Products and Solutions 2015

Roche Diagnostics

THE POWER OF KNOWING

At Roche Diagnostics,
we're giving you the answers today
for a healthier tomorrow.

We give you
The Power of Knowing

Diseases raise many questions. We empower laboratories, doctors and patients with the information they need to answer these questions.

As the world leader in diagnostics, Roche's vision is simple: We believe that by providing the Power of Knowing – you are enabled to deliver the correct diagnostic result – which then allows doctors to determine the right treatment. This ultimately leads to disease prevention as well as predicting the care patients need.

You need to make decisions quickly, so our diagnostics give you the power of faster testing. You need accurate results, so our systems are built on the most reliable technologies. You want to predict and prevent disease, so we're constantly pushing the boundaries through innovation.

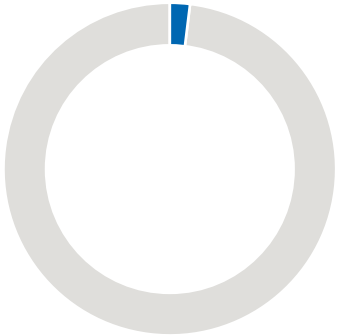
We as Roche Diagnostics are commited to delivering the best diagnostic solutions possible to improve patients lives.

We give you The Power of Knowing.

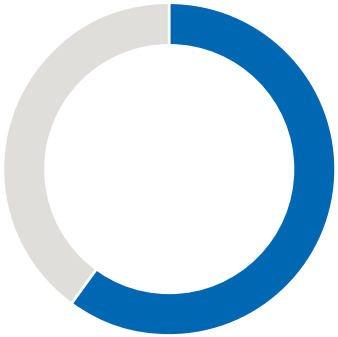
The value of in vitro diagnostics

Laboratories play a pivotal role in clinical decision-making

IVD accounts for ~ 2 % of worldwide healthcare spending



IVD influences > 60 % of clinical decision-making



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 IVD will probably get even stronger with today’s changes in healthcare. With the development of Personalized Healthcare (PHC) 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

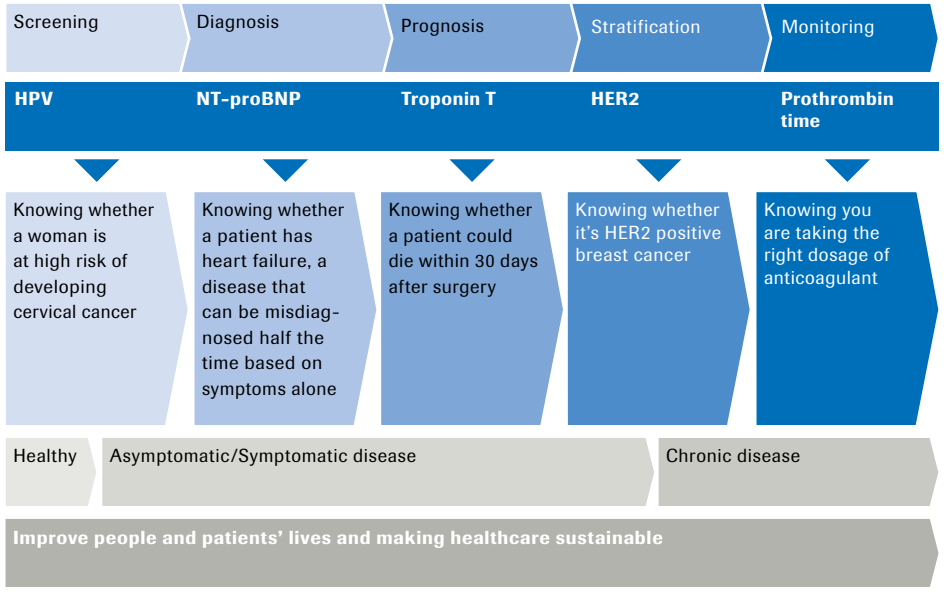
At Roche we combine technical competence with therapeutic insights.

