot plates for archiving. From a deck capacity of 500 tubes, primary pools of 1, 6, 24, 96 and 480 may be created. The instrument utilizes Roche standard 5-position racks and rack trays to help streamline workflow with Roche pre-analytics and analytic systems. The **cobas p 680** instrument combines proprietary pipette tip technology and liquid level monitoring to ensure reliable sample transfer during pooling. Connect up to six **cobas p 680** instruments to the **cobas®** 6800/8800 Systems to meet your lab's needs.



*cobas p 680 instrument*

## Your benefit

### Improved workflow efficiencies

- Automated loading of racks onto instrument, once rack tray is deposited
- Error lane allows user to easily identify tubes with pipetting errors

### Confidence in full traceability

- Full integration in the **cobas** 6800/8800 Systems software ensures full traceability of sample pool creation to final result
- Secondary tubes are barcoded for improved workflow efficiency and full traceability

## Product characteristics

### Flexible Pool Creation

Creation of pools with fewer samples than the configured pool size (e.g., creation of a pool of six with five samples); additional aliquots will be taken from samples to complete the pool. Aliquot plates may be created offline for sample archiving.

### TADM

Total aspiration and dispense monitoring (TADM) of the pressure within the pipette tip during the pipetting process ensures accurate sample transfer.

### Liquid level detection

Capacitive liquid level detection monitors the level of sample in a tube or plate to prevent overflow and carryover contamination during pipetting.

### CO-RE tip technology

Compressed O-ring expansion (CO-RE) tip technology locks pipette tips in place with an expanding O-ring. The tip is released when the O-ring gently decompresses, preventing the creation aerosols to minimize contamination. Disposable filter tips are utilized to prevent cross-contamination.





**Safe blood supply**  
*Nucleic Acid Testing*  
**Serology**  
*Blood screening laboratories*  
**Pre-analytics**  
*IT solutions*  
**Reliable results**  
*Full automation*  
**Roche Blood Safety Solutions**  
*Efficient processes*

## Roche Blood Safety Solutions

Blood screening laboratories are managing critical workflow processes and provide uninterrupted service to ensure timely release of safe blood products.

Roche understands that challenge and is dedicated to be a trusted partner now and in the future.

Roche Blood Safety Solutions offers a comprehensive portfolio through Personalized Lab Automation which integrates nucleic acid testing, serology testing, pre-analytics and IT solutions. Roche is the first company to offer a connectivity of serology and nucleic acid testing, setting new standards in your daily routine.

The **cobas**<sup>®</sup> systems are designed to efficiently fulfill the demanding safety and reliability of blood bank standards. All supported by a first-class team of skilled professionals in your area who are ready to respond when needed most.

# Roche Blood Safety Solutions

*Striving for continual improvement to meet blood banks' evolving needs*

## Your benefit

### Reliability

- Innovative technologies tailor-made to meet individual needs
- Systems which have a high reliability on the market while preventing cross-contamination and offering full sample traceability

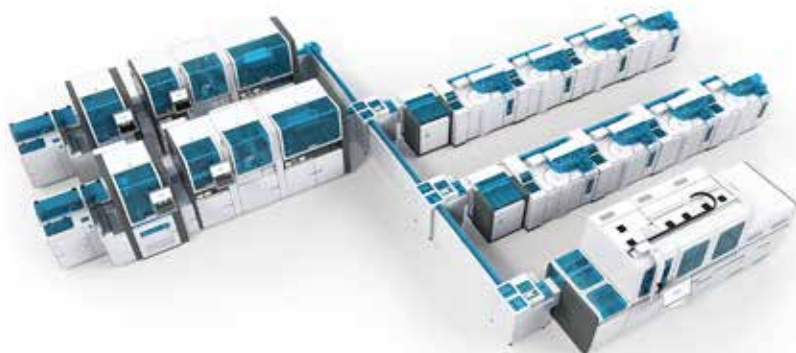
### Efficiency

- High assay specificity and innovative technologies (multi-dye for NAT, ECL for serology) reduce the need for retesting
- Short turnaround times, automation and uninterrupted workflow generate time savings

### Safety

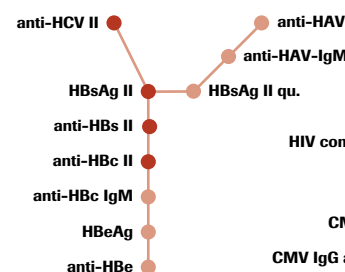
- State-of-the-art assay sensitivity and genotype coverage allow reliable detection at the earliest detectable stage of infection in all parts of the world
- Highly standardized processes which reduce manual handling and risk of error

*A fully integrated solution for standardizing blood bank workflow*



## Test menu

### Serology:



### NAT:

- TaqScreen MPX, v2.0
- TaqScreen WNV
- TaqScreen DPX
- cobas® MPX
- cobas® WNV
- cobas® DPX
- cobas® HEV
- cobas® CHIKV/DENV

- Bloodscreening assays
- Additional serology assays
- Product under development

## Solution components

### Technologies that support timely and reliable release of safe blood products

| Serology                       | Nucleic Acid Testing             | Personalized Lab Automation                                                                   |
|--------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------|
| <br>cobas 6000      cobas 8000 | <br>cobas 6800/8800, cobas p 680 | <br>cobas p 312    cobas p 512    cobas p 612    CCM                                          |
| <br>cobas e 411                | <br>cobas s 201                  | <br>cobas IT solutions<br>cobas infinity blood safety<br>cobas IT middleware<br>cobas Synergy |

Please contact your local Roche representative for detailed information.

**cobas®**



**Point of Care**  
*CoaguChek*  
**Anticoagulation**  
*Glucose*  
**Accu-Chek**  
*POC IT*  
**cobas**  
*Cardiovascular*  
**Diabetes**  
*Dyslipidemia*  
**Critical care**

## Point-of-care testing

The goal of Point of Care from Roche is to help both healthcare professionals and patients achieve improved clinical and health-economic outcomes, by delivering robust, connected, easy to use point-of-care solutions outside the central lab, providing immediate results and thus allowing treatment decisions to be made more quickly – inside or outside the hospital.

Point of Care delivers those solutions meeting the clinical need for quick and accurate test results delivered where needed, when needed; on the device, in the electronic healthcare record on a patient/ward monitor, to the clinician on the move and directly to the patient.

While the responsibility for providing the service is in the hands of professionals, we also provide IT tools to be able to control all aspects of testing to ensure quality patient care:

- Provide accurate and timely analyses and match them to the right patient
- Ensure that operators are competent in the use of the system
- Provide reports that are useful to the clinician treating the patient
- Document testing and QC for audit purposes

For coagulation patient self-monitoring we also provide solutions for remote support and monitoring.

For more information please visit [www.cobas.com](http://www.cobas.com) and [www.CoaguChek.com](http://www.CoaguChek.com)

# Overview of point-of-care diagnostic tests



www.cobas.com



|                                      | Combur<br>(visual strips) | TROP T sensitive<br>(visual strip) | cobas h 232 | Accu-Chek®<br>Inform II | CoaguChek® XS | CoaguChek® Pro II | Accutrend® Plus | Unisys 1100® | cobas b 101 | Reflotron® Plus and<br>Reflotron® sprint | cobas b 123* | cobas b 221* | CoaguChek®<br>INRange |
|--------------------------------------|---------------------------|------------------------------------|-------------|-------------------------|---------------|-------------------|-----------------|--------------|-------------|------------------------------------------|--------------|--------------|-----------------------|
| <b>Anemia</b>                        |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Bilirubin                            |                           |                                    |             |                         |               |                   |                 | •            |             | •                                        | •            | •            |                       |
| Bilirubin neonatal                   |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Hemoglobin total                     | •                         |                                    |             |                         |               |                   |                 | •            |             | •                                        | •            | •            |                       |
| Hematocrit                           |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Oxygen saturation (sO <sub>2</sub> ) |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| <b>Blood gas</b>                     |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| pH                                   |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| pCO <sub>2</sub>                     |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| pO <sub>2</sub>                      |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| <b>Electrolytes</b>                  |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Ca <sup>2+</sup>                     |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Cl <sup>-</sup>                      |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| K <sup>+</sup>                       |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Na <sup>+</sup>                      |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| <b>CO-oximetry</b>                   |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| tHb-COOX                             |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| O <sub>2</sub> Hb                    |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| HHb                                  |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| COHb                                 |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| MetHb                                |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| sO <sub>2</sub> COOX                 |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Bilirubin neonatal                   |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Barmetric pressure (Baro)            |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| <b>Cardiac</b>                       |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Troponin T                           |                           | •                                  | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |
| CK-MB                                |                           |                                    | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |

\*In addition several calculated parameters are available.

|                             | Combur<br>(visual strips) | TROP T sensitive<br>(visual strip) | cobas h 232 | Accu-Chek®<br>Inform II | CoaguChek® XS | CoaguChek® Pro II | Accutrend® Plus | Unisys 1100® | cobas b 101 | Reflotron® Plus and<br>Reflotron® sprint | cobas b 123* | cobas b 221* | CoaguChek®<br>INRange |
|-----------------------------|---------------------------|------------------------------------|-------------|-------------------------|---------------|-------------------|-----------------|--------------|-------------|------------------------------------------|--------------|--------------|-----------------------|
| Myoglobin                   |                           |                                    | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |
| D-dimer                     |                           |                                    | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |
| HDL cholesterol (or HDL-C)  |                           |                                    |             |                         |               |                   |                 |              | •           | •                                        |              |              |                       |
| LDL cholesterol (or LDL-C)  |                           |                                    |             |                         |               |                   |                 |              | •           | •                                        |              |              |                       |
| NT-proBNP                   |                           |                                    | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |
| <b>Coagulation</b>          |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| D-dimer                     |                           |                                    | •           |                         |               |                   |                 |              |             |                                          |              |              |                       |
| PT (INR/% Quick/sec.)       |                           |                                    |             |                         | •             | •                 |                 |              |             |                                          |              |              | •                     |
| aPTT                        |                           |                                    |             |                         |               | •                 |                 |              |             |                                          |              |              |                       |
| <b>Metabolic</b>            |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Ca <sup>2+</sup>            |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Cl <sup>-</sup>             |                           |                                    |             |                         |               |                   |                 |              |             |                                          | •            | •            |                       |
| Glucose                     |                           |                                    |             | •                       |               |                   | •               | •            |             | •                                        | •            | •            |                       |
| HbA1c                       |                           |                                    |             |                         |               |                   |                 |              | •           | •                                        |              |              |                       |
| HDL cholesterol (or HDL-C)  |                           |                                    |             |                         |               |                   |                 |              | •           | •                                        |              |              |                       |
| Ketone                      | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| LDL cholesterol (or LDL-C)  |                           |                                    |             |                         |               |                   |                 |              | •           |                                          |              |              |                       |
| Lactate                     |                           |                                    |             |                         |               |                   | •               |              |             | •                                        | •            | •            |                       |
| Potassium                   |                           |                                    |             |                         |               |                   |                 |              |             | •                                        | •            | •            |                       |
| Sodium                      |                           |                                    |             |                         |               |                   |                 |              |             | •                                        | •            | •            |                       |
| Total cholesterol (or CHOL) |                           |                                    |             |                         |               |                   | •               |              | •           | •                                        |              |              |                       |
| Triglycerides (or TG)       |                           |                                    |             |                         |               |                   | •               |              | •           | •                                        |              |              |                       |
| <b>Hepatology</b>           |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Alkaline phosphatase        |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Bilirubin                   |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Creatine kinase             |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| GGT                         |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |

# cobas® POC IT solution

## Bringing it all together



|                        | Combur<br>(visual strips) | TROP T sensitive<br>(visual strip) | cobas h 232 | Accu-Chek®<br>Inform II | CoaguChek® XS | CoaguChek® Pro II | Accutrend® Plus | Unisys 1100® | cobas b 101 | Reflotron® Plus and<br>Reflotron® sprint | cobas b 123* | cobas b 221* | CoaguChek®<br>INRange |
|------------------------|---------------------------|------------------------------------|-------------|-------------------------|---------------|-------------------|-----------------|--------------|-------------|------------------------------------------|--------------|--------------|-----------------------|
| <b>Hepatology</b>      |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| GOT (AST)              |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| GPT (ALT)              |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Pancreatic amylase     |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Urobilinogen           | •                         |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| <b>Renal and urine</b> |                           |                                    |             |                         |               |                   |                 |              |             |                                          |              |              |                       |
| Bilirubin              | •                         |                                    |             |                         |               |                   |                 | •            |             | •                                        |              |              |                       |
| Creatinine             |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Erythrocytes (Hb)      | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Glucose                | •                         |                                    |             |                         |               |                   |                 | •            |             | •                                        |              |              |                       |
| Ketone                 | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Leukocytes             | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Nitrite                | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| pH                     | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Protein                | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Specific gravity       | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |
| Urea (BUN)             |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              | •            |                       |
| Uric acid              |                           |                                    |             |                         |               |                   |                 |              |             | •                                        |              |              |                       |
| Urobilinogen           | •                         |                                    |             |                         |               |                   |                 | •            |             |                                          |              |              |                       |

\*In addition several calculated parameters are available.

**cobas** POC IT is responsible for collecting results from POC analyzers that are distributed across hospitals and primary care centres.

The **cobas** POC IT solution brings all POC information together to provide oversight via your POC program. Furthermore, it provides you with the insight required to ensure compliance and the long-range view to plan for improvements and expansion in the future.

Roche is committed to assisting POC Coordinators with powerful tools required to effectively manage POC testing, improve workflows and meet accreditation and regulatory requirements around the world.

Proven open connectivity to a wide menu of POC devices gives you the freedom of choice to grow your POC program.



### Your benefit

#### Coordinated user management

- A central point of control for all POC testing devices and users ensures result security
- Efficient customizable online e-learning with automatic operator recertification saving time for the Point of care coordinator

#### Innovative functionality

- Over a decade of collecting user input and workflows has resulted in a high level of innovation



Open connectivity at its best

**cobas®**



such as true wireless communication and observed competency on-board POC devices, as well as positive patient ID – ensuring patient safety

### Local service and support

- Quick and easy access to Roche service personnel in your time zone and language provides efficient turnaround time for your questions and ensures maximum uptime for the systems

### Proven commitment

- The **cobas**® POC IT solutions are proven to perform in over 1,450 systems in > 50 countries with 70,000 connected devices.
- Including over > 50 Roche and non-Roche POC devices – with a long-term commitment to enhancing value for patients and POC coordinators missing period

### Product characteristics

#### cobas IT 1000 application

- **cobas IT 1000** application gives you complete management of POC testing, including remote configuration and control of devices, user management and LIS/HIS interfacing from a single point of control

- Connects the full Roche POC portfolio including Accu-Chek Inform II, CoaguChek XS Plus and Pro, CoaguChek Pro II, **cobas**® Liat®, **cobas h** 232, **cobas b** 101, Urysis 1100, **cobas b** 121 system, **cobas b** 123 POC system and **cobas b** 221 system.

### Roche POC e-learning

- Efficient user training, integrated into your existing hospital platforms and customizable to your needs. Roche offer SCORM compliant e-learning modules can be hosted on your existing hospital learning management system (LMS). **cobas**® IT 1000 can be seamlessly linked to your hospital LMS enabling the automatic update of operator elearning exam results. Simple for nurses and POC coordinators.

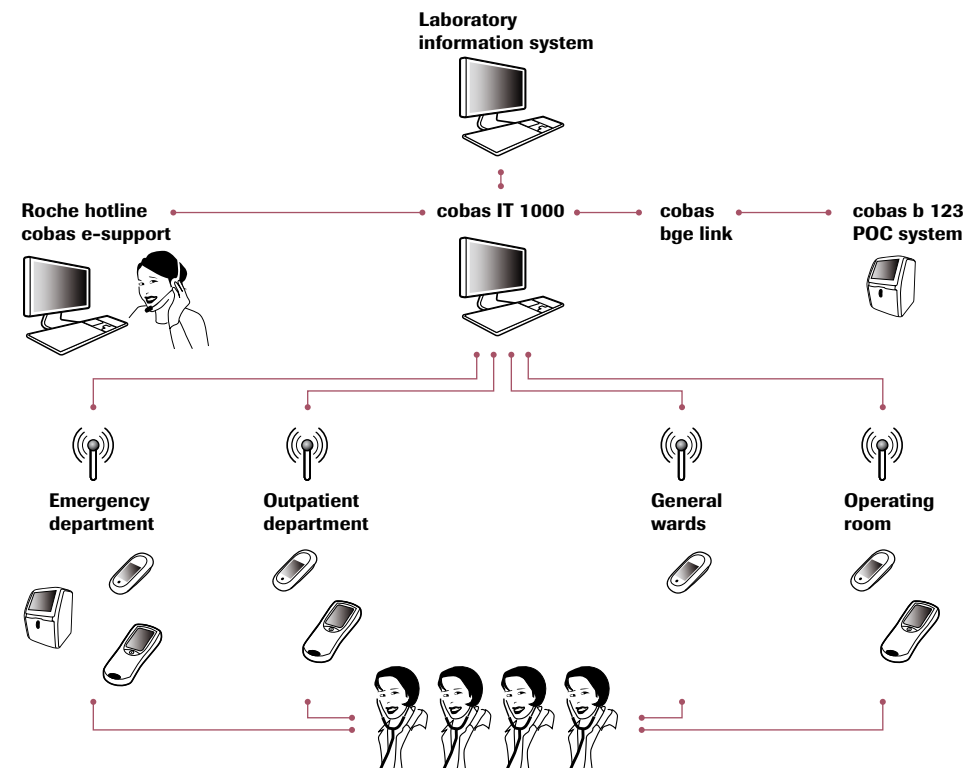
### cobas bge link

- The **cobas bge link** software gives you complete and easy remote management of POC blood gas analyzers, allowing you to view and control device operations simply and efficiently.

### cobas® e-services

- Gives your local Roche experts remote access, enabling them to quickly and efficiently answer your questions in your time zone and language.

### cobas® POC IT solution



# NEW cobas® infinity POC tablet

## Move and work

**cobas® infinity** POC tablet is an app for iOS and Android tablet devices. It is designed to help POC Coordinators (POCCs) manage their complete POC testing program whilst moving around. The app enables POC Coordinators to realise the full potential of working with a tablet, allowing them to become really efficient by; automating the coordination of competence and performance and supporting them to better manage complex job tasks. The POCC can take their work with them into meetings, review quality control (QC) performance with nurses directly on the ward, record corrective and preventative actions or discuss the training status of users with the hospital's education manager.

### Your benefit

#### Automate Operator & Device Management

With **cobas® infinity** POC tablet, a POC Coordinator can easily monitor operator and device status. Enabling them to quickly identify where they are needed for problem-solving.