With our leading Pharmaceuticals and Diagnostics businesses under one roof, we are better positioned to deliver Personalized Healthcare than any other company. An exchange of know-how and intellectual property, combined with our breadth of diagnostic technologies, allows for fast assay development and technical validation. A robust research diagnostic is essential to identify patient subsets for clinical trials, and once the targeted medicine is in the marketplace, the approved IVD test is used for treatment selection, response prediction and therapeutic monitoring. Personalized Healthcare is our core strategy and around 60 % of our solutions in the pipeline involve this approach.

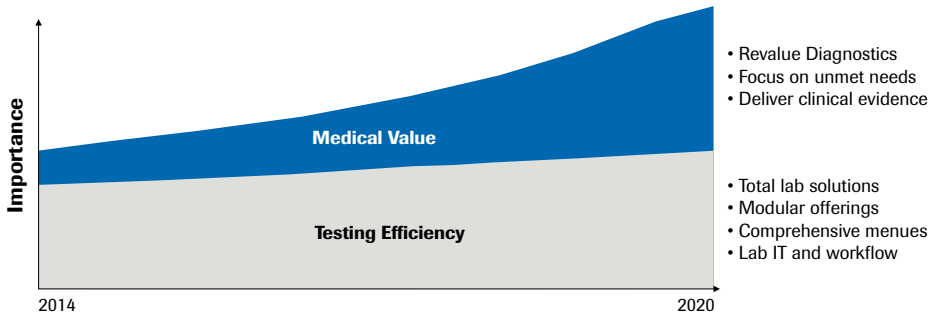
Our business strategy

Testing efficiency with high medical value along 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.



Continuum of care with examples of diagnostic tests in different disease areas and the support they give in clinical decision-making.



Roche Diagnostics differentiates itself through innovation in testing efficiency and medical value

We develop evidence-based diagnostic tests that address unmet medical needs. Our tests and highly efficient laboratory solutions help improve people's health and quality of life.

Enhancing medical value

Increasingly our efforts are concentrated on leveraging advanced scientific knowledge and technological progress to increase the medical value of our diagnostic offering. Medical value is delivered by tests for screening, diagnosis, prediction, and monitoring of disease, as well as by companion diagnostic tests used for treatment selection or predicting a patient's response to a specific drug.

We prioritize those areas with the highest unmet medical need and devote substantial resources to acquiring the necessary intellectual property to develop new tests and then demonstrate their clinical utility and health economic benefit.

Increasing testing efficiency

Roche continues to develop diagnostic solutions with improved speed, accuracy and reliability through automation, workflow, and IT integration. We enable laboratories to better manage expanding testing and data volumes. We further drive laboratory efficiency by providing our customers with modular solutions and comprehensive test menus.

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 monitor treatment progress. And, through our successful collaboration with laboratories, we provide the fast and reliable results needed for life-changing decisions.

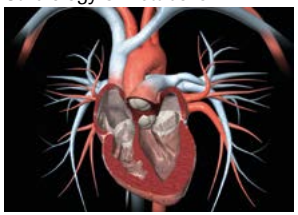
"We are committed to delivering the best possible diagnostic solutions to improve people's lives. Sustainable healthcare depends on diagnostics, and as the leader in the industry, we have the opportunity to shape healthcare delivery, to optimize resources, and to ultimately benefit society as a whole."

Roland Diggelmann, COO Roche Diagnostics

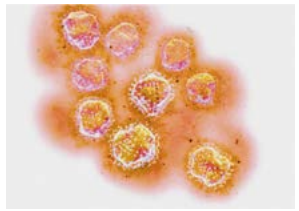
We focus on all major healthcare areas

Oncology

Cardiology & metabolism



Infectious diseases



Blood safety

Women's health

Critical care

Roche Diagnostics organizational setup
Committed to deliver innovation and excellence

Business Areas / Units
Specialized Business Areas / Units are responsible for research and development, product portfolio management, global strategic direction and marketing, along with business development in their area of expertise.



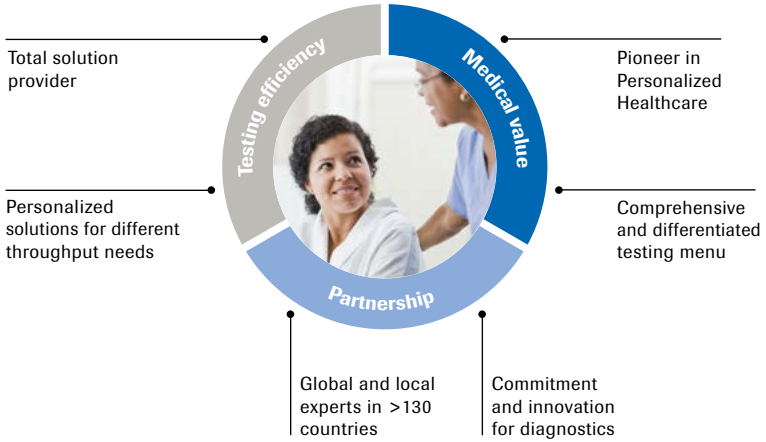

Professional Diagnostics Business Area	**Molecular Diagnostics** Business Area	**Tissue Diagnostics** Business Area	**Diabetes Care** Business Unit
Serum work area	Virology	Primary staining	Blood glucose monitoring
Point-of-care testing	Blood screening	Advanced staining	Insulin delivery
Speciality testing	Genomics / oncology	Workflow management	Diabetes workflow management
IT- and workflow	Microbiology	Digital pathology	
Custom Biotech	Women's health		
	Biochemical reagents		
	Nucleic acid purification and real-time PCR		

Sequencing Unit
Offering sequencing solutions for both clinical and life science segments

We offer a pioneering partnership to make the maximum contribution to patient care
As a leading solution provider in IVD testing, we support you as the one partner including any technologies we have in the centralized and decentralized settings, in molecular and tissue testing as well as automation and IT solutions.

In a pioneering partnership we provide not only products to increase testing efficiency and to provide medical value, but also support you with our 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 for diagnostics and the rich pipeline of differentiated solutions supports you in providing improved patient care – today but also tomorrow.



Contents

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.

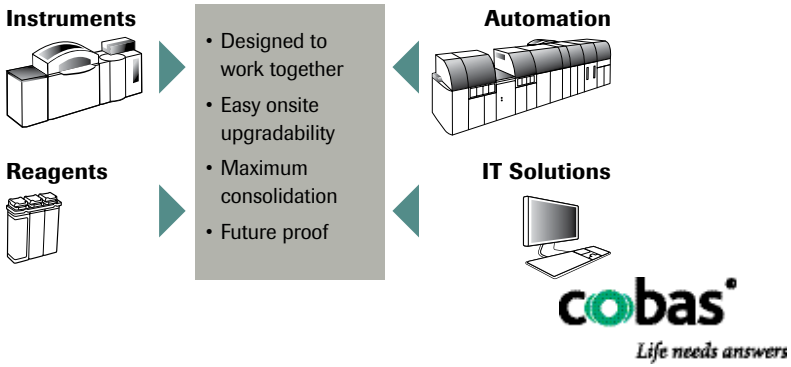
Roche's automated pre- and post-analytical solutions are integral to providing complete flexibility and process optimization. We offer a full array of stand-alone and networked solutions to meet all of your laboratories needs. From laboratory layout to full implementation of systems and services, you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

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

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. With our ready-to-use reagents and Elecsys® immunoassay and DuREL homogeneous assay technologies, we guarantee high quality results, combined with proven workflow convenience.