#### Efficient Quality Control Management

Manage quality control results by exception. Rules can be configured so that the POC coordinator is alerted only to specific types of issues, enabling them to use their time more efficiently.

The QC review concept has been designed specifically for POC coordinators to utilize the full potential of the tablet experience. With one click on the interactive QC chart all result-related information is presented for review, and troubleshooting becomes much easier.

### Product characteristics

**cobas® infinity** POC tablet enables the POCC to efficiently manage their complete POC testing program by supporting the following workflows:

- Quality control management
- Documentation of QC corrective and preventative actions
- Device replacement and relocation
- Check device status
- Adding and updating operators
- Check and update operator training status
- Export list of operators requiring training

#### Technical requirements:

- **cobas®** IT1000 v2.07 or higher
- Tablet device on hospital network
- iOS 9 or higher
- Android 4.3 or higher
- (VPN for remote connection)



Simple, one-touch QC review with full information for every result.

# cobas® infinity POC mobile

*Always with you*



www.cobas.com



**cobas® infinity** POC mobile is a mobile app for iOS and Android devices, which works in conjunction with **cobas IT 1000**. It is designed to help POC Coordinators (POCCs) complete key tasks whilst on the go.

Due to the nature of the testing that they support, a POCC does a lot of their work while “out and about” around hospital locations. Some of their time is spent at their desk, some walking around and for many tasks, they need to find a PC in order to access a desktop.

This dictates how POC Coordinators work, and limits productivity. **cobas® infinity** POC mobile empowers the POCC, freeing them from their office and enabling them to: save time managing devices, automate operator management and act on what’s important.

## Your benefit

### Save Time Managing Devices

The POCC can easily monitor device connectivity and QC status. Enabling them to quickly identify where they are needed for problem solving.

### Automate Operator Management

The POCC or Nurse Educator can easily review and update operator training status, quickly identifying those operators with expired or soon to expire certificates.

### Act on What’s Important

With **cobas® infinity** POC mobile, a POC Coordinator can monitor overall performance of POC testing and spot any issues that need to be dealt with quickly and easily.



## Product characteristics

Usability has been at the core of the design process and **cobas® infinity** POC mobile has been independently rated for usability, scoring extremely highly. The product has been designed from the bottom up to be easy to use from a mobile device.

**cobas® infinity** POC mobile enables the POCC to easily carryout key workflows whilst on the move:

- Device replacement
- Device relocation
- Checking device status
- Adding a new operator
- Editing existing operator details
- Checking operator training status
- Export a list of operators requiring training
- Update operator training status

## Technical requirements

- **cobas® IT 1000 v2.04.01** or higher and networked mobile device
- iOS 7 or higher
- Android 4.1 or higher
- Mobile device on hospital network
- (VPN for remote connection)



# cobas® bge link software

## Central control of your Roche blood gas and electrolyte analyzers



[www.cobas.com](http://www.cobas.com)



The **cobas bge link** software provides complete remote management and control of blood gas instruments from one workstation.

This valuable tool allows the complete management of all **cobas** blood gas analyzers that are connected to a hospital network. The **cobas bge link** software can improve workflow efficiency, freeing up valuable staff time and improving service to clinicians in critical care settings.

### Your benefit

#### Save time

- By not having to walk to each analyzer, with continuous remote status monitoring of your blood gas and electrolyte systems, from the laboratory

#### Improve analyzer uptime

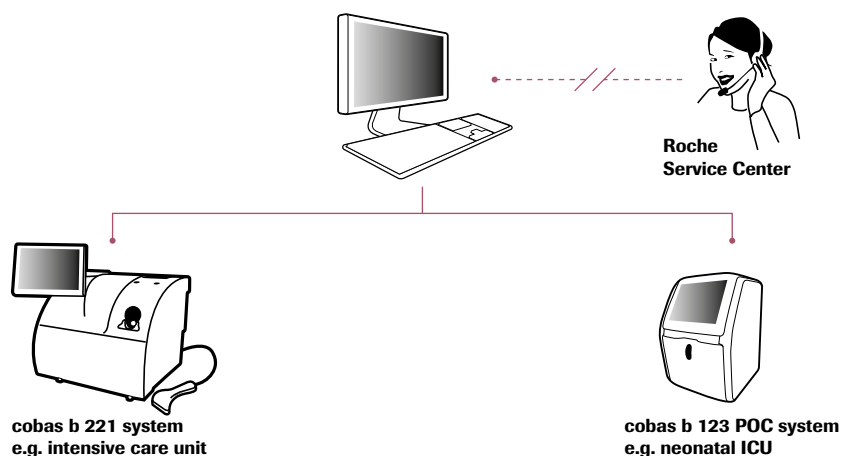
- With effective remote troubleshooting and remote control of analyzer functions (e.g. calibrations, QC, cleaning cycles, test functions)

#### Increase confidence and security

- With remote monitoring of analyzer performance and quality while offering a clear and comprehensive audit trail

### Product characteristics

- Information on analyzer status, parameters, reagents and reports in a clearly arranged layout
- Management of quality controls and calibration cycles
- Clear presentation of patient results measured with the blood gas and electrolyte systems from Roche
- Remote control of calibrations, cleaning cycles and test functions
- Initiation of quality control on the blood gas and electrolyte systems from Roche (AutoQC®), can be initiated from the laboratory
- Levy-Jennings overview of QC history and trends
- Extensive data management possible through integration into **cobas®** POC IT solution



# cobas b 221 system

## Convenience for your critical care testing



Blood gas analysis is considered the most important tool for diagnosis in critically ill patients. Analyzers should deliver rapid and reliable results, be easy to handle and require little maintenance. Our **cobas b 221** system offers these features – and a flexible configuration which can meet your specific requirements for critical care testing in high throughput departments.

### Your benefit

#### Fast diagnosis

- Results in less than 2 minutes to support timely clinical decision making

#### Flexibility of testing

- Comprehensive parameter menu to meet varying department needs

#### Confidence in result quality

- Lab-quality results where and when you need them

#### Improved uptime

- Long-life, maintenance-free electrodes and minimal preventative maintenance



cobas b 221 system



### Product characteristics

- Throughput: up to 50 samples/hour
- Time to result: less than 2 minutes with whole-blood sampling
- Optional module for automatic quality control
- Three different parameter combinations (see table below) including glucose, lactate, urea and bilirubin
- Durable, low-maintenance sensors
- Easy-to-use touchscreen and intuitive user interface
- Trending acid-base maps to support clinical decisions
- Reagent tracking
- Customizable features include a user-definable display and two types of sample application
- Connectable to network via the **cobas® bge link** software for remote control and to the **cobas POC IT** solution for comprehensive data management

| cobas b 221 system                                                                               | Versions |   |   |
|--------------------------------------------------------------------------------------------------|----------|---|---|
|                                                                                                  | 2        | 4 | 6 |
| pH/blood gas (PO <sub>2</sub> , PCO <sub>2</sub> , pH)/CO-oximetry                               | •        | • | • |
| Electrolytes (Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>2+</sup> , Cl <sup>-</sup> )/hematocrit |          | • | • |
| Metabolites Glu/Lac                                                                              |          |   | • |
| Metabolites Glu/Lac/Urea (BUN)                                                                   |          |   | • |
| Bilirubin                                                                                        | •        | • | • |

Source: cobas b 221 system IFU manual.

# cobas b 123 POC system

## Allowing you to focus on patient critical care



The **cobas b 123** POC system is a mobile, cartridge-based, critical care analyzer designed for POC testing. With flexible configurations and a throughput of up to 30 samples per hour, the **cobas b 123** POC system can easily be customized to the clinical needs of the ICU, ER, NICU, OR\*, dialysis units or the laboratory.

The operator-friendly system offers easy handling and requires no preventative maintenance, reducing analyzer downtime.



cobas b 123 POC system

### Your benefit

#### Easy to use

- Intuitive graphical user interface, touch-screen and graphically guided instructions allow handling steps to be learned in minutes and simplify the training of POC users

#### Safe

- Access control, clot prevention, data management including QC, remote control to increase analyzer uptime

#### Rapid results

- Near-patient, whole-blood sampling provides results in only 2 minutes to support timely clinical decision making

#### Flexibility and scalability

- Allows clinically relevant and cost-efficient POC testing including quality control



reddot design award  
winner 2011



\* Intensive care unit, emergency room, neonatal intensive care unit, operating room.

### Product characteristics

- Throughput: 30 samples/hour
- Integration of clot prevention features to ensure patient care without interruption and cost-efficient operation
- Optional mobile cart, battery operation and wireless connectivity enables instrument to be operated wherever it is needed
- Variety of sample types: whole blood, dialysis solution, QC solutions (both aqueous and blood-based)
- Connection to **cobas® bge link** software and **cobas** POC IT solution
- Automated user management through **cobas** e-learning



- Trending acid-base maps to support clinical decisions
- Fluid pack – sizes 200, 400 or 700 samples

| cobas b 123 POC system                                                                           | Versions |   |   |   |
|--------------------------------------------------------------------------------------------------|----------|---|---|---|
|                                                                                                  | 1        | 2 | 3 | 4 |
| pH/blood gas (pO <sub>2</sub> , pCO <sub>2</sub> , pH)                                           | •        | • | • | • |
| Electrolytes (Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>2+</sup> , Cl <sup>-</sup> )/Hematocrit | •        | • | • | • |
| Metabolites Glu/Lac                                                                              | •        | • | • | • |
| Bilirubin                                                                                        |          |   | • | • |
| Co-oximetry (tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, SO <sub>2</sub> )                         |          |   | • | • |
| Auto QC                                                                                          |          | • |   | • |

Plus an extensive range of calculated parameters.

Source: cobas b 123 POC system IFU manual.

# Accu-Chek® Inform II solution

*Safe for patients. Simple for professionals.*

*Efficient for hospitals.*

Roche offers a comprehensive solution for professional testing of blood glucose in hospitals. Blood glucose testing is an important standard of medical care in hospitals.

The Accu-Chek® Inform II system and the cobas infinity POC IT solutions together support Point of Care coordinators, physicians, nurses, IT experts and infection control managers to better manage their complex working tasks.



Accu-Chek Inform II system

## Your benefit



### Assured patient safety

- The Accu-Chek® Inform II solution brings laboratory safety standards to bedside glucose testing and ensures safety for patients and users



### Premium quality of results

- Enables POC testing to meet the highest lab standards when non-laboratory experts conduct glucose testing



### Automated re-certification

- Of device users and many other automated job tasks centralize the decentralized Point of Care traffic efficiently



### By your side support

- Is a given for continued success with your hospital blood glucose solution – provided by the market leader in hospital glucose testing

## Product characteristics



### Assured patient safety

- Infection control with an integrated product design of the meter, the strips and the lancets
- Improved clinical decision making with reports of actionable data per user needs



### Premium quality of results

- Lab standards met with lot-by-lot calibration and traceability to NIST
- High accuracy with proven repeatability and reproducibility, 190+ interferences tested



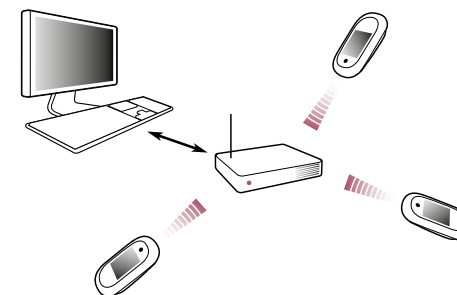
### Automated re-certification

- POC workflow automation with automated user re-certification and notifications
- Access and action of test results, operator performance, and system issues on the go



### By your side support

- More than 20 years of experience in service and support, with over 150,000 meter placements in the world and a broad expertise in system installation, analysis, consultancy and user training



# cobas h 232 POC system

## On-the-spot care & share



www.cobas.com



For Frontline Healthcare Providers, **cobas h 232** is a portable POC cardiac system that supports optimized treatment of patients with life-threatening symptoms because it enables confident and fast on-the-spot differential diagnosis based on evidence-based results, comparable with Roche Lab methods, that can be shared wirelessly for immediate feedback and response.

Thanks to its compact design, the **cobas h 232** POC system can easily be deployed near the POC patient where space is tight and mobile use is required, such as ambulances, general practitioners office, emergency room (ER), or a designated lab area.



Save time and optimize patient care with the **cobas h 232** POC system

### Your benefit

#### Fast and reliable patient stratification

- Flexible: Suitable for use in pre-hospital settings and ER for early triage of patients
- Quickly ready-to-use: Requires no sample preparation or lengthy setup procedures
- Confident: Accurate results, standardized with Roche central laboratory tests<sup>1,2,3,4,5</sup>

#### Safety

- Operator ID entry and lockout to ensure use by authorized staff
- Patient and user ID to ensure correct documentation of test results
- Quality control lockout

#### Control and traceability

- Enhanced connectivity through wireless technology and a unique QR code feature can result in fewer errors, increased safety and a streamlined workflow
- Connection to the **cobas**® POC IT solution allows extension of the testing network and ensures control of operators and quality assurance from the central laboratory
- Automatic recertification of operators through **cobas** academy to ensure use by trained operators only

### Available parameters

| Test       | Measuring range  | Time to results | Clinical utility                                                                                                                                                                                                     |
|------------|------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Troponin T | 40 – 2,000 ng/L  | 12 min.         | Identification of patients with suspected acute myocardial infarction at high risk of mortality <sup>4</sup>                                                                                                         |
| NT-proBNP  | 60 – 9,000 pg/mL | 12 min.         | Aid in diagnosis of patients with suspected heart failure, in monitoring of patients with compensated left ventricular dysfunction and in risk stratification of patients with acute coronary syndromes <sup>5</sup> |
| CK-MB      | 1.0 – 40 ng/mL   | 12 min.         | Diagnosis of acute coronary syndrome and myocardial infarction, assessment of re-infarction <sup>1</sup>                                                                                                             |
| D-Dimer    | 0.1 – 4.0 µg/mL  | 8 min.          | Exclusion of deep vein thrombosis and pulmonary embolism <sup>2</sup>                                                                                                                                                |
| Myoglobin  | 30 – 700 ng/mL   | 8 min.          | Early marker of myocardial damage to assist in diagnosis of acute coronary syndrome and myocardial infarction <sup>3</sup>                                                                                           |



Ambulance



GP office



Hospital

Save time!



**cobas h 232** POC tests

Standardized with Roche central laboratory tests

Sources:

- 1 Roche CARDIAC CK-MB-MethodSheet-package insert
- 2 Roche CARDIAC D-Dimer-MethodSheet-package insert
- 3 Roche CARDIAC M-MethodSheet-package insert
- 4 Roche CARDIAC POC Troponin T- MethodSheet-package insert
- 5 Roche CARDIAC proBNP +MethodSheet-package insert

# Roche CARDIAC® Trop T Sensitive test

## *Visual test for the rapid diagnosis of myocardial infarction*



www.cobas.com



Many patients seek medical attention only hours or even days after the onset of chest pain, especially on weekends. With the Roche CARDIAC Trop T Sensitive test you can make a diagnosis even several days (up to 10 – 14 days) after myocardial damage occurs.<sup>2</sup>

The Trop T Sensitive test is a visual troponin T test. Since it requires no system it can be easily deployed in rural areas near the point of patient care, at the bedside, in triage bays, emergency service areas, ambulances or a designated lab area. The Trop T Sensitive test is designed for qualitative determination of cardiac troponin T in the blood and elevated levels indicate acute myocardial infarction.<sup>2</sup>

Results from a large prospective clinical trial<sup>1</sup> in Denmark indicate that implementation of qualitative pre-hospital troponin T testing in the ambulance vehicle by paramedics is feasible in most patients, including non-ST segment elevation myocardial infarction (NSTEMI) patients whose condition is not detected by the classical electrocardiogram.

### Your benefit

#### Highly versatile

- Suitable for use in different clinical settings, e.g. emergency room, GP office or ambulance

#### Fast results

- Reliable yes/no result in 15 – 20 min.

#### Easy handling and portability

- Simple application that can be used anywhere
- No sample preparation
- Device independent

#### Reliable qualitative measurements

- Proven test strip technology

#### Cost-effective

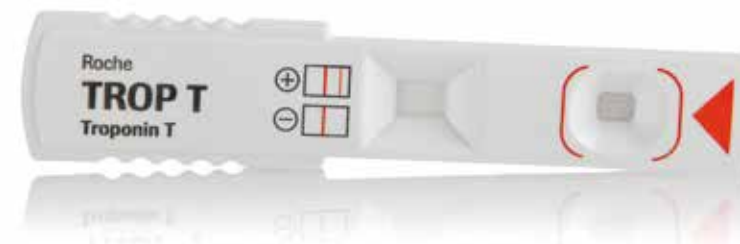
- Requires no external measurement system
- Requires no special training

#### On the spot rule-in acute myocardial infarction

- Specific cardiac marker – A positive result indicates myocardial damage
- Even if characteristic ECG changes are missing, a positive Roche CARDIAC Trop T Sensitive test with a non-ST-elevation myocardial infarction (NSTEMI) can aid the treatment decision<sup>2</sup>

### Product characteristics

- Qualitative detection of troponin in anticoagulated (EDTA or heparin) venous whole blood<sup>2</sup>
- Reaction time: 15 min.
- Positive result from a threshold (cut-off) of 100 ng/L
- Storage at 2 – 8° C (refrigerator)
- Test can be used immediately after removal from the refrigerator
- Storage for 1 week at room temperature (15 – 25° C)
- Roche CARDIAC Trop T Sensitive test is available in 5 and 10 pack sizes



1 Sørensen, J.T., Terkelsen, C.J., Steengaard, C.,... Prehospital troponin T testing in the diagnosis and triage of patients with suspected acute myocardial infarction. Am J Cardiol. 2011 May 15;107(10):1436-40.

2 TROP T Sensitive – Method Sheet – package insert

# CoaguChek® XS system

## Coagulation self-testing made easy



[www.CoaguChek.com](http://www.CoaguChek.com)



The CoaguChek® XS system is a convenient, portable and user-friendly instrument for monitoring warfarin therapy. It determines the INR value (International Normalized Ratio) from a drop of capillary whole blood – simple, precise and reliable.

The CoaguChek XS system is ready for use anywhere at any time. Patients can use it for self-monitoring at home or while on vacation.

### Your benefit

#### Fast, reliable results

- Accurate PT/INR results in one minute
- Built-in quality control checks every strip automatically
- Lab-comparable accuracy<sup>1</sup>

#### Simple fingerstick test

- Most patients prefer having a small drop of blood (just 8 µL) taken from a fingerstick to having blood drawn from a vein<sup>3</sup>

#### Improved patient outcomes

- Patients who self test have been shown to spend more time in therapeutic range and have less thromboembolic events<sup>2</sup>

### Product characteristics

- Detection system: Amperometric (electrochemical) determination of the PT time after activation of the coagulation with human recombinant thromboplastin
- User interface: Icon-based LCD display; on/off, mem and set buttons
- Measuring range:  
INR: 0.8 – 8.0  
%Quick: 120 – 5  
Seconds: 9.6 – 96



<sup>1</sup> Kitchen, D.P., Munroe, S., Kitchen, S., Jennings, I., Woods, T.A.L., Walker, I.D. (2008).