For more information please visit www.cobas.com



cobas® modular platform

Flexible family concept for tailormade 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 prepatation

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

- Unique, 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. STAT assays 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 21,500 **cobas** modular platform system installations 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 120 assays and applications on the clinical chemistry platform, ready-to-use in **cobas c** packs
- Almost 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 602>*

>100 configurations

cobas 6000 analyzer series
Mid volume

<c 501> *<e 601>*

7 configurations

cobas 4000 analyzer series
Low volume

<c 311> *<e 411>*

3 configurations

cobas®
Life needs answers

cobas® 8000 modular analyzer series
Intelligent LabPower

www.cobas.com

The **cobas** 8000 modular analyzer series is designed for high workload laboratories with a throughput of 2.5 to 15 million tests per year. A modular configuration consists of a core unit, an optional ISE unit (**cobas** ISE module), and up to four analytical modules: high throughput clinical chemistry modules (**cobas c** 702 and **cobas c** 701), medium throughput clinical chemistry module (**cobas c** 502) and the immunochemistry module (**cobas e** 602).

cobas 8000 modular analyzer series acts intelligently, empowering the laboratory to improve customer and patient services.

Your benefit

Efficiency
- Maximizes walk-away time
- Optimizes cost management
- Improves sample turn-around time and availability

Productivity
- Delivers throughput with maximum consolidation power
- Manages peak times efficiently
- Increases sample capacity on board

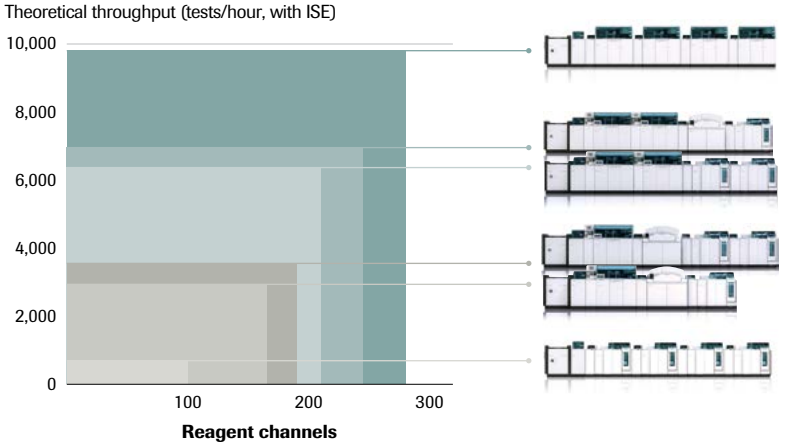
Process innovation
- Ensures unrestricted rack traffic flow for intelligent sample routing
- Optimizes workflow
- Provides confidence in results

cobas 8000 modular analyzer series

Consolidation
- Real tailor-made solutions for every lab and highly efficient change management
- Maximizes throughput and consolidation power without compromising workflow
- Consolidates very frequently requested tests with less frequently requested tests

Product characteristics
- High speed: From 170 to 680 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 100 configurations for tailored solutions with fast on-site expandability
- More than 120 clinical chemistry and almost 100 immunochemistry assays

Multidimensional modularity



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cobas® 8000 modular analyzer series

cobas 8000 modular analyzer series

1 cobas 8000 data manager
- Traceability records, for easy tracking of calibration and reagent information, offers more transparency
- User-defined, fully automated, selective rerun and reflex testing

2 Core unit
- Loading capacity of 300 samples
- Unloading capacity of 300 samples
- Throughput of up to 1,000 samples/hour
- Dedicated STAT port
- *Optional sample rotation unit*

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

4 cobas c 702 module*
- More than 120 assays and applications on the clinical chemistry platform including substrates, enzymes, proteins, DATs, and TDMs
- Throughput of up to 2,000 tests/hour
- 70 reagent channels directly accessible for pipetting
- Specimen integrity via serum indices, clot and liquid level detection
- Contact-free ultrasonic mixing

4a Reagent manager
- 10 reagent positions
- Reagent RFID reader
- Continuous reagent cassette loading and unloading during operation
- Reagent cassette decapping
- Reagent cassettes can be placed in the reagent manager at any time and as convenient

** Alternatively, cobas c 701 module can be used. It is based on the same technology and it offers the same number of channels as cobas c 702, but has no reagent manager function.*