*British Journal of Haematology*, Volume 141 Supplement 1: P188.

<sup>2</sup> Heneghan, et. al (2006). *Lancet*, 367; 404-411.

<sup>3</sup> Heneghan, C., Alonso-Coello, P., Garcia-Alamino, J.M., Perera, R., Meats, E., Glasziou, P. (2016).

*Lancet*; 367; 404-11.

# CoaguChek® Pro II system

*Delivering life-saving information with immediately actionable coagulation results at ALL points of care*



[www.CoaguChek.com](http://www.CoaguChek.com)



CoaguChek® Pro II system is the clinically vital point-of-care coagulation testing device. In addition to monitoring warfarin therapy, the Prothrombin Time (PT) and activated Partial Prothrombin Time (aPTT) tests will help in the determination of factor deficiencies and other coagulopathies in several point-of-care locations.

The enhanced connectivity options allow for immediate access to patients' data via their electronic health records because wireless technology ensures fast, accurate transmission so that workflow will be more streamlined and results will be available for immediate treatment decisions.

Convenient, portable and user-friendly, the CoaguChek Pro II system delivers precise and reliable results from just a drop of blood.

## Your benefit

- Greater insight into patients' coagulation status with both aPTT and PT
- Enhanced connectivity for a streamlined workflow
- Easy implementation with minimal training



CoaguChek Pro II system

## Product characteristics

- Detection system: Electrochemical determination of the PT and aPTT time after activation of coagulation cascade
- User interface: large TFT color touch-screen; screen icons allow intuitive operation
- Memory capacity: 2,000 test results
- Integrated 2D barcode reader for entering user/patient ID and lot numbers of controls
- Enhanced data management capabilities: WLAN and unique QR Code connectivity option



**CoaguChek®**

# Accutrend® Plus system

## Screening for cardiovascular risk factors



www.cobas.com



The Accutrend Plus system is a flexible, hand-held point-of-care device for the key parameters used to detect cardiovascular disease:

- Total cholesterol
- Triglycerides
- Glucose and lactate

The meter is suitable for professional use as well as for self-testing (except for glucose self-testing).



Accutrend Plus system

### Your benefit

- A significant number of patients in primary care are dyslipidemic and therefore at higher risk of cardiovascular disease<sup>1</sup>
- In addition, many patients with lipid disorders are either treated insufficiently or not treated at all<sup>1</sup>
- Point of care lipid testing can substantially improve recognition as well as management of dyslipidemic patients in primary care<sup>1</sup>

### Safety and reassurance

- Built-in automatic performance testing and meter self-testing for reliable results

### Ease of use

- Simplicity makes device ideal for testing in the physician office or in hospital settings

### Product characteristics

- Convenient determination of cholesterol, triglycerides, glucose and lactate using capillary blood
- Positive control strip and parameter recognition are used for calibration
- Test strips can be stored at room temperature
- Can store up to 100 different measurements with date, time and flags
- Great precision and accuracy across the measuring range



| Test          | Measuring ranges |             | Measuring time | Sample material                                                      | Sample volumes | Operating conditions                                          |
|---------------|------------------|-------------|----------------|----------------------------------------------------------------------|----------------|---------------------------------------------------------------|
|               | mg/dL            | mmol/L      |                |                                                                      |                |                                                               |
| Glucose       | 20 – 600         | 1.1 – 33.3  | 12 sec         | • Fresh capillary blood                                              | 15 – 50 µL     | 18° – 35° C                                                   |
| Cholesterol   | 150 – 300        | 3.88 – 7.76 | 180 sec        | • Fresh capillary blood<br>• Use of heparin-coated pipettes possible | 15 – 40 µL     | 18° – 35° C                                                   |
| Triglycerides | 70 – 600         | 0.80 – 6.86 | max. 174 sec   | • Fresh capillary blood<br>• Use of heparin-coated pipettes possible | 10 – 40 µL     | 18° – 30° C                                                   |
| Lactate       | 0.8 – 22 mmol/L  |             | 60 sec         | • Fresh capillary blood<br>• Use of heparin-coated pipettes possible | 15 – 50 µL     | 5° – 35° or 15° – 35° C depending on concentration of analyte |

<sup>1</sup> Taylor, J.R. and Lopez, A.M. (2004), Cholesterol: pointofcare testing. *Ann Pharmacother* 38: 1252-1257.

# Reflotron® Plus system and Reflotron® Sprint systems

*Flexible testing to support your clinical decisions*

The Reflotron Plus system is a single-test clinical chemistry system which allows the measurement of 17 parameters from whole blood, plasma or serum – including liver and pancreas enzymes, metabolites, blood lipids, hemoglobin and potassium.

Immediate and reliable test results ensure quick performance and verification of the diagnosis without delay.

The system is suitable for primary care settings, as a back-up system in hospitals and private labs, at screening sites and for health check-ups.



Reflotron Plus system

## Your benefit

### Reliability

- No storage concerns due to excellent test strip stability
- Little waste and almost no maintenance

### Faster clinical decision making

- Quick time to result
- No reagent preparation



Reflotron Sprint system



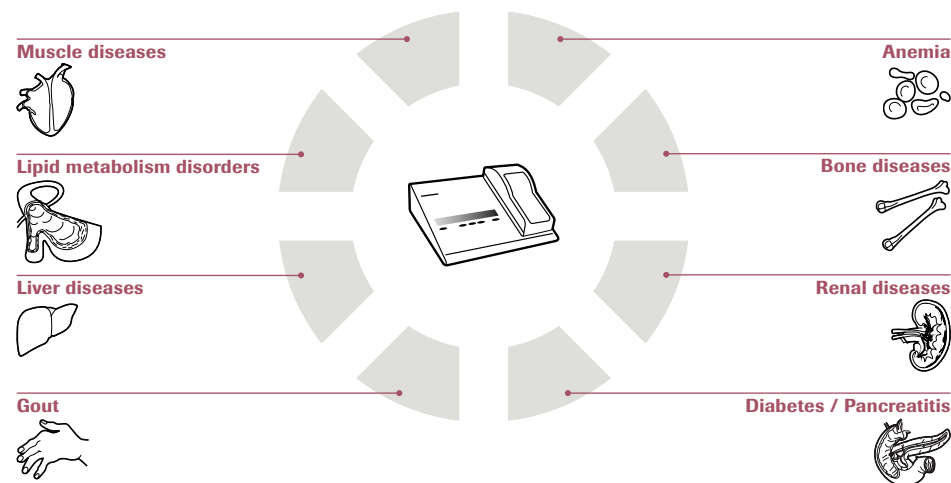
[www.cobas.com](http://www.cobas.com)



## Product characteristics

- Throughput of Reflotron® Sprint: Up to approx. 60 tests/hour
- Throughput of Reflotron Plus: Up to approx. 25 tests/hour
- Sample material: whole blood (capillary and venous) plasma or serum
- Sample volume: 30 µL
- Time-to-result: only 2 – 3 min. (depends on parameter)
- Integrated printer: Immediate documentation of results
- Barcode reader and/or keyboard for patient and sample ID input

## Covering a wide range of daily routine and emergency testing



# cobas b 101 system

## Managing diabetes and dyslipidemia at the point of “need”



www.cobas.com



The **cobas b 101** system is an IVD test system offering HbA1c and a complete lipid profile tests at the Point of Care. Fresh capillary blood, K<sub>2</sub> or K<sub>3</sub>-EDTA venous whole blood or plasma\* can be used.

The system delivers fast and reliable results and is intended for professional use in a clinical laboratory setting or at point-of-care locations.



cobas b 101 system

### Your benefit

#### Guideline compliant performance

- **cobas b 101** system complies with all relevant standards and methods (IFCC, DCCT/NGSP and NCEP)<sup>1</sup>

#### Easy and safe operation

- Direct blood application from a single finger stick with small volume
- No calibration needed, maintenance and service-free, graphical guidance for simplified use

#### Fast turnaround time

- An intuitive 15 min. workflow from patient preparation to results display of both HbA1c and lipid panel

IFCC: International Federation of Clinical Chemistry  
DCCT: Diabetes Control and Complications Trial  
NCEP: National Cholesterol Education Program  
NGSP: National Glycohemoglobin Standardization Program

\*Plasma for lipid panel only.

\*\*Calculated

1 Roche internal verification data (multi-center evaluation).

### Product characteristics

- User-friendly with a large touchscreen, full keyboard, and multiple languages support
- Robust, maintenance- and calibration-free with a wide operating temperature and humidity range
- Connection to the **cobas** POC IT solution
- External printer or barcode scanner allow an improved workflow and documentation
- Data download to USB stick or direct to PC are possible

### Disc features

- Direct sample application (no capillaries, tubes or pipettes are needed) and requires only very small sample volumes (2 µL for HbA1c, 19 µL for lipids)
- Discs are color-coded and clearly labelled to support correct use. Flap for high operator safety
- Discs can be stored for more than 13 months from production at room temperature (2 – 30°C)<sup>1,2</sup>



### Parameters and measuring range in the therapeutically important range

- HbA1c disc:
  - IFCC: 20 – 130 mmol/mol
  - NGSP: 4 – 14 %
  - eAG\*\*
- Lipid disc:
  - CHOL: 50 – 500 mg/dL
  - TG: 45 – 650 mg/dL
  - HDL: 15 – 100 mg/dL
  - LDL, Non-HDL and TC/HDL\*\*

1 cobas HbA1c Test – MethodSheet – package insert

2 cobas Lipid Panel – MethodSheet – package insert

# CoaguChek® INRange system

*Discover the freedom of monitoring on your own terms*

CoaguChek INRange is the new connected self-testing meter that gives you the freedom to test your PT/INR at home, on the go or wherever you happen to be.

Its Bluetooth® technology allows you to wirelessly transmit PT/INR results to your healthcare provider, so your doctor can help you stay in therapeutic range.

By engaging in your own therapy through self-monitoring, you can spend more time in your therapeutic range (TTR)<sup>1</sup> and less time in the clinic<sup>1,2</sup>. The CoaguChek INRange system makes self-monitoring and reporting easy.



CoaguChek INRange

## Your Benefits

### Control

- Increase time in therapeutic range (TTR) and less time waiting for appointments

### Convenience

- It is easy to use and takes just a small drop of blood for virtually pain-free testing

### Fast

- Results in less than a minute. You'll know if you're in range and on track



## Product Characteristics

- Detection system: amperometric (electrochemical) determination of the PT time after activation of the coagulation with human recombinant thromboplastin
- User interface: intuitive user interface with color display, on/off, enter, back and up/down button
- Interface: USB (Type B) and Bluetooth
- Measuring range INR: 0.8 – 8.0
- Size: 145 × 75 × 30 mm
- Weight: 135 g (without batteries)
- Memory: 400 Test Results
- Sample type: fresh capillary whole blood
- Sample size: 8 µL



1 Heneghan, C., Ward, A., Perera, R., et al. (2012). Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. *Lancet* 379: 322-334.

2 Sharma, P., Scotland, G., Cruickshank, M., Tassie, E., Fraser, C., et al (2015). Is self-monitoring an effective option for people receiving long-term vitamin K antagonist therapy? A systematic review and economic evaluation. *BMJ Open* 5: e007758.



**VENTANA**

*Innovative diagnostic instruments*

**High-value assays**

*Digital pathology and workflow*

**Companion diagnostics**

*Consultative services*

## Tissue diagnostics

Roche Tissue Diagnostics, is one of the world's leading cancer diagnostic companies and is an innovator of tissue-based tests that enable the delivery of Personalized Healthcare to cancer patients.

The company known as Ventana Medical Systems, Inc., founded by Thomas Grogan, M.D., Professor of Pathology, University of Arizona, established the concept of a single, complete report covering all aspects of a patient's case, which helps to improve survivability.

Roche Tissue Diagnostics is passionate about its mission to improve the lives of all patients afflicted with cancer by developing and delivering medical diagnostic systems and tissue-based cancer tests that are shaping the future of healthcare. VENTANA products provide healthcare professionals with a comprehensive solution for the critical steps involved in the analysis of tissue samples.

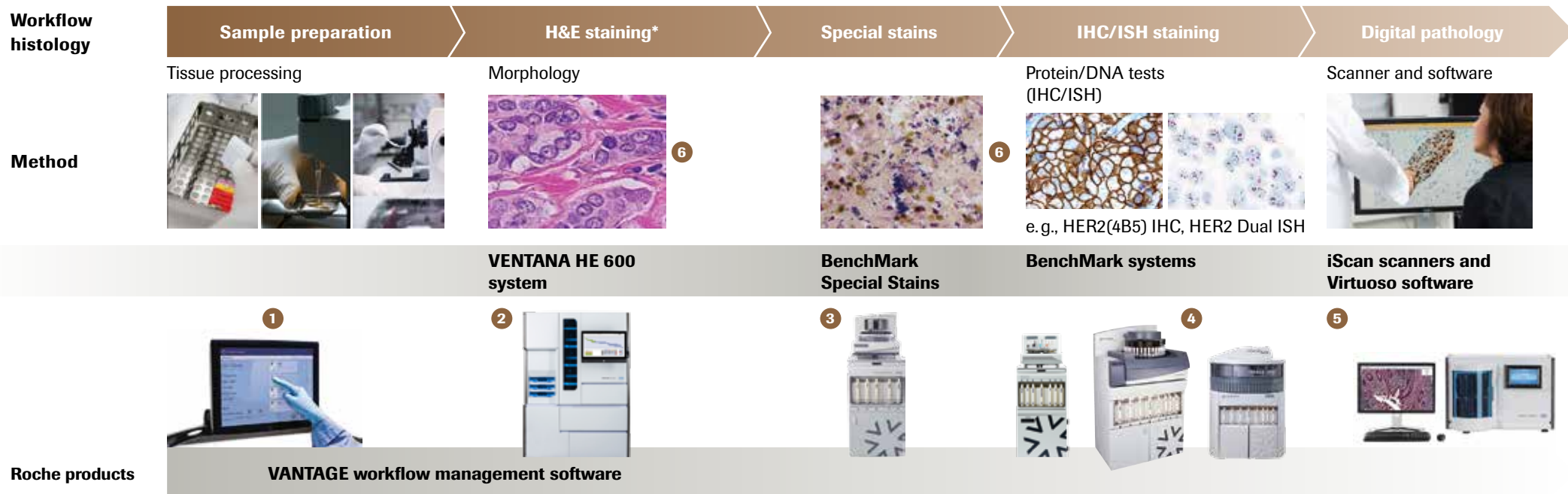
In addition, Roche Tissue Diagnostics offers premier workflow solutions specially designed to improve laboratory efficiency and protect patient safety.

Recognizing the world's increasing medical needs, Roche Tissue Diagnostics focuses on accelerating the discovery and development of new prognostic and predictive cancer tests that help enable Personalized Healthcare. These tests allow pathologists to analyze patient samples at the molecular, cellular and tissue level to help determine the best course of therapy for individual patients.

**For more information please  
visit [www.ventana.com](http://www.ventana.com)**

# Tissue diagnostics

## Leading future innovation



### 1 VANTAGE software

- Workflow solution from sample preparation to statistics monitoring
- Tracking of both samples and monitoring of the lab activity to help ensure quality
- Workflow consulting to optimise processes

### 2 VENTANA HE 600 system

- Individual slide staining technology for H&E
- Fully automated H&E staining from drying to glass coverslipping
- Elimination of xylene and alcohol from the H&E process

### 3 BenchMark Special Stains instrument

- Fully automated special stains from baking to staining
- Capacity up to 20 slides per run
- Individual heater pads
- Complete ready-to-use reagent kits

### 4 VENTANA BenchMark IHC/ISH systems

- Fully automated IHC\* and ISH\* systems, driven by easy-to-use barcoded slides and reagents and ISH systems with individ-

- ually controlled slide heater pads for maximum protocol flexibility
- Systems with different capacity available to fit small to large laboratories
- Open systems for antibodies
- Broad portfolio of 250+ ready-to-use assays

### 5 Digital pathology

- Comprehensive digital pathology solution – from scanning and image viewing to customized reporting
- VENTANA iScan HT and iScan Coreo scanners – combine unprecedented flexibility, throughput and reliability

- VIRTUOSO image and workflow management software – designed for clinical laboratory use
- Industry-leading Companion Algorithm image analysis solution delivers consistent and objective results, time after time

### 6 Reagents

- H&E, IHC\*, ISH\*, SpSt\*
- More than 250 antibodies
- Ready-to-use and barcoded reagents

\* H&E = Hematoxylin and Eosin, ISH = In situ Hybridisation, IHC = Immunohistochemistry, SpSt = Special stains

# VENTANA HE 600 system

## *Master the art and science of H&E staining*

Histology laboratories face a critical challenge – even in today's high-tech world. H&E slide preparation continues to be a laborious and time consuming process. The VENTANA HE 600 system is the newest innovation from Roche Tissue Diagnostics that enables high levels of efficiency, stain quality, and improved safety, all while providing unprecedented flexibility in the pathology laboratory – creating better results for you, your laboratory and your patients.



VENTANA HE 600 system

### Your benefit

#### Create seamless workflow and efficiency

- Provides optimal efficiency by reducing touch points and wait points in the H&E process by consolidating ovens, stainers, and coverslipping into a single system
- Frees technicians to focus on value added activities

#### Make every patients slide a masterpiece

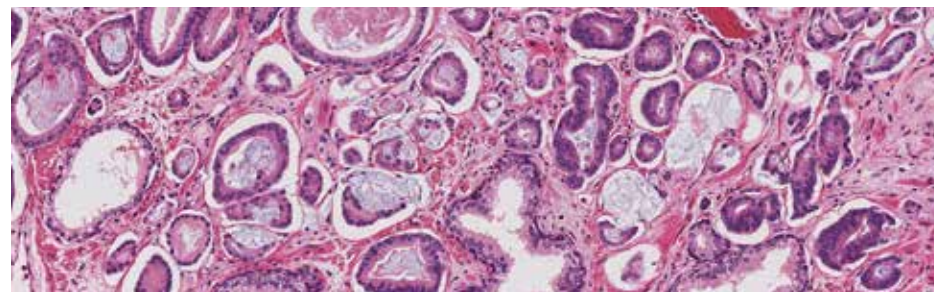
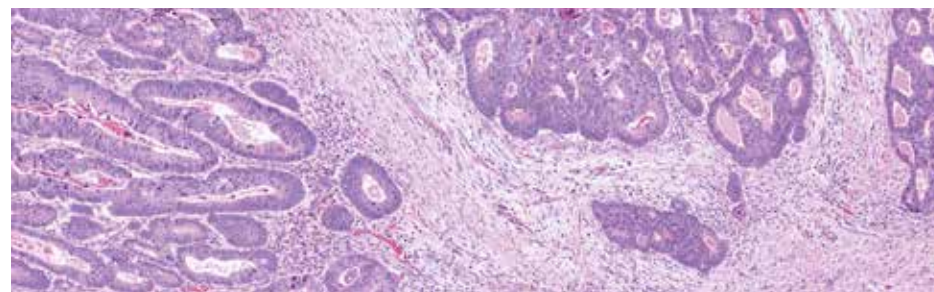
- Individual slide staining provides high levels of stain consistency and reproducibly to ensure your first slide of the day has the same level of quality as your last
- Ready-to-use reagents that are certified and tested for quality to provide consistent, high-quality stains

#### Improved patient and technologist safety

- Individual slide staining with fresh reagents on every slide mitigates tissue cross-contamination and reagent carryover in the H&E process
- Eliminates xylene and alcohol for the H&E process

### Product characteristics

- Throughput: 180 – 200 slides per hour at mid stain protocols
- System integration from drying through glass coverslipping
- Easily customizable staining protocols for unmatched staining flexibility
- Enables over 400 customized protocols to optimize staining
- Barcode tracking provides full chain of custody
- LIS connectivity through the VENTANA workflow solutions
- CareGiver remote support is an automated remote monitoring and diagnostics solution that enables continuous monitoring and remote service for VENTANA HE 600 system



# BenchMark Special Stains

## *Automated slide stainer*

The VENTANA BenchMark Special Stains automated slide stainer brings complete baking through staining to the histology laboratory for special stains, so your lab can consistently deliver exceptional quality. Productivity features such as random batch access, as well as full process integration, including deparaffinization through staining, improves turnaround time and optimizes workflow.

Reduce manual processes and improve your capabilities by allocating your skilled laboratory professionals to higher value contributions.



*BenchMark Special Stains*

### Your benefit

#### Excellent special stains workflow efficiency

- Eliminates manual processes and temperature dependencies with automated deparaffinization and independent slide heating

#### Consistent quality

- Enhanced protocol flexibility with expanded user selectable options in order to meet pathologists' preferences
- Individual slide staining using quality-controlled, ready to use reagents delivers consistent, high quality results

### Reduced risk

- Individual slide staining mitigates risk for cross contamination
- Ready to use reagents reduces technician risk by limiting exposure to harmful chemicals

### Product features/specifications

- Workflow: Fully automated baking, deparaffinization and staining of special stains
- Slide carousel: 1–20 slides with independent temperature control for each position
- Reagent carousel: 25 reagent positions
- Slides: 25 x 75 mm, 1 x 3" or 26 x 76 mm positively charged
- Bulk fluids: Up to 4 bulk fluids in 3 to 6 liter on-board containers

### Special Stains reagents

The BenchMark Special Stains system brings reproducible, high quality staining capabilities by providing ready-to-use, quality controlled reagents.



### Special Stains menu:

- |                       |                       |
|-----------------------|-----------------------|
| • AFB III             | • Iron                |
| • Alcian Blue         | • Jones Light Green   |
| • Alcian Blue for PAS | • Jones Hematoxylin   |
| • Alcian Yellow       | • Light Green for PAS |
| • Congo Red           | • Mucicarmine         |
| • Diastase            | • PAS                 |
| • Elastic             | • Reticulum II        |
| • Giemsa              | • Steiner II          |
| • GMS II              | • Trichrome Blue      |
| • Gram                | • Green for Trichrome |

# VENTANA BenchMark systems

## *Fully-automated IHC/ISH slide staining systems*

Achieve high quality assays that are both consistent and reproducible, improve laboratory workflow and testing efficiency, and access companion and complementary diagnostics with VENTANA BenchMark systems.

The VENTANA BenchMark GX, BenchMark XT and BenchMark ULTRA systems ... These systems offer the flexibility to run any assay side-by-side, broaden your test menu with 250+ ready-to-use assays, and improve overall laboratory efficiency.

### Your benefit

#### Fully automated

- Standardised IHC and ISH staining
- Improve quality, workflow and testing efficiency

#### Flexibility

- Individually controlled slide heater pads enable users to run any assay side-by-side
- Customize time and temperature protocols for each individual slide position

#### Optimal quality

- Individual slide heaters, liquid coverslip and air vortex mixers provide an optimal puddle staining environment
- Sensitive detection chemistries and a broad portfolio of ready-to-use assays

### Workflow

- Optimize throughput capacity with single piece workflow
- Increase laboratory productivity and reduce re-run rates

### BenchMark system features

Unique and innovative technologies designed to deliver diagnostic confidence

- Individual slide drawers of BenchMark ULTRA
- Protocol flexibility via individually controlled slide heater pads
- Unique Slide ID and LIS compatibility with Ventana System Software 12.5

#### BenchMark GX system

- 20 slide positions
- 25 reagent positions
- Low to medium throughput
- Small footprint, proven automation

#### BenchMark XT system

- 30 slide positions
- 35 reagent positions
- Medium to high throughput
- Proven automation with enhanced protocol flexibility



#### BenchMark ULTRA system

- 30 slide positions
- Ability to add or remove bulk reagents and waste without interrupting cases in process
- 35 reagent positions
- Continuous and random slide processing to optimize laboratory workflow

#### LIS or VANTAGE software connection

- Connect multiple systems with a single computer or add a new system to existing ones
- Share reagents and protocols across instruments through Central Management software
- Download patient accession and test information from LIS to slide staining system to mitigate data entry errors



BenchMark GX system



BenchMark XT system



BenchMark ULTRA system

# IHC and ISH detection

*Meet your needs, and then go beyond*



## Performance-drive reagents

Roche Tissue Diagnostics offers a comprehensive menu of ready-to-use detection reagents optimized for use on the fully automated VENTANA BenchMark IHC/ISH slide staining systems.

Our innovative and robust detection chemistries will help you achieve consistent, high-quality results in all your IHC and ISH applications.

### IHC detection offerings

- iVIEW DAB Detection Kit
- ultraView Universal DAB Detection Kit
- ultraView Universal Alkaline Phosphatase Red Detection Kit
- OptiView DAB IHC Detection Kit

### ISH detection offerings

- ISH iVIEW Blue Detection Kit (Ex-US)
- ISH iVIEW Blue Plus Detection Kit
- ultraView SISH Detection Kit
- ultraView SISH DNP Detection Kit
- ultraView Red ISH DIG Detection Kit

## Innovative technology

### Multimer molecules

Our biotin-free ultraView detection kits use multimer molecules for IHC and ISH signal amplification.

Multimers are proprietary antibodies directly conjugated to multiple Horseradish Peroxidase (HRP) or Alkaline Phosphatase enzymes.

These small molecules minimize steric hindrance and easily penetrate tissue, increasing the sensitivity and specificity of detection reactions.

### Synthetic Haptens

Our most recent addition to the detection portfolio – OptiView DAB IHC – contains secondary antibodies conjugated to numerous copies of a synthetic, non-endogenous HQ hapten.

HRP multimers will then recognize the HQ haptens and exponentially multiply the number of signaling molecules, enabling exceptional levels of staining intensity without increase in background.

## Featured Detection Chemistries

### ultraView Universal DAB Detection

ultraView DAB produces consistent, high-quality staining results over an extensive selection of markers and tissue types with minimal optimization.

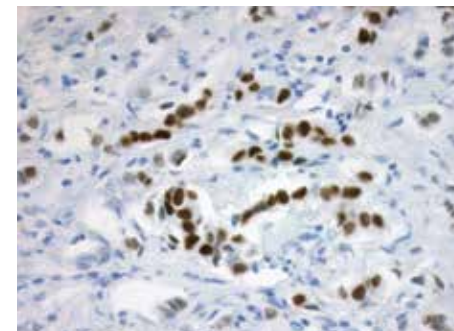
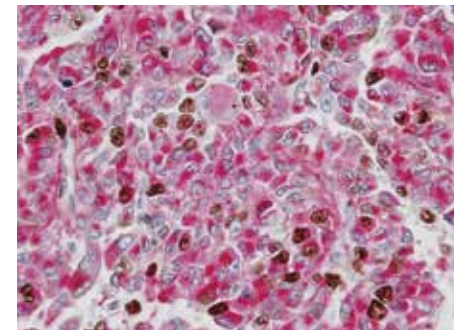
This detection chemistry is ideal for your everyday IHC needs.

### OptiView DAB IHC Detection

In addition to biotin-free multimer technology, OptiView DAB introduces synthetic HQ haptens that provide unprecedented levels of staining intensity and specificity.

OptiView software further enables users to customize pre-treatment options, control incubation times and optimize temperatures for different reaction steps.

This detection chemistry was designed to help you detect low-expressing and/or sensitive IHC markers requiring very specific staining conditions.



# Primary antibodies

Over 250 ready-to-use clinical reagents, optimized for use on VENTANA BenchMark staining platforms



## Ready-to-use antibodies

Roche Tissue Diagnostics antibodies, including a world-class breast panel, cover the pathology world’s diagnostic requests. Roche Tissue Diagnostics antibodies include IVD/CE-IVD antibodies, as well as novel antibodies still in the research phase. Staining analysis is facilitated by advanced antibody performance and multiple detection technologies.

| Breast                                         | Cervical                                                                     |
|------------------------------------------------|------------------------------------------------------------------------------|
| Actin, Smooth Muscle (1A4)                     | CINtec® PLUS Cytology p16/Ki-67 dual stain (Cytology) (E6H4™ and 274-11 AC3) |
| Beta-catenin (14)                              |                                                                              |
| Calponin-1 (EP798Y)                            | CINtec® Histology (E6H4)                                                     |
| Cytokeratin 14 (SP53)                          |                                                                              |
| Cytokeratin 5/6 (D5/16B4)                      | <b>Colorectal and Gastrointestinal</b>                                       |
| E-cadherin (36), CONFIRM                       | Beta-catenin (14)                                                            |
| E-cadherin (EP700Y)                            | BRAF-V600E (VE1)                                                             |
| Estrogen Receptor (ER) (SP1), CONFIRM          | c-KIT (9.7), PATHWAY                                                         |
|                                                | Cadherin 17 (SP183)                                                          |
| FoxA1 (2F-83)                                  | CEA (TF3H8-1)                                                                |
| GATA3 (L50-823)                                | CEA (CEA31)                                                                  |
| GCDPF-15 (EP1582Y)                             | CDX-2 (EPR2764Y)                                                             |
| HER2 Dual ISH DNA Probe Cocktail assay, INFORM | COX-2 (SP21)                                                                 |
| HER-2/neu (4B5), PATHWAY                       | Cytokeratin 7 (SP52), CONFIRM                                                |
| HER-2/neu (4B5), VENTANA                       | Cytokeratin 19 (A53-B/A2.26)                                                 |
| IGF-1R (G11)                                   | Cytokeratin 20 (SP33), CONFIRM                                               |
| Ki-67 (30-9), CONFIRM                          | DOG1 (SP31)                                                                  |
| p120 (98)                                      | Glutamine Synthetase (GS-6)                                                  |
| p53 (DO-7), CONFIRM                            | Helicobacter pylori (SP48), VENTANA                                          |
| p63 (4A4)                                      | MLH-1 (M1)                                                                   |
| Progesterone Receptor (PR) (1E2),CONFIRM       | MSH2 (G219-1129)                                                             |
|                                                | MSH6 (44), CONFIRM                                                           |
|                                                | MUC1 (H23)                                                                   |
| TAG-72 (B72.3)                                 | MUC2 (MRQ-18)                                                                |
| Topoisomerase IIa (JS5B4), CONFIRM             | PMS2 (EPR3947)                                                               |

| Dermatopathology                                 |
|--------------------------------------------------|
| Albumin, FITC                                    |
| a-1-Antichymotrypsin (ACT)                       |
| a-1-Antitrypsin (AAT)                            |
| CEA (CEA31)                                      |
| Carcinoembryonic Antigen (CEA) (TF3H8-1)         |
| CD2 (MRQ-11)                                     |
| CD3 (2GV6), CONFIRM                              |
| CD31 (JC70)                                      |
| CD34 (QBEnd/10), CONFIRM                         |
| CD63 (NK1/C3)                                    |
| Cytokeratin (34bE12), CONFIRM                    |
| Cytokeratin (AE1), CONFIRM                       |
| Cytokeratin 8 and 18 (B22.1 and B23.1), CONFIRM  |
| Desmin (DE-R-11), CONFIRM                        |
| EMA (Epithelial Membrane Antigen) (E29), CONFIRM |
| Ep-CAM (Epithelial Specific Antigen) (Ber-EP4)   |
| Factor VIII Related Antigen                      |
| Factor XIIIa (AC-1A1)                            |
| Factor XIIIa (EP3372)                            |
| C1q, FITC                                        |
| C3, FITC                                         |

|                                              |
|----------------------------------------------|
| C4, FITC                                     |
| Fibrinogen, FITC                             |
| Kappa, FITC                                  |
| Lambda, FITC                                 |
| HHV-8 (Human Herpes Virus Type 8) (13B10)    |
| IgA (Immunoglobulin A)                       |
| IgA (Immunoglobulin A), FITC                 |
| IgG (Immunoglobulin G)                       |
| IgG (Immunoglobulin G), FITC                 |
| IgM (Immunoglobulin M)                       |
| IgM (Immunoglobulin M), FITC                 |
| Macrophage (HAM-56)                          |
| MART-1/melan A (A103), CONFIRM               |
| Melanoma Associated Antigen (KBA.62)         |
| Melanoma Associated Antigen (PNL2)           |
| Melanoma Triple Cocktail (A103, HMB45, T311) |
| Melanosome (HMB45), CONFIRM                  |
| MITF (C5/D5), CONFIRM                        |
| Neurofilament (2F11)                         |
| p53 (DO-7), CONFIRM                          |
| p53 (Bp53-11)                                |
| Podoplanin (D2-40)                           |
| S100 (4C4.9), CONFIRM                        |
| S100 (Polyclonal), CONFIRM                   |
| SOX-10 (SP267)                               |
| Synaptophysin (MRQ-40)                       |
| Synaptophysin (SP11), CONFIRM                |
| Tryptase (G3)                                |
| Tyrosinase (T311), CONFIRM                   |
| Vimentin (V9), CONFIRM                       |
| Vimentin (Vim 3B4), CONFIRM                  |

| Hematopathology              |
|------------------------------|
| ALK1 (ALK01), CONFIRM        |
| Annexin A1 (MRQ-3)           |
| bcl-2 (SP66)                 |
| bcl-2 (124), CONFIRM         |
| bcl-6 (GI191E/A8)            |
| BOB.1 (SP92)                 |
| c-Myc (Y69)                  |
| CD1a (EP3622)                |
| CD2 (MRQ-11)                 |
| CD3 (2GV6), CONFIRM          |
| CD4 (SP35), CONFIRM          |
| CD5 (SP19), CONFIRM          |
| CD7 (SP94)                   |
| CD8 (SP57)                   |
| CD10 (SP67), VENTANA         |
| CD13 (SP187)                 |
| CD14 (EPR3653)               |
| CD15 (MMA), CONFIRM          |
| CD16 (SP175)                 |
| CD20 (L26), CONFIRM          |
| CD22 (SP104)                 |
| CD23 (SP23), CONFIRM         |
| CD25 (4C9)                   |
| CD30 (Ber-H2)                |
| CD31 (JC70)                  |
| CD34 (QBEnd/10), CONFIRM     |
| CD38 (SP149)                 |
| CD43 (L60)                   |
| CD45 (LCA) (2B11 and PD7/26) |
| CD45 (LCA) (RP2/18), CONFIRM |
| CD45R (MB1)                  |
| CD45RO (UCHL-1), CONFIRM     |
| CD56 (123C3), CONFIRM        |
| CD56 (MRQ-42)                |

|                            |
|----------------------------|
| CD57 (NK-1)                |
| CD61 (2f2)                 |
| CD68 (KP-1), CONFIRM       |
| CD71 (MRQ-48)              |
| CD79a (SP18), CONFIRM      |
| CD99 (O13), CONFIRM        |
| CD138 (Syndecan-1) (B-A38) |
| Cyclin D1 (SP4-R)          |
| Fascin (55k-2)             |
| FoxP1 (SP133)              |
| Galectin-3 (9C4)           |
| Glycophorin A (GA-R2)      |
| Granzyme B                 |
| Hemoglobin A (SP212)       |
| HGAL (MRQ-49)              |
| IgA (Immunoglobulin A)     |
| IgD (Immunoglobulin D)     |
| IgG (Immunoglobulin G)     |
| IgM (Immunoglobulin M)     |
| Kappa, CONFIRM             |
| Lambda, CONFIRM            |
| LMO2 (1A9-1), CONFIRM      |
| LMO2 (SP51)                |
| Lysozyme                   |
| MUM1 (MRQ-43)              |
| Myeloperoxidase            |
| Oct-2 (MRQ-2)              |
| PAX5 (SP34), CONFIRM       |
| PD-1 (NAT-105)             |
| SOX-11 (MRQ-58)            |
| Spectrin (RBC2/3D5)        |
| T-bet (MRQ-46)             |
| TdT                        |
| TRAcP (9C5)                |
| ZAP-70 (2F3.2)             |

# Breast cancer diagnostics

## Empowering clinical confidence



### Lung

|                                                        |
|--------------------------------------------------------|
| ALK (D5F3), VENTANA                                    |
| c-MET Total (SP44), CONFIRM                            |
| Calretinin (SP65), CONFIRM                             |
| Carcinoembryonic Antigen (CEA) (TF3H8-1)               |
| Caveolin-1 (SP43)                                      |
| CD56 (123C3), CONFIRM                                  |
| CD56 (MRQ-42)                                          |
| CEA (CEA31)                                            |
| Chromogranin A (LK2H10)                                |
| Cytokeratin (CAM 5.2)                                  |
| Cytokeratin 5 (SP27)                                   |
| Cytokeratin 5/6 (D5/16B4)                              |
| Cytokeratin 5/14 (EP1601Y/LL002)                       |
| Cytokeratin 7 (SP52), CONFIRM                          |
| Cytokeratin 17 (SP95)                                  |
| Cytokeratin 20 (SP33), CONFIRM                         |
| E-cadherin (36), VENTANA                               |
| E-cadherin (EP700Y)                                    |
| EGFR E746-A750 del (SP111)                             |
| EGFR (Epidermal Growth Factor Receptor) (5B7), CONFIRM |
| EGFR (Epidermal Growth Factor Receptor) (3C6), CONFIRM |
| EGFR L858R (SP125)                                     |

|                                                   |
|---------------------------------------------------|
| EMA (Epithelial Membrane Antigen) (E29), CONFIRM  |
| Epithelial-Related Antigen (MOC-31)               |
| Epithelial-Specific Antigen/Ep-CAM (Ber-EP4)      |
| IGF-1R(G11), CONFIRM                              |
| Mesothelial Cell HBME-1 (HBME-1)                  |
| MUC1 (H23)                                        |
| Napsin A (MRQ-60)                                 |
| NSE (MRQ-55)                                      |
| p40 (BC28)                                        |
| p63 (4A4), VENTANA                                |
| Pan Keratin (AE1/AE3/PCK26) Primary Antibody      |
| PD-L1 (SP142) Assay, VENTANA                      |
| PD-L1 (SP263), VENTANA                            |
| SOX-2 (SP76)                                      |
| Synaptophysin (MRQ-40)                            |
| Synaptophysin (SP11), CONFIRM                     |
| TAG-72 (B72.3)                                    |
| Thyroid Transcription Factor-1 (8G7G3/1), CONFIRM |
| Thyroid Transcription Factor-1 (SP141)            |
| WT1 (6F-H2)                                       |
| Desmoglein 3 (5G11)                               |

### Prostate

|                                           |
|-------------------------------------------|
| Androgen Receptor (SP107)                 |
| Basal Cell Cocktail (34&E12+p63), VENTANA |
| Cytokeratin 5/6 (D5/16B4)                 |
| Cytokeratin 7 (SP52), CONFIRM             |
| Cytokeratin 20 (SP33), CONFIRM            |
| ERG (EPR3864)                             |
| EZH2 (SP129)                              |
| p63 (4A4), VENTANA                        |
| PSA, CONFIRM                              |
| PSA (ER-PR8)                              |
| PSAP (PASE/4LJ)                           |
| NKX3.1 (EP356)                            |
| <b>OTHER</b>                              |
| Olig2 (EP112)                             |
| PD-L1 (SP142) Assay, VENTANA              |

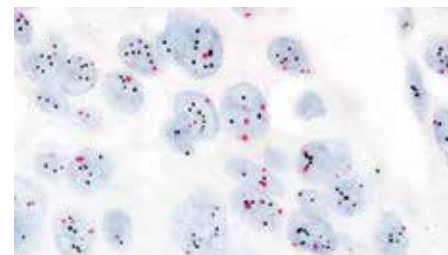
Roche Tissue Diagnostics delivers a comprehensive suite of validated immunohistochemistry and *in situ* hybridisation diagnostic solutions for breast cancer – so you can deliver the right test, with clinical confidence.