5 cobas c 502 module
- More than 120 assays and applications on the clinical chemistry platform including substrates, enzymes, proteins, DATs, TDMs, and electrolytes
- HbA1c (whole-blood measurement)
- Throughput of up to 600 tests/hour
- 60 reagent channels directly accessible for pipetting
- Automatic reagent loading and unloading during operation
- Specimen integrity via serum indices, clot and liquid level detection
- Contact-free ultrasonic mixing

6 cobas e 602 module
- Heterogeneous immunochemistry testing with almost 100 assays for 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, liquid level, and air bubbles detection

7 Module sample buffer
- Capacity for 20 sample racks resulting in additional capacity of 100 samples per module
- Freely definable STAT positions
- Environmentally controlled compartment for 5 Auto QC racks
- Backup operation port
- Switch gates for shortcuts; gripper for moving the racks from line to line
- Random access to racks; racks can go from anywhere to everywhere

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cobas® 6000 analyzer series

The success story continues

www.cobas.com

The **cobas** 6000 analyzer series is a member of the **cobas** modular platform family. It offers medium to high workload laboratories tailor-made solutions for clinical chemistry and immunochemistry testing. Depending on the configuration, the **cobas** 6000 analyzer series achieves a throughput of up to 2.5 million tests per year. The **cobas** 6000 analyzer series is the result of vast know-how, and decades of experience, combined into one successful concept. With over 10,000 systems in operation worldwide, the **cobas** 6000 analyzer series is the most successful SWA analyzer worldwide.

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
- That you can trust and are right the first time
- Predictable turnaround time
- Peace of mind

Maximum uptime
- Highly reliable system based on more than 35 years of experience
- Superior support provided by Roche organizations worldwide

Optimized workflow
- Wide range of pre- and post-analytical solutions and complete IT solutions
- Workflow efficiency and reduced complexity

Product characteristics

High system reliability
- More than 10,000 systems in operation worldwide
- Proactive automated maintenance for over 96% uptime including maintenance on a 24/7 basis

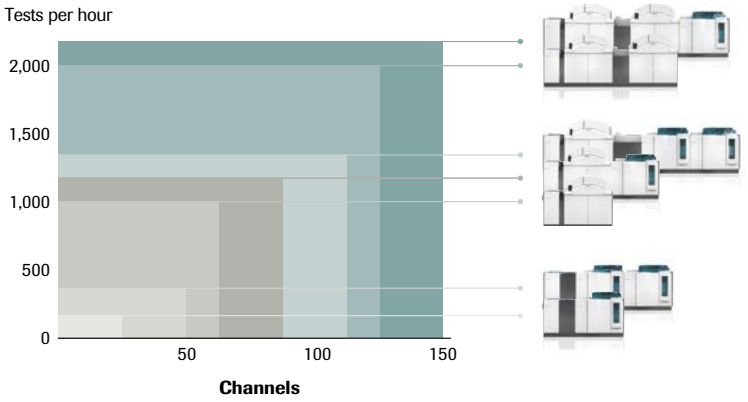
Unique reagent concept
- No preparation and no mixing required, economic usage with high stabilities and convenient kit sizes

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

Intelligent sample workflow
- Combines STAT with routine testing without disruption

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

Delivers customized solutions for various work and testing requirements



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Life needs answers

cobas® 6000 analyzer series
The success story continues

www.cobas.com

True workflow consolidation

cobas 6000 analyzer series

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

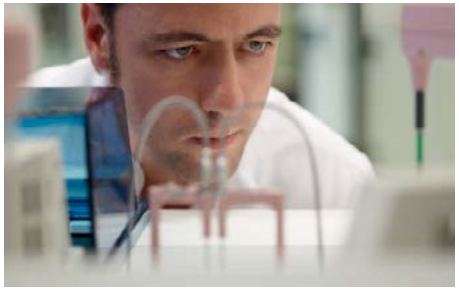
2 Rack rotor
- Capacity for 20 sample racks
- Freely definable STAT positions
- Option of three Auto QC racks
- Random access for the racks

3 cobas c 501 module
- ISE measurements (K, Na, Cl)
- More than 120 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
- Specimen integrity via serum indices, clot and liquid level detection
- 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, liquid level, and air bubble detection