Our breast cancer predictive diagnostic offerings (HER2 IHC and ISH, ER, PR) in combination with our supporting diagnostic assays (Ki-67, p120 and E-cadherin) are fully automated on VENTANA BenchMark systems, which reduces the time to result and resources required compared to manual or semiautomated solutions.

### Your benefit

#### Clinical confidence

- High accuracy and clinical confidence in a short turnaround time to identify patients other assays can miss



Breast carcinoma INFORM HER2 Dual ISH DNA Probe Cocktail non-amplified; magnification: 40X.

#### Analytical superiority

- Specific and sensitive rabbit monoclonal antibodies, probes and powerful detection systems

#### Testing efficiency

- Comprehensive breast cancer solution
- Fully automated assays, with digital pathology and workflow solutions

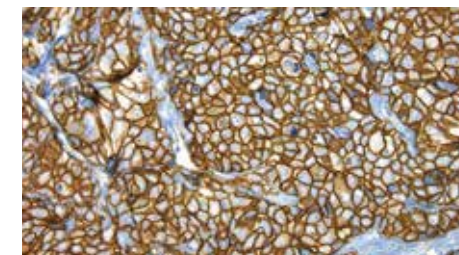
### Product characteristics

#### INFORM HER2 Dual ISH DNA Probe Cocktail assay

- Brightfield detection allows evaluation of HER2 gene status with morphological context

#### HER2 (4B5) Rabbit Monoclonal Antibody

- Clinical confidence with a world-class HER2 rabbit monoclonal antibody



Breast carcinoma HER2 (4B5) positive Score: 3+; magnification: 40X.

# Cervical disease diagnostics

The Roche cervical cancer portfolio provides the focus needed to make decisions for each patient with confidence and conclusiveness. Roche has three clinically validated tests when used in powerful combination help identify women at risk and improve detection and confirmation of high-grade disease in the first round of screening.

The Roche cervical cancer portfolio includes three clinically validated tests:

- 1) The **cobas**<sup>®</sup> HPV Test is the screening test to determine the presence of high-risk HPV.
- 2) The CINtec<sup>®</sup> **PLUS** Cytology test is the triage test. It is used to triage primary screening results from Pap cytology and/or HPV test results. It is the test that uses dual-biomarker technology to simultaneously detect p16 and Ki-67 to provide a strong indicator of the presence of transforming HPV infection.
- 3) The CINtec<sup>®</sup> Histology test is used for diagnostic confirmation of the presence or absence of high-grade cervical disease.

The CINtec<sup>®</sup> family of products, exclusively from Roche, utilise biomarker technology to identify cells which have undergone high-risk HPV-mediated oncogenic transformation and identify women at high risk of developing high-grade cervical disease.

The overexpression of p16 (a cyclin-dependent kinase inhibitor) in cervical specimens, detected by CINtec<sup>®</sup> products, is highly correlated with oncogenic transformation caused by persistent high-risk HPV (hrHPV) infections.

**CINtec<sup>®</sup> PLUS Cytology\*** – unique to Roche, is the only test, that detects the simultaneous overexpression of p16 and Ki-67 within the same cervical epithelial cell, indicating the likely presence of a transforming HPV infection.<sup>1,2,3</sup>

The CINtec<sup>®</sup> **PLUS** Cytology test identifies cervical cells where HPV has disrupted cellular control (p16/Ki-67 positive), confirming the presence of a transforming HPV infection, accurately predicting which women are most likely to have pre-cancerous cervical lesions and therefore would benefit from immediate colposcopy.

CINtec<sup>®</sup> **PLUS** Cytology test can be used to efficiently triage

- Positive HPV primary screening results<sup>1,2</sup>
- ASC-US cytology results<sup>3</sup>
- LSIL cytology results<sup>3</sup>
- Negative cytology (NILM) in the presence of HPV infection<sup>4</sup>

**CINtec<sup>®</sup> Histology** – is the IVD p16 immunohistochemistry (IHC) test to identify overexpression of p16 in cervical biopsies.

The CINtec<sup>®</sup> Histology test significantly increases accuracy in diagnosing ≥CIN2 lesions when used in conjunction with H&E, identifying the most appropriate patients for treatment and intervention.<sup>5</sup>

Over 100 peer-reviewed publications, medical society recommendations<sup>6,7</sup>, a major Pan-European clinical study<sup>5</sup>, and the largest U.S. immunohistochemistry registrational trial<sup>8</sup> support the scientific and medical value of CINtec<sup>®</sup> Histology for use in evaluation of cervical biopsy specimens.

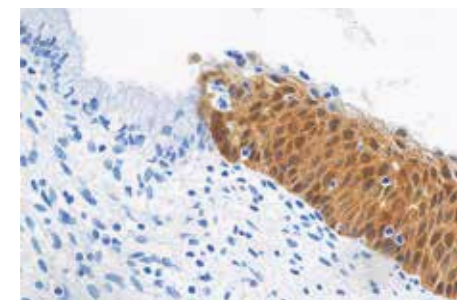
*\*CINtec<sup>®</sup> PLUS Cytology is a CE/IVD product, intended for clinical use. CINtec<sup>®</sup> PLUS Cytology is not available for this use in the United States or Japan. Check with your local Roche representative for the availability of products in your region and the applicable intended use.*

*See also the cobas HPV test.*

- 1 Wentzensen, N., et al. (2015). JNCI. 107(12):djv257. doi:10.1093/jnci.djv257.
- 2 Gustinucci, D., et al. (2016). AJCP. 145(1),35-45. doi:10.1093/ajcp.AQV019.
- 3 Schmidt, D., et al. (2011). Cancer Cytopathol. 119(3), 158-166. doi:10.1002/cncy.20140.
- 4 Petry, K.U., et al. (2011). Gynecol Oncol. 121 (3), 505-509. doi: 10.1016/j.ygyno.2011.02.033.
- 5 Bergeron, C., et al. (2010). Am J Clin Pathol.133 (3), 395-406.doi:10.1309/AJCPXSVCDZ3D5MZM.
- 6 Darragh, T, et al. (2012). J Low Genit Tract Dis.16(3):205-242. Erratum in J Low Genit Tract Dis. 2013; 17(3):368.



*Co-expression of p16<sup>INK4a</sup> (brown cytoplasmic immunostain) and Ki-67 (red nuclear immunostain) within the same cell demonstrates a positive CINtec<sup>®</sup> PLUS Cytology test result*



*Diffuse p16 immunostained cervical specimen demonstrating positive CINtec<sup>®</sup> Histology status*

- 7 Stoler, M, et al. Tumours of the Uterine Cervix. In Kurman, RJ, Carcangiu, ML, Herrington, CS, Young, RH (Eds.), WHO Classification of Tumours of Female Reproductive Organs. Lyon, France: IARC and WHO, 2014:169-206.
- 8 Roche, data on file. 2016.

# Colorectal diagnostics

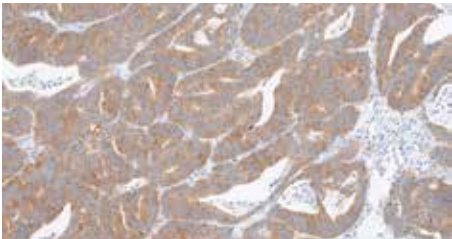
## Assist in diagnosis, risk stratification and subtyping of colorectal cancer



The stages and subtypes of colorectal cancer vary significantly in prognosis and treatment options, demonstrating a need for tools that assist pathologists in detecting and subtyping colorectal malignancies.

Roche Tissue Diagnostics offers a comprehensive panel of ready-to-use rabbit and mouse colorectal assays, including IHC assays for the four most common mismatch repair (MMR) proteins, MLH-1 (M1) Mouse Monoclonal Primary Antibody, MSH2 (G219-1129), CONFIRM MSH6 (44) Mouse Monoclonal Primary Antibody and PMS2 (EPR3947), along with the BRAF V600E (VE1) Mouse Monoclonal Primary Antibody, for use on the fully-automated VENTANA BenchMark systems.

The Roche Tissue Diagnostics colorectal primary antibodies assist in diagnosis, risk stratification and subtyping while helping inform clinical decisions, and are supported by innovative automation, detection and workflow solutions.



BRAF V600E (VE1) Mouse Monoclonal Primary Antibody

### Informing clinical decisions

Our colorectal and gastrointestinal tools aid in diagnosis, subtyping and risk stratification with ready-to-use assays that include:

- MMR protein and BRAF V600E (VE1) assays facilitate efficient and cost-effective subtyping within the anatomic pathology laboratory
- Gastrointestinal IHC assays such as PATHWAY c-KIT (9.7) Primary Antibody and VENTANA Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody
- Highly sensitive and specific rabbit and mouse monoclonal assays

### Mismatch repair IHC staining patterns in colorectal cancer

| MMR mutations | IHC result MLH1 | IHC result PMS2 | IHC result MSH2 | IHC result MSH6 |
|---------------|-----------------|-----------------|-----------------|-----------------|
| MLH1 mutation | Loss<br>        | Loss<br>        | Preserved<br>   | Preserved<br>   |
| MSH2 mutation | Preserved<br>   | Preserved<br>   | Loss<br>        | Loss<br>        |
| MSH6 mutation | Preserved<br>   | Preserved<br>   | Preserved<br>   | Loss<br>        |
| PMS2 mutation | Preserved<br>   | Loss<br>        | Preserved<br>   | Preserved<br>   |

Powered by the OptiView DAB IHC detection system.

# Hematopathology diagnostics

*A comprehensive solution helping you detect and subtype*

Hematological cancers vary significantly in both prognosis and aggressiveness, demonstrating a need for tools that assist pathologists in making confident diagnoses and helping to inform clinical decisions. We offer over 65 cornerstone and novel hematopathology ready-to-use reagents, including key IHC antibodies and ISH probes, that aid in the detection of lymphomas, leukemias and other hematopoietic malignancies.

The dynamic range of VENTANA OptiView DAB IHC detection delivers high sensitivity and specificity so you can detect antigens across a wide range of expression levels. Our hematopathology assays are optimized for use on the fully-automated VENTANA BenchMark systems, maximizing quality and laboratory efficiency.

## Comprehensive menu to aid in diagnosis and subtyping

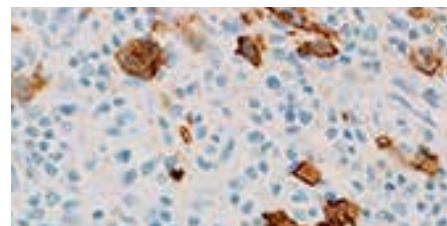


*bcl-2 (SP66) Rabbit Monoclonal Primary Antibody*

Roche Tissue Diagnostics hematopathology suite of ready-to-use immunohistochemistry (IHC) and in situ hybridization (ISH) assays feature:

- Exclusive assays such as the BRAF V600E (VE1) Mouse Monoclonal Primary Antibody
- New products such as SOX-11 (MRQ-58) Mouse Monoclonal Primary Antibody, CD13 (SP187) Rabbit Monoclonal Primary Antibody and CD16 (SP175) Rabbit Monoclonal Primary Antibody
- Choice of detection systems that allows visualization of antigens with low expression

## CD30: cornerstone biomarker that helps inform clinical decisions



*CD30 (Ber-H2) Mouse Monoclonal Primary Antibody*

We are excited to provide you with the reformulated CD30 (Ber-H2) Mouse Monoclonal Primary Antibody. A cornerstone tissue marker for lymphoma, CD30 delivers clinical confidence by aiding the pathologist in:

- Diagnosis of T-cell and B-cell lymphomas
- Identification of Reed-Sternberg cells in Hodgkins Lymphoma (HL)
- Diagnosis of Anaplastic Large Cell Lymphoma (ALCL)

This reformulation features updated protocols for both OptiView DAB Detection and ultraView Universal DAB IHC Detection.



# Lung cancer diagnostic solutions

## *Driving Personalized Healthcare with key markers for detection and subtyping*

The statistics associated with lung cancer clearly demonstrate the aggressive nature of this deadly disease, Roche Tissue Diagnostics offers a robust menu of tools to aid in the diagnosis of patients facing this challenge. “With the introduction of targeted therapies that can result in dramatically different outcomes based on subtype, the importance of accurate classification has been amplified.”<sup>1</sup>

Our portfolio of products, which includes rabbit monoclonal antibodies, novel biomarkers and detection kits, delivers the high sensitivity and specificity needed from diagnostic assays.

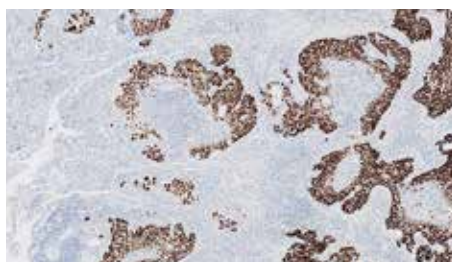
Our antibodies are ready-to-use on the fully-automated VENTANA BenchMark systems, which reduces the time to complete diagnosis and resources required with manual or semi-automated solutions.

### Differentiating between adenocarcinoma and squamous cell carcinoma

Confidently differentiate between lung adenocarcinoma (ADC) and squamous cell carcinoma (SCC) with four key markers, including the p40 (BC28) Mouse Monoclonal Primary Antibody.

#### **p40 (BC28) Mouse Monoclonal Primary Antibody**

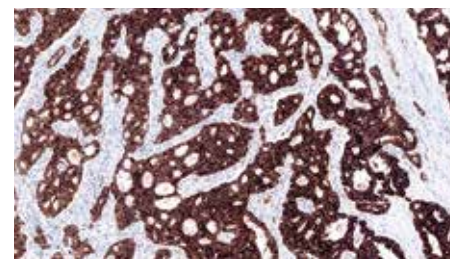
p40 (BC28) is a sensitive and specific antibody for the detection of the p40 ( $\Delta$ Np63) protein. In a panel with other key markers in our portfolio (TTF-1, CK 5/6, Napsin A), p40 (BC28) can provide an accurate and reliable method for differentiating pulmonary adenocarcinoma from squamous cell carcinoma.<sup>2</sup>



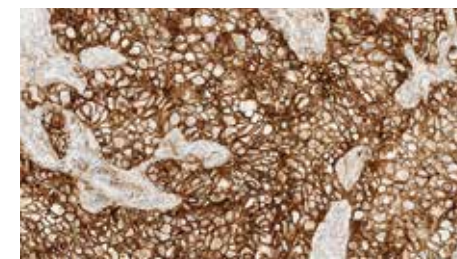
*Squamous cell carcinoma stained positive with the p40 (BC28) assay using OptiView DAB IHC detection*

- 1 Tacha, D., Yu, C., Bremer, R., Qi, W., Haas, T. (2012). *Appl Immunohistochem Mol Morphol* 20, 201-207.
- 2 Wei, Z., Hui, W., Yan, P., Bo, T., Lei, P., Da-Chuan, Z. (2014).  $\Delta$ Np63, CK5/6, TTF-1 and napsin A, a reliable panel to subtype non-small cell lung cancer in biopsy specimens. *Int J Clin Exp Pathol*, 7(7), 4247-4253.
- 3 Shaw et al. (2011). *J Natl. Compr. Canc. Netw.* 9,1335-1341.

### Gain a clear view by detecting ALK and PD-L1 protein expression



*NSCLC stained with VENTANA ALK (D5F3), and OptiView DAB IHC detection with AMP*



*NSCLC stained with VENTANA PD-L1 (SP263)*

#### **VENTANA ALK (D5F3) Rabbit Monoclonal Primary Antibody**

VENTANA ALK (D5F3) is indicated as an aid in identifying patients eligible for treatment with XALKORI (crizotinib). It is, therefore, critical that ALK positive patients are accurately identified. Shaw et al. highlights this importance and demonstrates that ALK testing via IHC represents a reliable and cost effective alternative to FISH.<sup>3</sup>

Clone D5F3 has been identified as “one of the most promising antibodies for the detection of ALK rearrangement in NSCLC.” In a study of 296 patients with advanced NSCLC clinically referred for ALK testing, the “ultrasensitive” VENTANA ALK (D5F3) assay showed high correlation with FISH and 100% sensitivity and specificity.<sup>4</sup>

#### **VENTANA PD-L1 (SP263) Rabbit Monoclonal Primary Antibody**

The VENTANA PD-L1 (SP263) antibody is produced against programmed death-ligand 1 (PD-L1) B7 homolog 1 (B7-H1, CD274). It recognizes a transmembrane bound glycoprotein that has a molecular mass of 45–55 kDa. This antibody produces membranous, and/or cytoplasmic staining.

It is indicated as an aid in the assessment of PD-L1 expression in non-small cell lung cancer (NSCLC) and other tumor types.<sup>5</sup>

<sup>4</sup> Minca et al. (2013). *J Mol Diagn.* 15(3).

<sup>5</sup> Zou, W., Chen, L. (2008). Inhibitory B7-family molecules in the tumour microenvironment. *Nat Rev Immunol*, 8(6), 467-77.

# Prostate cancer diagnostics

*Diagnostic solutions and innovative tools for emerging utility*

Our prostate cancer diagnostic portfolio can give you the confidence you need to improve patient care.

Empower your lab with our portfolio of biomarkers that deliver increased value for men's health. Our antibodies are pre-diluted and optimized for use on the fully-automated VENTANA BenchMark systems for quality results that are both consistent and reproducible. We continue to develop novel biomarkers with promising utility – such as the EZH2 (SP129) Rabbit Monoclonal Antibody and the Androgen Receptor (SP107) Rabbit Monoclonal Antibody.

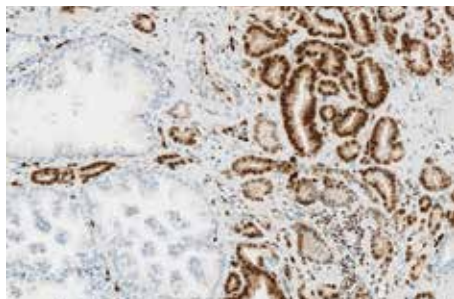
## **ERG (EPR3864) Rabbit Monoclonal Primary Antibody**

Developed for high sensitivity and specificity, the ERG (EPR3864) Rabbit Monoclonal Primary Antibody delivers:

- Specificity for prostate cancer which may aid in detection and diagnosis
- Ability to identify a molecular prostate cancer subtype
- High concordance to ERG FISH

## **VENTANA p63 (4A4) Mouse Monoclonal Primary Antibody**

The p63 (4A4) antibody empowers you to make informed, confident decisions.



*Prostate carcinoma stained with ERG (EPR3864) Rabbit Monoclonal Primary Antibody*

- Consistently strong nuclear staining allows for easier interpretation
- Like high molecular weight cytokeratin 34 $\beta$ E12, p63 is specific and sensitive for basal cells in the prostate gland

## **VENTANA Basal Cell Cocktail 34 $\beta$ E12+p63**

Our Basal Cell Cocktail combines p63 (4A4) with 34 $\beta$ E12 to aid in the differentiation of benign and malignant prostatic lesions.

- Increases the sensitivity of basal cell detection
- Decreases staining variability
- Offers more consistent basal cell immunostaining

# Connectivity solutions

Work confidently with Connectivity Solutions from Roche Tissue Diagnostics that help you optimize lab efficiency, patient safety, and equipment uptime through direct connections to your Roche Tissue Diagnostics platforms. From remote support to Laboratory Information Systems (LIS) connectivity, we have you covered.

## **CareGiver Remote Support**

Monitoring your lab's Roche Tissue Diagnostics instruments in real-time, the CareGiver remote support software delivers enhanced system performance, decreased downtime and world-class customer support. Your instruments are talking; CareGiver remote support is listening.

## **VENTANA Connect middleware**

VENTANA Connect middleware provides a simple, flexible and scalable point of integration between the Lab Information System (LIS), BenchMark and VENTANA HE 600 instruments, and the VANTAGE Workflow Solution and Roche Digital Pathology systems. VENTANA Connect middleware helps to ensure important case information flows seamlessly between instruments and systems through a single, standardized and secure connection.



# VANTAGE workflow solution

*A proven system for quality to increase patient safety*

Today's histology lab managers are under increasing pressure to improve laboratory workflow, sample tracking, quality and patient safety.

VANTAGE solutions have been designed to enable histology laboratories to address these challenges:

Our comprehensive solution for histology labs — hardware, software and workflow consulting — offers a commanding view of your complex operation from a single strategic perspective. It is an end-to-end product that automates, streamlines and integrates lab work and information flow to help provide maximum productivity and improvements to patient safety. The VANTAGE workflow solution is designed using Lean Six Sigma principles and includes expert workflow consulting support to help you obtain immediate and ongoing workflow benefits.

## Your benefit

### Eliminate redundancies, reduce errors

- Reduce data re-entry, relabelling and labelling errors with “one label, one time” technology and barcode scanners at every workstation

### Lean workflow

- Prevent bottlenecks before they happen. The VANTAGE workflow solution gives you a clear view of your lab, so you can maintain optimal performance
- Collaborate with lean histology experts to improve your workflow
- Simplify workflow steps
- See a comprehensive dashboard of lab performance at any time
- Identify opportunities to improve quality, staffing and efficiency

### Establish your chain of custody

- The VANTAGE workflow management system brings all of our automated platforms together, creating a chain of custody that encompasses your entire lab

## Full and fast control

- Locate any specimen, block or slide immediately
- Ask the VANTAGE system to locate any patient's slide, on any instrument, at any point in your process — and count on immediate, accurate results

## Full transparency

- Populate patient details accurately
- Retrieve patient details with a quick barcode scan

## Product characteristics

- Includes all VENTANA Connect characteristics
- Cassette verification/identification
- Slide label generation and management
- Harmonised unique slide identification
- Centralized instrument slide/test status
- Specimen chain of custody
- Block/slide tracking and locating
- Workflow process report and workload statistics
- QA/QC management and reports
- Specimen archive



# Companion diagnostics

## *Deliver Personalized Healthcare to those who need it*

For every ten cancer patients treated, an average of only half will benefit. For some, the treatment won't have any effect; others may suffer from serious side effects.<sup>1</sup> Ventana Medical Systems, Inc. A Member of the Roche Group is working at our industry's forefront to change this dynamic by customizing therapy to individual patients, helping you to improve diagnostic accuracy, lab efficiency and patient safety.

In collaboration with leading pharmaceutical companies, we identify and develop innovative companion diagnostics to target those patients who are likely to respond to specific therapies. Because we recognize the tremendous potential for these solutions, we continue to focus on addressing unmet medical needs by developing the cutting-edge tools you need.

You can be confident that VENTANA products, from Roche, are the right solution to empower you to deliver the high-quality diagnostic information for patients – today and in the future.

One of the global leaders in tissue-based cancer diagnostics, we provide a premier end-to-end offering, with expertise at every stage from discovery to commercialization. Working together under one roof, Roche and pharma increase the efficiency and speed of developing patient selection biomarkers.

- Brings 180+ biomarker projects with a strong track record – reliably on time and on budget
- Provides global access through the Roche commercial network and install base
- Offers a differentiated, broad instrument and reagent portfolio

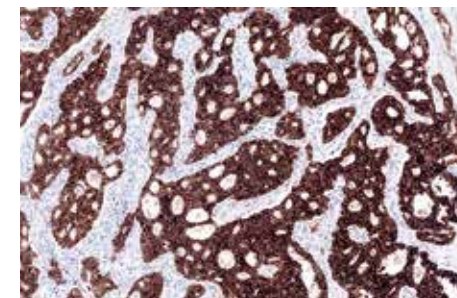
### Helping to deliver the promise of Personalized Healthcare

- Companion tissue tests help determine the best course of treatment
- We are committed to expanding our market-leading HER2 diagnostic franchise
- The VENTANA ALK IHC Rabbit Monoclonal Primary Antibody aids in early detection and treatment decisions for non-small cell lung cancer patients
- The VENTANA PD-L1 assays generate results you can trust, so you can make timely diagnostic decisions and therapeutic choices
- The majority of the Roche oncology-focused targeted therapies, currently in late stage clinical trials, have an associated VENTANA tissue companion diagnostic

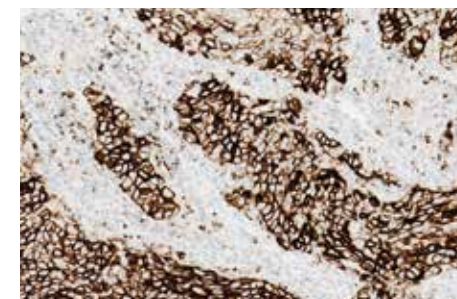
### Product portfolio:

- HER2
- HER2 Dual ISH
- VENTANA ALK (D5F3)
- VENTANA PD-L1 (SP142)
- VENTANA PD-L1 (SP263)

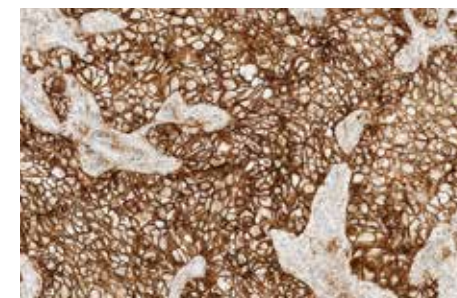
<sup>1</sup> Source: Roche Personalized Healthcare brochure, 2011.



VENTANA ALK (D5F3) Rabbit Monoclonal Antibody



VENTANA PD-L1 (SP142) Assay



VENTANA PD-L1 (SP263) Assay

# Digital pathology

## *Virtual consultation, image analysis and education*

Digital Pathology is transforming the practice of pathology by developing innovative technologies that deliver medical value, inform decision making and improve cancer care. The integrated solution consists of high-quality scanners, image analysis software, image and workflow management software and education applications, all working together globally to optimize laboratories. Digital pathology enables more efficient and informed treatment decisions for patients – enhancing care by eliminating the boundaries of time and distance.

### Your benefit

#### Virtual consultation

- Maximize pathologist time
- Enable flexibility for tumor boards, case sharing and collaboration
- Enable fast turnaround time for expert opinions
- Provide access to sub-specialists

#### Image analysis

- Build clinical confidence with US and CE-IVD validated Companion Algorithm image analysis software
- Facilitate consistent, objective interpretations for breast IHC – verified by a pathologist – for every patient

#### Education

- Enrich and accelerate learning in a collaborative environment
- Allow students to review material anywhere, anytime, from the device of their choice



VENTANA iScan Coreo

VENTANA iScan HT

### Product features

#### VENTANA Virtuoso image and workflow management software

- Anytime, anywhere access to slide images
- Optimized digital workflow and decision-making environment
- Web-based application to support remote consults and image analysis

#### VENTANA Algorithm image analysis software

- US and CE-IVD validated image analysis algorithms for the full breast panel: HER2, ER, PR, Ki-67 and p53
- Semi-quantitative scores for markers requiring cell counts
- Fully validated as part of a systems approach – includes reagents, staining platforms, scanners and software

#### VENTANA iScan Coreo slide scanner

- Intended for low- to mid-volume scanning sites
- Brightfield scanning capability (160 slide capacity) at various magnifications – 4x, 10x, 20x, 40x
- Live mode (remotely controlled robotic microscope)



#### VENTANA iScan HT slide scanner

- Intended for high-volume scanning sites
- Brightfield scanning capability (360 slide capacity) at various magnifications – 20x, 40x
- Continuous random access and STAT processing – with no workflow interruption

#### VENTANA Vector education and collaboration software

- Support education and collaboration with digital images
- Standardize content and eliminate sharing resources (slides or microscopes)
- Allow students to review material anywhere, anytime, from the device of their choice (mobile-capable on iOS and Android devices)



**Clinical research**  
*DNA sequencing*  
**Innovation**  
*Sequence capture*

## Roche Sequencing Solutions: a Unifying Force in NGS

Roche is bringing together technologies across the workflow to make next-generation sequencing (NGS) simple and accessible.

Our sample preparation products, like SeqCap EZ and KAPA HyperPrep, require fewer steps, improve turn-around times, and are backed by award-winning customer care. With a growing suite of products, including the Harmony Prenatal Test, Roche Sequencing Solutions has tools to help you develop insight into important questions in genetics, infectious disease, and cancer.

**For more information please visit**  
<http://sequencing.roche.com>

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Not for use in diagnostic procedures.*

# HEAT-Seq Target Enrichment Systems

*Simple workflow. Confident variant detection.*

HEAT-Seq Target Enrichment Systems provide an amplification-based enrichment method that combines a fast and easy workflow with powerful SNV detection for targeted resequencing applications in human genetic disease and cancer research.

The HEAT-Seq Target Enrichment system is a complete solution that helps enable rapid enrichment of regions of interest in a single day with an easy single-tube protocol. Created using proprietary technologies and extensive expertise in genomics, HEAT-Seq systems employ a refined probe structure and lab protocol.



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Data on file.*

## Your benefit

### Fast and simple workflow

- The enrichment workflow has been streamlined and optimized to minimize steps and reduce hands-on time. Go from sample DNA to sequencing in 8 hours with under 2 hours of hands-on time using a single tube

### Confident variant detection

- Easily identify and remove bias and duplicates using UID molecular barcodes. Defining a set of reads that accurately represents the complexity of the original sample helps enable the detection of variants at as low as 1% MAF and below with extremely low false positive rates

### Create custom panels with ease

- A simple process allows you to obtain a custom design with high levels of uniformity and overall performance by drawing from our database of empirically tested probes. Custom HEAT-Seq panels are made using the performance information in our database, allowing you to spend less time worrying about optimization and more time focusing on your data

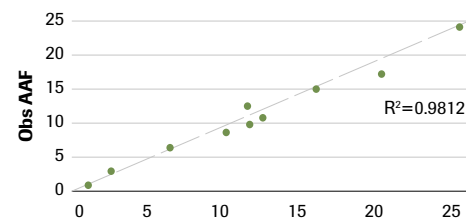
## Product characteristics

|                                    | HEAT-Seq Ultra<br>Oncology HotSpot Panel | Illumina TruSeq<br>Amplicon Cancer Panel | Thermo Fisher Ion<br>AmpliSeq™ Cancer Panel v2 |
|------------------------------------|------------------------------------------|------------------------------------------|------------------------------------------------|
| <b>Average False-Positive Rate</b> | 0.014 %                                  | 0.213 %                                  | 3.071 %                                        |
| <b>Range</b>                       | 0.0 – 0.2 %                              | 0.0 – 0.4 %                              | 0.0 – 11.1 %                                   |
| <b>Missed Calls</b>                | 0                                        | 2                                        | 0                                              |

*False-positive rate in detection of variants using various methods*

The performance of the HEAT-Seq Ultra Oncology HotSpot Panel is compared to similar kits to assess allele frequency detection accuracy and data quality. The HEAT-Seq panel presents a similar or improved variant detection ability, but also presents an extremely low false-positive rate. The proprietary process of removing duplicates using molecular barcoding is the core of the HEAT-Seq system that enables not only accurate variant calls but also the confident removal of process induced errors that appear as false positives.

**Observed vs. Expected allele frequency detection using formalin-compromised samples:** The HEAT-Seq Ultra Oncology HotSpot Panel was tested using an FFPE control sample with known mutations at between 0.9% and 25% frequencies. Observed allele frequencies strongly matched the known frequencies, showing the sensitivity and accuracy of this panel.



# SeqCap Target Enrichment

## *Confident and efficient genetic variant detection*



Next-generation sequencing (NGS) target enrichment enables you to focus on your regions of interest in the human genome, hence greatly improving sample capacity and enabling faster results. Compared to other hybridization-based enrichment technologies on the market, Roche products provide the highest capture efficiency and coverage uniformity available,<sup>1,2</sup> as a result of its advanced design algorithms and proprietary probe synthesis technology.

Roche sequence capture products have enabled effective enrichment of a wide variety of genome regions from a broad range of sample types for high-fidelity detection of SNVs (single nucleotide variations), CNVs (copy number variations), indels (insertions and deletions), translocations, epigenomic events, RNA transcription and more.



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Unless otherwise referenced, all data on file.*

### Your benefit

#### Most relevant content

- Uniform coverage of your target region, from the specialist in custom designs, building highest confidence in variant detection and data reporting

#### Proven performance

- Best-in-class<sup>3</sup> capture efficiency, proven by independent leading researchers year over year, leading to optimal sample throughput

#### Maximum convenience

- Complete and cost-effective enrichment workflow coverage, from one source, greatly simplifying your validation process

### Product characteristics

SeqCap Target Enrichment Systems is a solution-based capture method that enables enrichment of the whole exome or customer regions of interest in a single test tube with up to 2.1 million overlapping probes.

- **SeqCap EZ Systems** enable enrichment for DNA sequencing on a variety of product offerings from whole-exome to targeted designs. Additional designs are available for custom developed designs, or fixed designs agriculture biology, crop genomes, or model organisms.
- **SeqCap Epi Systems** enable enrichment of bisulfite treated DNA for epigenomic applications of research. Products are available in a fixed design for whole-exome epigenomic analysis, or custom designs can be developed for human or model organisms.
- **SeqCap RNA Systems** are designed for target enrichment of cDNA or RNA. Products are available in a fixed design for researching long-coding RNA or custom designs can be developed for human or model organisms.



- **NimbleDesign service** is a free online tool that enables you to quickly and easily design SeqCap EZ Choice and SeqCap RNA Choice Systems.

#### Flexible and Fast workflow

*New HyperCap workflow* combines Kapa Hyper Libraries with optimized SeqCap EZ protocol to yield an automation friendly workflow with excellent performance across multiple sample types and starting amounts, optional Kapa Hyper Plus enzymatic fragmentation offers further workflow streamlining and removes capital equipment needs.

1 Clark, M., et al. (2011). *Nat. Biotech.*; doi:10.1038/nbt.1975.

2 Bodi, K., et al. (2013). *J Biomol Tech. Jul*;24(2):73-86. doi: 10.1171/jbt.13-2402-002.

3 Garcia-Garcia, G., et al. (2016). *Sci Rep; Feb*;6:20948. doi: 10.1038/srep20948.

# Harmony Prenatal Test

*Clear ANSWERS to question that matter*

The Harmony Prenatal Test is a cell-free DNA based technology or non-invasive prenatal test (NIPT) that provides an assessment for the probability of fetal trisomies 21 (Down syndrome), 18, and 13. The test can also screen for sex chromosome (X, Y) aneuploidies and fetal sex. This screening test can be performed starting at 10 weeks gestation.

The Harmony Prenatal Test is available to laboratories around the world via the Ariosa cell-free DNA System (AcfS) or as a test send out service (TSO).

## Ariosa cell-free DNA System (AcfS)\*

*Non-Invasive Prenatal Testing Performed in your Laboratory*

The AcfS is a modular, microarray-based, system designed to streamline the Harmony (DANSR/FORTE) prenatal test for decentralized testing at local laboratories. AcfS is optimized for laboratories performing 400 or more NIPTs per month and can easily scale to accommodate tens of thousands of tests per year. The Harmony reagent kit for the AcfS system is available in CE-IVD and RUO versions.\*

## Harmony prenatal test as Test Send Out service (TSO)

Laboratories and physicians can offer the Harmony Prenatal Test by sending whole blood specimen directly to the CLIA and CAP accredited laboratory located in San Jose, CA USA.