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

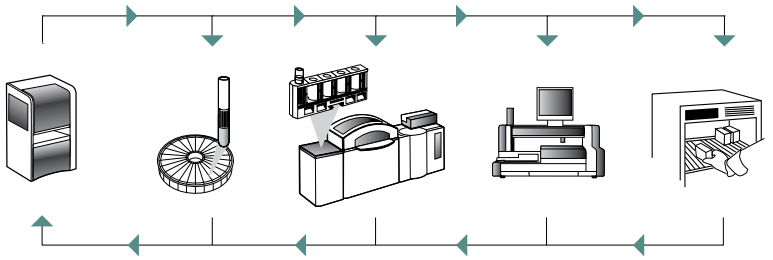
cobas p 312 pre-analytical system is the ideal companion for the cobas® 6000 analyzer series, for a fully harmonized and complete solution.



Safe and efficient workflows with minimum complexity, using a single square meter footprint. The **cobas p** 312 pre-analytical system is Roche's answer to fulfill automation needs of many small to mid-sized laboratories. It includes the necessary functionality to significantly improve laboratory organization and increase workflow efficiency. This on a single square meter.

The simplicity of this solution and the small space requirements allow its easy implementation in almost any laboratory.

The **cobas p** 312 pre-analytical system will executes the following key tasks:
- Sample registration at a single entry point
- Sorting and distribution of samples
- Recursive workflow
- Archiving



cobas®
Life needs answers

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 250 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** IT solutions 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.

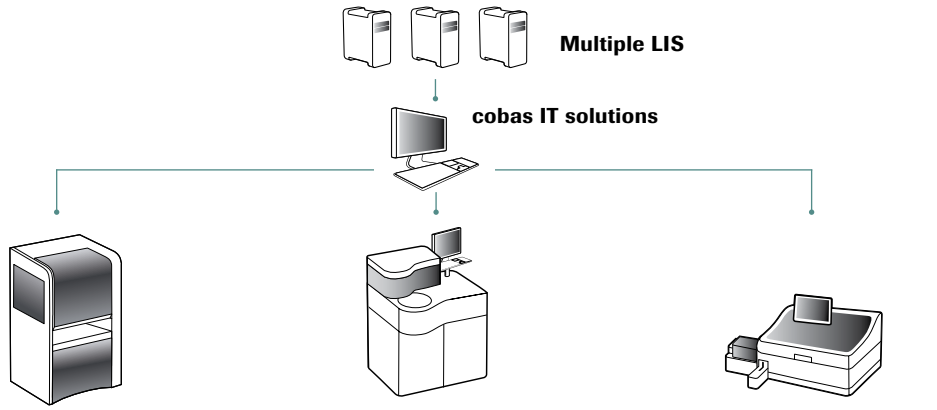
Your benefit

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
- Superior support by Roche organisations worldwide

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

cobas® 4000 analyzer series solution



cobas p 312 pre-analytical system

cobas c 311 clinical chemistry analyzer

cobas e 411 immunochemistry analyzer (rack system)

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)

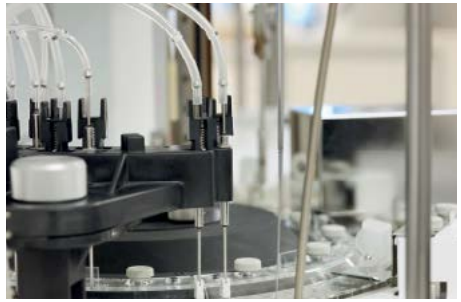
Intelligent sample workflow
- 108 sample positions with continuous random access and flexible STAT priority settings

Unique reagent concept
- Convenient and error-free 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
- Almost 100 assays available
- Throughput: up to 86 tests / h
- Superior immunoassay testing using ECL technology
- 9 min. STAT applications including Troponin, CK-MB, Myoglobin, ß-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 10,000 analyzers installed worldwide
- High uptime of 99.8 %