### Your benefit

The Harmony Prenatal Test is Validated for Pregnant Women of Any Age or Risk\*\* and Trusted by Clinicians Worldwide

- Studied extensively in blinded prospective trials<sup>1</sup>
- Harmony Test significantly outperformed First Trimester Combined Screening (FTS\*\*) in both trisomy 21 detection and false-positive rate in a blinded, prospective head-to-head comparison<sup>2</sup>

## Technology benefit of the directed analysis (DANSR), individualized assessment (FORTE)

**DANSR** assay allows for deeper analysis by focusing on the specific chromosomes of interest, rather than random, whole genome sequencing.

**FORTE** algorithm measures, incorporates, and reports fetal fraction for every sample. Incorporation of maternal and gestational age provides for an individualized result as opposed to an arbitrary positive/negative value.

## Greater efficiency at lower cost

The Harmony test second generation custom microarray technology improves the precision and throughput of DANSR/FORTE3, while reducing time-to-result, overall labor, and reportable results costs.

## Ariosa cell-free DNA System: Features and Benefits

### Operational efficiency

- Maximum hands-free operation
- No manual pipetting

### Workflow and scalability

- Custom microarray technology and rapid quantification streamlines workflow
- Modular AcfS allows for cost-efficient system expansion as needed

### Integrated user interface

- User-friendly Director interface provides full process automation control
- Director ensures accurate library-to-results sample tracking for optimal control

### Security and transparency

- Patient data housed on local server to avoid exposure on the cloud
- Complete price clarity: no hidden fees or unexpected requirements



\*Not available in all markets. \*\*Both under 35 and over 35 age groups, studies have included women ages 18-48. The disclaimers are at the end of the booklet.

1 Stokowski et al. Prenat Diagn. 2015 Oct; DOI: 10.1002/pd.4686  
 2 Norton et al. N Engl J Med. 2015 Apr 23;372(17):1589-97.  
 3 Juneau et al. Fetal Diagn Ther. 2014;36(4):282-6.

## AVENIO Millisect Instrument\*

*Precise, consistent and confident microdissection of FFPE tissue samples*

### The AVENIO Millisect Instrument

(**Millisect**) is an automated tissue dissection system will enable the capture of challenging tumor samples while providing precision, accuracy, and consistency. Users can confidently transfer annotated reference slides to serial cut sections with greater accuracy when compared to manual methods.

Millisect will allow pathology and molecular laboratories to perform automated FFPE tissue dissection while ensuring high precision and proper chain of custody, thereby helping to advance the standard of oncology testing utilizing molecular testing technologies.



\*Expected launch – June 2017.  
Data on file.

### Your benefit

#### High quality and precision

- Prevent loss of precious samples with 300 µm minimum precision level and equivalent recovery comparing to manual dissection
- Provide consistency across samples and for operators with automated dissection

#### Efficient turn-around time

- Dissect up to four slides in 5 to 10 minutes
- Free up time for other tasks by reducing the number of hands-on operations

#### Intuitive and integrated workflow

- Easy-to-use intuitive user interface, practical and all-in one touchscreen PC
- Offer flexibility for downstream applications with most user-defined buffers

#### Proper chain of custody

- Track reference and sample barcodes, time of collection, and sample collection data on area of interest automatically
- Provide a comprehensive PDF report for every case

## Cell-Free DNA Collection Tube

*Stable, durable and reliable blood collection tubes for cell free DNA preservation and transport*



The **Cell-Free DNA Collection Tube** is a direct-draw tube for the collection, stabilization and transportation of whole blood specimens, and for preservation of nucleated cells to enable analysis of cell-free DNA.



### Your benefit

#### Specimen stability

- Proprietary solution prevents cell lysis to enable greater detection of cfDNA
- K3EDTA prevents blood coagulation

#### Safety and durability

- Manufactured in accordance with ISO 9001 and EN ISO 13485
- Made from safe, durable polyethylene terephthalate (PET), which minimizes costly glass breakage during transport and specimen centrifugation

#### Proven and reliable

- Over 1 million tubes used in cell-free DNA applications by laboratories worldwide
- Supported by Roche's large service and large distribution network

| Product                            | Pack Size                                | Catalog Number |
|------------------------------------|------------------------------------------|----------------|
| RUO* Cell-Free DNA Collection Tube | 1 box of 50 tubes                        | 07785674001    |
|                                    | 24 boxes of 50 tubes (1,200 tubes total) | 07832397001    |

| Product                                | Pack Size                                | Catalog Number |
|----------------------------------------|------------------------------------------|----------------|
| CE-IVD Cell-Free DNA Collection Tube** | 1 box of 50 tubes                        | 07785666001    |
|                                        | 24 boxes of 50 tubes (1,200 tubes total) | 07832389001    |

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\*\* Available for countries that accept CE-Mark

# KAPA DNA Library Preparation Kits for Illumina

*It's complex, but we have it covered*

## KAPA DNA Library Preparation Kits for Illumina. It's complex, but we have it covered.

KAPA DNA Library Preparation Kits for Illumina® sequencing platforms contain evolved and optimally formulated enzymes that enable the high overall coverage from the least amount of total sequencing. Kits are optimized to achieve significantly high library yields and contain KAPA HiFi for high-fidelity, high-efficiency and low-bias library amplification. This ensures the high library and sequence data quality, particularly from low-input and difficult samples such as FFPE and ChIP DNA.

### Your benefit

#### Achieve great molecular complexity

- High yields of adapter-ligated library translates to high molecular complexity
- Fewer cycles of amplification are needed, which results in lower PCR duplication rates
- PCR-free workflows possible from inputs  $\geq 100$  ng\*

#### Reduce amplification bias and improve coverage

- KAPA HiFi reduces PCR bias\*
- Improves coverage uniformity of GC- and AT-rich regions, promoters, low complexity and other challenging regions\*

#### Create high-quality libraries from challenging samples

- High-quality whole exome sequencing from libraries prepared using as little as 10 ng human genomic DNA\*
- High success rates with 250 ng FFPE or less\*
- Routine library construction from  $\geq 100$  pg ChIP DNA\*

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*\*Data on file.*



# NEW KAPA HyperPrep Kits

*Shift your workflow into hyperdrive*



The KAPA HyperPrep Kit is a versatile, streamlined solution for DNA library preparation for Illumina® sequencing.

The novel one-tube chemistry, contain optimally formulated and evolved enzymes that enable high yields of adapter-ligated library and low amplification bias. This translates to high library diversity, lower duplication rates and more uniform coverage, particularly for FFPE and low-input samples.

## Your benefit

### Improved speed and convenience

- Lower duplication rates and higher sequencing coverage
- Improved performance with low-input samples
- High-quality library construction from FFPE samples
- PCR-free workflows

## Product characteristics

### Improve library yields and sequence quality

- High library yields translate to great molecular complexity
- Fewer cycles of amplification with KAPA HiFi DNA Polymerase results in lower duplication rates and improved coverage

### Create high-quality libraries from FFPE samples

- Generate high-quality libraries from 250 ng FFPE DNA or less\*
- Significantly lower duplication rates and higher coverage\*

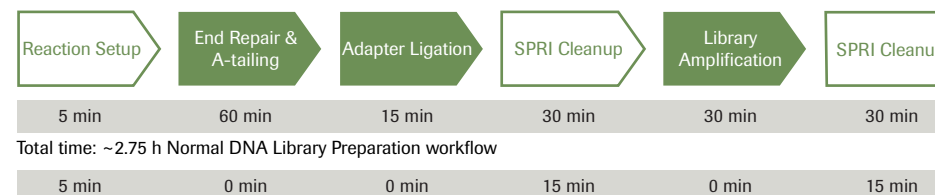
### Complete library construction in less than 3 hours

- One-tube workflow with minimal cleanup steps reduces overall time, and minimizes hands-on time
- Sample-to-library in <2 hours for PCR-free workflows, or <3 hours with amplification\*
- Fewer handling steps lead to improved consistency and reproducibility

### Improve performance with low-input samples

- Generate more sequence-quality library molecules without increasing adapter-dimers
- Increase yields without inducing size bias

## Streamlined KAPA HyperPrep workflow



Hand-on time: ~35 min KAPA HyperPrep Kit workflow

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\*Data on file.

# KAPA HyperPlus Kits

*NGS library preparation. Evolved.*

The KAPA HyperPlus Kit provides a streamlined workflow that includes fragmentation and library preparation in a single tube. Building on industry-leading library construction efficiencies, this integrated solution combines enzymatic fragmentation, similar in quality to mechanical shearing, with the speed and convenience of tagmentation-based workflows.

## Your benefit

### Tunable and reproducible fragmentation

- Adjust library insert sizes from 150 – 800 bp by varying fragmentation time
- Reproducible insert sizes across a range of GC content and DNA input amounts

### Industry leading library yields...

- Routinely achieve conversion rates >80 % from  $\geq 100$  ng input\*
- Superior performance across a range of DNA input amounts\*
- High library yields enable PCR-free workflows from as little as 50 ng starting material\*

## ...can enable superior sequencing results

- High conversion rates results in fewer amplification cycles and lower duplication rates
- Detect low-frequency mutations with high confidence due to greater library diversity and more uniform sequence coverage

### Minimal sequence coverage bias

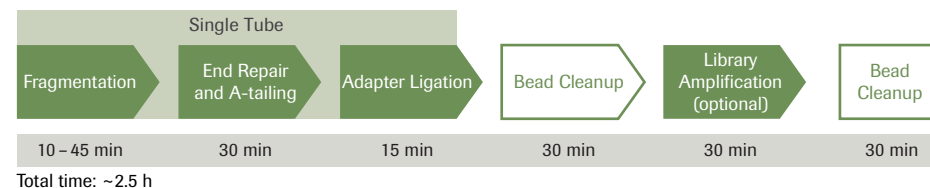
- Lower sequence bias when compared to tagmentation and other enzymatic fragmentation methods\*
- Equivalent performance to mechanical shearing\*
- Less bias leads to more uniform sequencing coverage and reduced sequencing costs\*

## Product characteristics

- DNA fragmentation and library prep in 2.5 hours\*
- Flexible DNA sample input from 1 ng – 1  $\mu$ g\*
- Reduced bias and maximize sequence coverage\*
- PCR-free workflows



## Streamlined KAPA HyperPlus workflow



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\*Data on file.

## KAPA Stranded mRNA-Seq Kits

*Even difficult messages should be understood*

The KAPA Stranded mRNA-Seq Kits generate libraries with greater than 99% strand specificity and superior sequence quality. Kits are optimized for the improved coverage of GC-rich and low-abundance transcripts, resulting in the identification of more genes. The KAPA Stranded mRNA-Seq Kits contain KAPA HiFi for high-efficiency and low bias library amplification.

### Your benefit

- 100 ng – 4 µg of total RNA
- 99% strand specificity
- KAPA mRNA Capture Beads
- Streamlined “with-bead” protocol optimized for<sup>1</sup>

### Product characteristics

#### Uncover challenging transcripts

- Improved coverage of GC-rich transcripts
- Enhanced identification of exonic regions

#### Detect low-abundance transcripts

- Enables identification of transcripts missed by competitor kits, even with high input
- High uniformity across varying amounts of sample input

#### Identify more genes

- Higher percentage of uniquely mapped reads compared to Illumina® TruSeq® Stranded mRNA Sample Prep Kits
- Lower duplication rates yield better coverage

## KAPA Stranded RNA-Seq with RiboErase

*Evolved to focus*



The KAPA Stranded RNA-Seq Kit with RiboErase offers a high-quality, comprehensive solution for transcriptome sequencing. By utilizing a targeted enzymatic method for depletion, our workflow enables superior reduction of ribosomal RNA (rRNA) and a more complete representation of the transcriptome, including precursor mRNAs and non-coding RNA (ncRNA). Kits also contain KAPA HiFi for high-efficiency and low-bias library amplification, and include a streamlined, “with-bead” protocol.

### Your benefit

- Up to 99.98% rRNA depletion
- Flexible input of 100 ng – 1 µg total RNA for human, mouse, or rat species
- Robust and reproducible results across various input amounts
- An automation-friendly workflow

### Product characteristics

#### Industry-leading rRNA depletion

- Very good rRNA depletion from high-quality and FFPE samples
- More economical NGS sequencing due to decreased rRNA reads, providing deeper sequencing of transcripts of interest

#### Maximum coverage uniformity

- Uniform distribution of reads over each transcript
- Minimal 5' – 3' bias across transcripts

#### High-quality sequencing data

- Detection of more genes and unique transcripts
- Accurate and clear identification of splice sites and alternative gene splicing
- Improved coverage enabling better detection of difficult and GC-rich transcripts

#### Highly reproducible sequencing results

- High correlation even between different testing conditions
- Low sample-to-sample variation for more reliable results

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Data on file.

<sup>1</sup> 6:20948. doi: 10.1038/srep20948.

# KAPA Library Quantification Kits

*Next-generation DNA Sequencing meets  
Next-generation qPCR*

Current standard protocols for commercial next generation sequencing platforms employ laborious, costly, and often unreliable methods for quantifying DNA libraries.

Accurate quantification of PCR-competent sequencing templates is crucial for reliable clonal amplification via either emulsion PCR (emPCR) or bridge PCR (bPCR) – underestimation usually results in non-clonality, while overestimation can lead to inefficiency via poor yields of clonally amplified templates.

Standard methods for quantifying NGS libraries have a number of important disadvantages. Electrophoresis and spectrophotometry measure total nucleic acid concentrations, whereas optimal cluster density or template-to-bead ratio depend on the appropriate concentration of PCR-amplifiable DNA molecules. These methods also have low sensitivity, consuming nanograms of precious samples, and are not suitable for high-throughput workflows. Quantitative PCR (qPCR) is inherently well-suited for next-generation sequencing library quantification:

- qPCR specifically quantifies only PCR-competent DNA molecules
- is highly sensitive allowing accurate quantification of low concentration libraries

## Your benefit

- Reliable and sensitive quantification of all sequencing-competent library molecules
- Accurate and reproducible quantitation across a wide range of library types, concentrations, fragment length distributions and GC content
- More efficient, equimolar pooling for multiplexed sequencing
- Flexibility to support manual and automated, high-throughput pipelines; as well as PCR-free workflows

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*Data on file.*



## Product characteristics

### qPCR library quantification results in streamlined workflows

KAPA Library Quantification Kits eliminate the need for time-consuming and expensive titrations and provide a conducive format for streamlining high-throughput workflows.

### Reliable quantification results in consistent cluster density

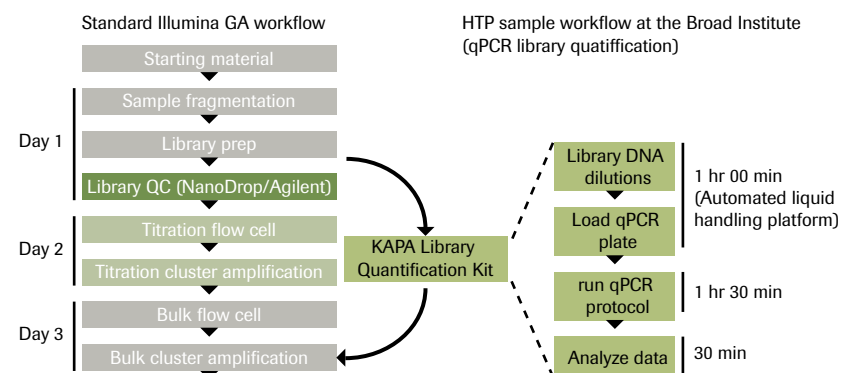
### Efficient amplification of a wide range of templates during qPCR

Traditional qPCR reagents are optimized for short amplification targets; longer targets, unbalanced GC-content, and problematic secondary structures may result in low

amplification efficiency and unreliable quantification of some library molecules. To address the demands of quantifying complex DNA libraries, Kapa Biosystems has engineered a DNA polymerase specifically for SYBR® Green-based qPCR, enabling efficient amplification of targets that present a challenge to wild-type enzymes. KAPA Library Quantification Kits contain this engineered polymerase to ensure robust amplification of longer fragments, across a broad range of GC-content, required for accurate library quantification.

### Reliable DNA quantification standards with minimal variability from lot-to-lot

## qPCR Library Quantification results in streamlined workflows



# KAPA Library Amplification Kits

## *The gold standard for NGS library amplification*



KAPA HiFi has become the enzyme of choice for NGS library amplification due to its ability to amplify complex DNA populations with high fidelity, high efficiency, decreased PCR duplication rates and very low bias. This results in lower duplication rates and improved coverage of GC- and AT rich regions, promoters, low complexity and other challenging regions in all NGS library construction workflows requiring library amplification.

In addition to the standard library amplification formulation, KAPA HiFi is available in a unique real-time formulation, for applications that demand precise control over library amplification. A uracil-tolerant variant, KAPA HiFi Uracil+ is also available for the high-efficiency, high-fidelity, low-bias amplification of libraries constructed from bisulfite-treated DNA.

### Your benefit

#### **Achieve the lowest amplification bias and duplication rates**

- Lower amplification bias result in improved representation of all library fragments and sequence regions
- High-efficiency amplification leads to fewer amplification cycles and lower PCR duplicates
- Less additional next-generation or Sanger sequencing needed to complete genomes

#### **Improve coverage of GC- and AT-rich regions**

- Lower amplification bias improves coverage uniformity of GC- and AT-rich regions, promoters, low complexity and other challenging regions
- Improved overall coverage and coverage uniformity observed on both Illumina and Ion Torrent™ sequencing platforms

### Exercise precise control over library amplification

- KAPA Real-Time Amplification Kits allow for library amplification to be observed in real time
- Terminate amplification at the optimal point for individual samples
- Optimize library amplification parameters for higher throughput workflows

### Product characteristics

#### **Improved amplification of GC- and AT-rich genomic regions**

- Reduced enzyme bias resulting in improved sequencing coverage
- High fidelity

# KAPA hgDNA Quantification and QC Kits

## *Quality matters*

KAPA hgDNA Quantification and QC Kits contain all the reagents needed for the qPCR-based quantification and quality assessment of human genomic DNA samples prior to NGS library construction.

Kits contain KAPA SYBR® FAST qPCR Master Mix, optimized for high-performance SYBR Green I-based qPCR. Further, they contain a pre-diluted set of DNA standards and primer premixes targeting different portions of a highly conserved single-copy human locus. Absolute quantification is achieved with the primer pair defining the shortest fragment, whereas the additional primers are used to derive information about the amount of amplifiable template in the DNA sample. Quality scores (or Q-ratios) generated with the kit may be used to predict the outcome of library construction, or tailor workflows for samples of variable quality, particularly FFPE DNA. The method is easy to automate and can be applied to any process or workflow that requires accurate quantification of dilute DNA samples, or samples that may contain a high proportion of DNA that is recalcitrant to PCR amplification.

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### Your benefit

#### Obtain concentration and quality information with a single assay

- Allows for absolute quantification of dilute DNA samples
- Quantification with an additional primer pair provides a Q-ratio that is indicative of sample quality

#### Employ quality scores in the analysis of NGS library construction workflows

- Q-ratios can provide valuable insights into the bottlenecks in NGS library construction workflows
- For FFPE samples, library and sequence quality is primarily limited by inefficient conversion of input DNA to adapter-ligated library

#### Obtain actionable data for sample preparation with FFPE DNA

- Q-ratios correlate with key sequencing metrics such as duplication rates and mean target coverage
- FFPE samples with a Q score >0.4 yield libraries of acceptable quality when processed in standard sample preparations for target capture

*Data on file.*



### Product characteristics

- Reliably quantify low concentration DNA samples
- QC variable-quality DNA such as FFPE
- Predict success of library construction, post-amplification yield and mean insert size

# NEW KAPA Accessories

## Attract what matters

**KAPA Pure Beads** offer a tunable and highly consistent solution for reaction purification and size selection in DNA and RNA next-generation sequencing library construction workflows.

### Your benefit

#### Seamless integration into NGS workflows

- Compatible with all KAPA DNA and RNA library preparation protocols
- Achieve equivalent yields and size distribution in comparison to Agencourt® AMPure® XP
- Readily incorporated into existing automation applications

#### Tunable and highly reproducible size selection

- Obtain consistent library size distributions
- Flexible implementation at various points during library construction
- Adjustable size selection parameters to achieve desired library sizes

### Product characteristics

- High recovery of single- and double-stranded DNA (1 ng – 5 µg) in a single cleanup
- Fast and efficient cleanups to remove unwanted reaction components
- Easy substitution into bead-based workflows
- Enables adjustable size selection
- Automation friendly

### KAPA single-indexed adapter kits

contain high-quality, ready-to-use adapters for Illumina® library construction. Each adapter includes a single, 6-nt index (barcode) for multiplexed sequencing applications. KAPA Single-Indexed Adapters are available in two concentrations, and are compatible with all KAPA library preparation kits for DNA and RNA sequencing applications.

KAPA Single-Indexed Adapters undergo extensive qPCR- and sequencing-based functional and QC testing to confirm:

- optimal library construction efficiency
- minimal levels of adapter-dimer formation
- nominal levels of barcode cross-contamination

### Product selection guide

| Kit                                                  | Recommended Adapter Concentration by Input |                          |
|------------------------------------------------------|--------------------------------------------|--------------------------|
|                                                      | 30 µM                                      | 1.5 µM                   |
| KAPA HyperPlus and Hyper Prep Kits                   | ≥5 ng – 1 µg                               | <5 ng                    |
| KAPA HTP or LTP “with-bead” Library Preparation Kits | ≥100 ng*                                   | ≤100 ng*                 |
| KAPA Library Preparation Kits                        | all inputs (1 – 5 µg)                      | not recommended          |
| KAPA Stranded RNA-Seq Kits with RiboErase            | not recommended                            | all inputs               |
| KAPA Stranded RNA-Seq and mRNA-Seq Kits              | not recommended                            | all inputs and workflows |

\* For 100 ng input the recommended adapter concentration depends on average insert size

For Research Use Only.

Not for use in diagnostic procedures.

Data on file.

# KAPA RNA HyperPrep Kits

## Single-Day RNA



The KAPA RNA HyperPrep Kits utilize novel chemistry that enables the combination of enzymatic steps and fewer reaction purifications, resulting in a truly streamlined solution for the preparation of high-quality RNA-seq libraries. The strand-specific workflow is flexible—supporting library construction from lower-input amounts and degraded samples—and is compatible with both mRNA capture and ribosomal depletion. Kits contain all reagents required for RNA enrichment (if performed) and library preparation, with the exception of KAPA Adapters (available separately).

### Your benefit

#### Single-tube, single-day library prep

- Reduce hands-on and overall time through fewer enzymatic and reaction cleanup steps
- Produce strand-specific, sequencing-ready libraries from input RNA in approximately 4 hours
- Complete entire workflow – inclusive of mRNA capture or ribosomal depletion – in a standard workday
- Achieve high throughput and consistency with an automation-friendly workflow

For Research Use Only.  
Not for use in diagnostic procedures.

### Flexible workflow options

- Use the KAPA RNA HyperPrep Kit as a standalone workflow, or combine with either the mRNA capture or KAPA RiboErase (HMR) ribosomal RNA depletion modules

### Enable a variety of strand-specific applications

- Input less starting material than other commercially-available workflows
- Generate high-quality libraries – even with degraded samples, such as FFPE

### Sequence what matters

- Waste fewer reads due to the combination of rRNA carryover and PCR duplicates
- Identify more unique transcripts and genes with equivalent sequencing

### Achieve increased coverage uniformity

- Obtain more uniform distribution of reads across transcripts
- Improve coverage of difficult GC-rich regions

Data on file.

### Generate high-quality libraries from degraded samples

- Input as little as 25 ng with FFPE samples, depending on total RNA quality
- Achieve low duplication rates and highly efficient, reproducible rRNA removal with degraded samples
- Identify more unique transcripts and genes with equivalent sequencing

### Achieve reliable results with degraded inputs

- Attain a high degree of expression correlation between paired FFPE and fresh frozen samples, providing increased confidence in sequence data accuracy

### Product characteristics

- Single-day library construction, inclusive of RNA enrichment
- High success rates with low-input and degraded samples
- Robust performance across different sample types and input amounts
- KAPA Pure Beads for reaction purifications

|                              | KAPA RNA HyperPrep Kits                                                                                                                      | KAPA RNA HyperPrep Kits with RiboErase (HMR)         | KAPA mRNA HyperPrep Kits         |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------|
| RNA Enrichment               | None                                                                                                                                         | rRNA Depletion                                       | Poly(A) Selection                |
| Input Amount                 | 1 – 100 ng into library prep                                                                                                                 | 25 ng – 1 µg into rRNA depletion                     | 50 ng – 1 µg into mRNA capture   |
| Sample Type                  | High-quality total RNA<br>Degraded or FFPE total RNA<br>Previously enriched RNA                                                              | High-quality total RNA<br>Degraded or FFPE total RNA | High-quality total RNA           |
| Species                      | Eukaryotic (animal, plant, etc.)<br>Prokaryotic (bacterial, etc.)                                                                            | Human, mouse, and rat                                | Eukaryotic (animal, plant, etc.) |
| Differentiating Applications | Whole transcriptome                                                                                                                          | Non-coding RNA<br>Whole transcriptome                | mRNA-Seq                         |
| Shared Applications          | Gene expression analysis; detection of gene fusions, isoforms, and other structural variants; novel transcript identification; SNV discovery |                                                      |                                  |

A workflow to meet a variety of needs. The KAPA RNA HyperPrep workflow is available in three formats: with mRNA capture, with KAPA RiboErase (HMR) for rRNA depletion, or with no RNA enrichment reagents. This flexibility allows users to select the workflow that best meets the needs of their specific application.

**Consultancy**  
*Laboratories*  
**Efficiency**  
*Future*  
**Quality**  
*Workflow solution*  
**cobas**  
*Continuous improvement*

## Consultancy services



Healthcare budgets are continually being squeezed, which means laboratories and other diagnostic service providers are faced not just with operational but also commercial challenges.

Budget cuts, lack of personnel, limited space, attracting new customers and promoting the value of diagnostic services – all of these factors have become important considerations.

Based on our experience in serving laboratories for IVD testing, and supported by global and local experts, Roche provides consultancy services for all areas of testing, including molecular and tissue diagnostics.

Roche's mission is not only to help implement an optimal, future-proof solution but also to work with service providers in developing a service strategy that is able to cope with the many demands of a constantly changing market.

# Consultancy services

## *Inspiring continuous improvement*

In a climate of deep financial crisis and acute competition, laboratories need to evolve their business into a model that allows them the flexibility to react efficiently to a very fast healthcare market dynamic.

The Roche consultancy team can help you build the right, fact based strategy to meet both current and future demand. They will support you in the implementation of the strategy by building LEAN efficient processes and selecting the right equipment to precisely match the clinical needs securing a direct transfer of the value of your services into outstanding patient outcome.

### Your benefit

- Empower your people to embrace continuous performance improvement
- Co-derived sustainable solutions with optimized workflow
- Rapid implementation according to fact based concept
- Increase operational efficiency and effectiveness
- A working environment with harmonised prosperity and performance
- Long term sustainable partnership

### Consultancy process

Laboratory service performance improvement:

- Identification of strategic goals
- Analysis of main streams using LEAN management methodology to derive the optimum solution
- Implementation of proposed solution through a series of rapid improvement events which will validate the proposed solutions
- Monitoring of improvement through the benefit tracker which will indicate the status in concrete KPI's for each milestone



### A structured approach

#### 6. Continuous improvement

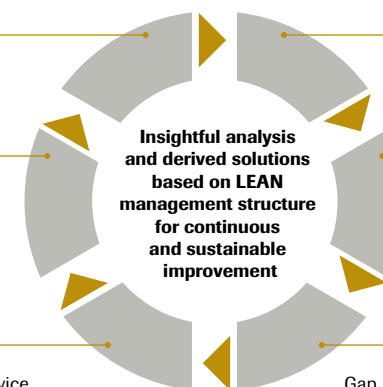
Assess on-going performance against KPIs and through benchmarking

#### 5. Implementation

Empower staff to continually look for process improvements

#### 4. Devised solution

Specifically tailored to your service  
Pilot and measure recommended improvement plan  
Derive improvement plan



#### 1. Scoping

Scope the project, define objectives and deliverables

#### 2. Fact-finding

Value stream mapping of sample journey from requesting to results delivery  
Measure process performance within the value stream maps to identify bottlenecks

#### 3. Analysis

Gap analysis to reveal difference between current state and target objectives

# Digital Services

*Easy*

**Simple**

*Engaging*

**Transparent**

*Relevant information*

**Collaboration**

## Digital Services

The consolidation and growth of medical laboratories is leading to ever-more complex processes and diagnostics systems are evolving constantly to keep pace.

Roche is developing a growing range of digital services and solutions that enable increased operational efficiency in every aspect of laboratory management.



# Roche DiaLog

## *One Roche at your Fingertips*

### Introducing Roche DiaLog

A single platform designed to give you faster and more convenient online access to all the information and services your need.

#### Your benefit

- Simplicity: One gateway to Roche
- Increased transparency of your processes
- Receive personalized support
- Stay up-to-date

#### Product characteristics

**Single point of access:** One point of entry to all Roche Diagnostics online services. Access with just one login and password from any device (PC, tablet, mobile).

**Online Services\*** are applications to support your core business.

They include:

**Technical Product Information** provides instant access to all documentation to operate instruments and reagents. It contains a powerful search engine and the ability to subscribe and receive updates and notifications on your most frequently used documents.

**e-Delivery** provides a comprehensive overview of all order-related information, including past orders, delivery notes and invoices. You can also track the connections among these.

**Live support chat** is an additional channel, which provides direct access to Roche support agents whenever needed. You can exchange pictures and documents to better and more quickly explain challenges and solutions.

And this is just the beginning. Roche DiaLog is always evolving, continuously introducing improvements and new services.



*\*Not all services are available in all countries.*

# Roche Inventory Solutions

## *Clarity at a click*



Roche Inventory Solutions is an application to manage inventory, designed for the specific needs of laboratories, optimizing supply chain processes and providing real-time management insights.

#### Your benefit



**Simplicity:** Hassle-free integration into your existing infrastructure and a user-friendly handheld that's easy to use



**Transparency:** Know your true stock levels, and the numbers behind them, to gain important insights across your entire organization



**Peace of mind:** Confidence starts with knowing you're never out of stock, reducing urgent shipments and the potential for error



**Universal:** Industry-standard technology ensures an ideal fit for any lab, regardless of size, complexity, product and vendor portfolio

#### Product characteristics

Roche Inventory Solutions can help laboratories to optimize their inventory levels, so there's never too much (expiring on the shelves), nor too little (stock-outs) providing full transparency on a key cost driver.

Roche Inventory Solutions uses an intuitive hand-held device to track deliveries and consumption.

Based on user-defined quantities, consumption patterns and order data, the system indicates upcoming shortages, can suggest or even automatically trigger an order. It works for any product from any vendor and provides management insights into the supply chain.

We have taken our proven track record in laboratory processes to create an inventory management solution that meets the specific needs of laboratories.



*\*Roche Inventory Solutions is not available in all countries.*

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|                    |                           |                 |
|--------------------|---------------------------|-----------------|
| ACCU-CHEK          | COBAS X                   | NIMBLEGEN       |
| ACCU-CHEK INFORM   | COBAS Z                   | NIMBLEDESIGN    |
| ACCU-CHEK PERFORMA | COMBUR-TEST               | OPTIVIEW        |
| ACCU-TREND         | CONFIRM                   | PATHWAY         |
| AMPERASE           | COMPANION ALGORITHM       | REALTIME READY  |
| AMPLICOR           | DISCOVERY                 | REFLOTRON       |
| AMPLILINK          | ELECSYS                   | ROCHE CARDIAC   |
| AUTOQC             | 454                       | SEPTIFAST       |
| AMPLIPREP          | GS JUNIOR                 | SEQCAP          |
| AVENIO             | GS FLX                    | SOFTCLIX        |
| BENCHMARK          | HERCEPTIN                 | TAQMAN          |
| CAREGIVER          | INFORM                    | TARCEVA         |
| CINTEC             | ISCAN COREO               | TINA-QUANT      |
| COAGUCHEK          | KAPA                      | TROPT           |
| COBAS              | LIAT                      | ULTRAVIEW       |
| COBAS B            | LIFE NEEDS ANSWERS        | URISYS          |
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| COBAS C            | MAGNA PURE                | VANTAGE         |
| COBAS E            | MICRAL-TEST               | VENTANA         |
| COBAS H            | MILLISECT                 | VENTANA ISCAN   |
| COBAS INFINITY     | MODULAR                   | VENTANA HE      |
| COBAS INTEGRA      | MODULAR ANALYTICS EVO     | VENTANA CONNECT |
| COBAS P            | MODULAR PRE-ANALYTICS EVO | VENTANA VECTOR  |
| COBAS S            | MRSA ADVANCED             | VIRTUOSO        |
| COBAS U            | MULTIPLATE                | ZELBORAF        |

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Harmony is a non-invasive prenatal test (NIPT) based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. Before making any treatment decisions, all women should discuss their results with their healthcare provider, who can recommend confirmatory, diagnostic testing where appropriate.

## Legal statement

### No warranty and no liability

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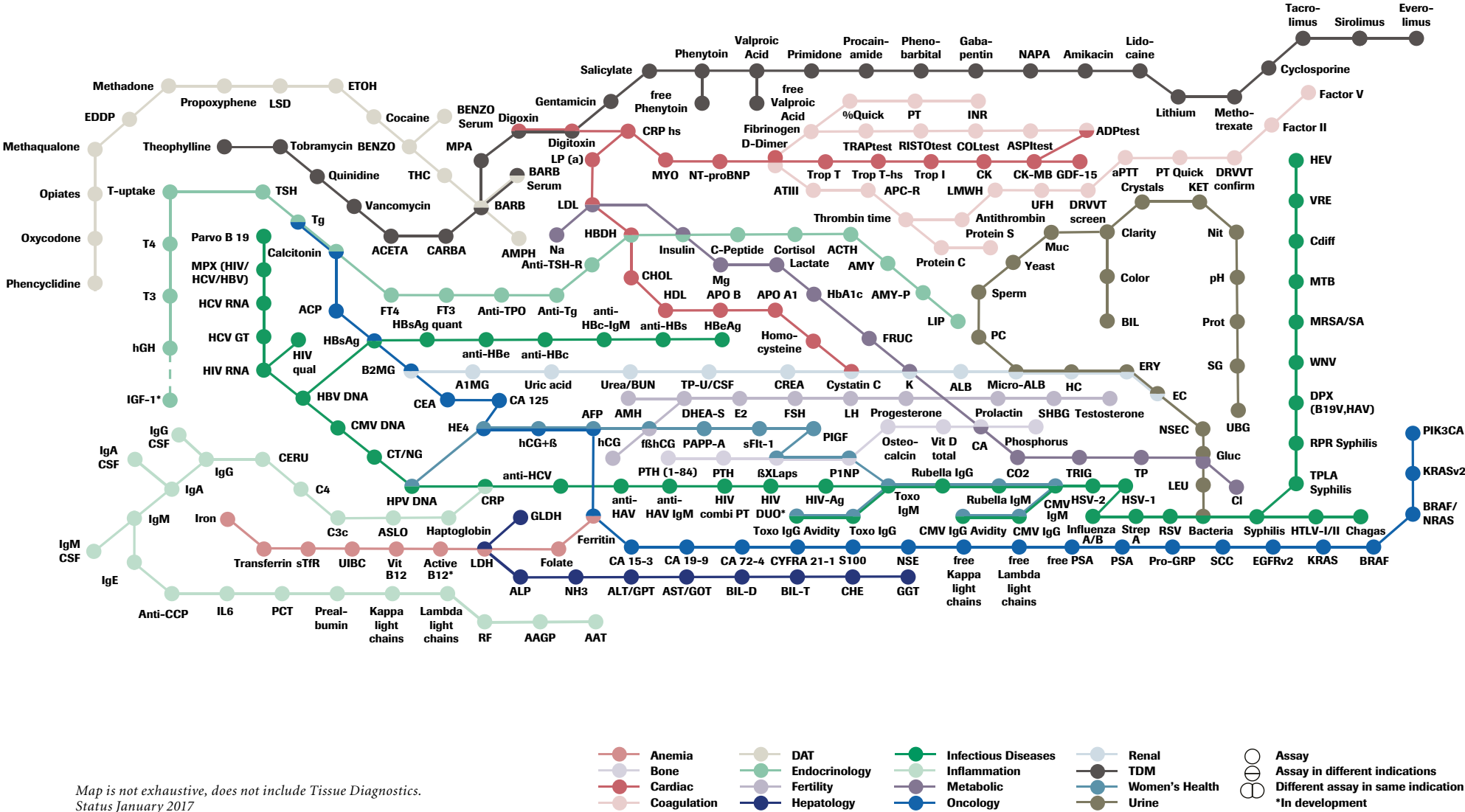
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Roche Diagnostics test portfolio





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CH-6346 Rotkreuz  
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