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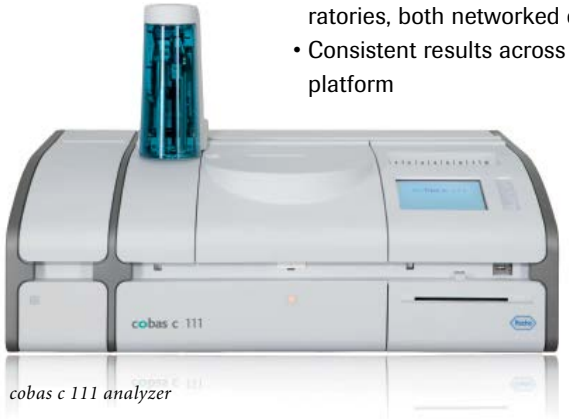
cobas c 111 analyzer

Small box. Big performance.

www.cobas.com

The **cobas c** 111 analyzer is the smallest member of the **cobas**® 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 the first time, every time

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

Maximum uptime
- Highly reliable system delivering > 99 % uptime
- Superior 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[1]

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

Network compatibility
- Ability to connect to local IT environment
- Common reagent chemistry across the **cobas**® platform

1 Bowling, J.L., Katayev, A. (2010). *Labmedicine, 41*(7): 398-402.

cobas®
Life needs answers

COBAS INTEGRA® 400 plus

The specialist in the routine laboratory

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 the first time, and every time

Increased efficiency

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

Optimized workflow

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

COBAS INTEGRA 400 plus

Product characteristics

First class performance

- More than 120 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 pipetting safeguards

Unique reagent concept

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

cobas
Life needs answers

Automation solutions
Personalized Lab Automation

www.cobas.com

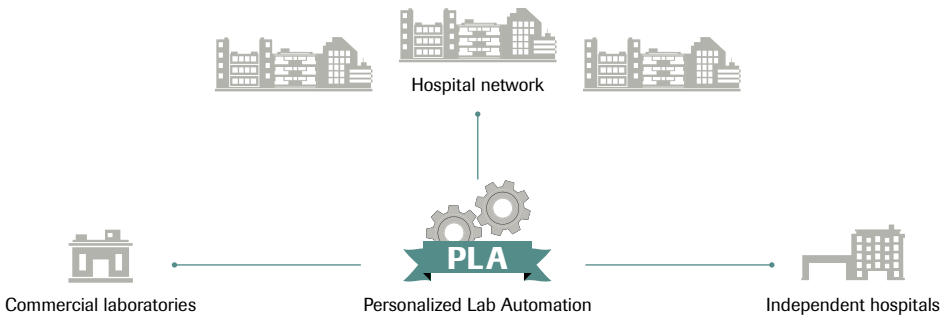
At Roche, laboratory automated solutions deliver the **quality** and **reliability** you expect, with the **personalization** required by low-, mid- and high-volume laboratories.

With the most complete portfolio in the market, Roche's Personalized Lab Automation provides the best customized solution for every lab.

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 **cobas** instruments, third-party instruments and host systems to enable efficient sample workflow
cobas infinity IT solutions	Scalable IT solutions that go beyond workflow management and operate across various lab disciplines. Serve as middleware or add LIS functionality – flexible according to customers' needs
cobas laboratory information solutions	Lab information solutions that streamline patient data and information flows across various clinical disciplines to the Hospital Information System

2. Standalone Automation

cobas p 312 pre-analytical system	A small-footprint system for sorting, decapping and archiving IVD test tubes
cobas p 512/p 612 pre-analytical systems	High throughput systems for sorting, decapping, aliquoting and re-capping of IVD test tubes
cobas p 501/p 701 post-analytical units	Refrigerated archiving systems enabling sample retrieval and add-on test management

3. Connected Automation

MODULAR® *PRE-ANALYTICS* EVO	Consolidation of analytics and process organization through integration of automation solutions
cobas 8100 automated workflow series	Fully automated solution featuring intelligent sample routing and prioritizing STAT workflow
cobas connection modules (CCM)	Connection of Standalone Automation systems to analytics and post-analytics through a fast track easy to operate

cobas
Life needs answers

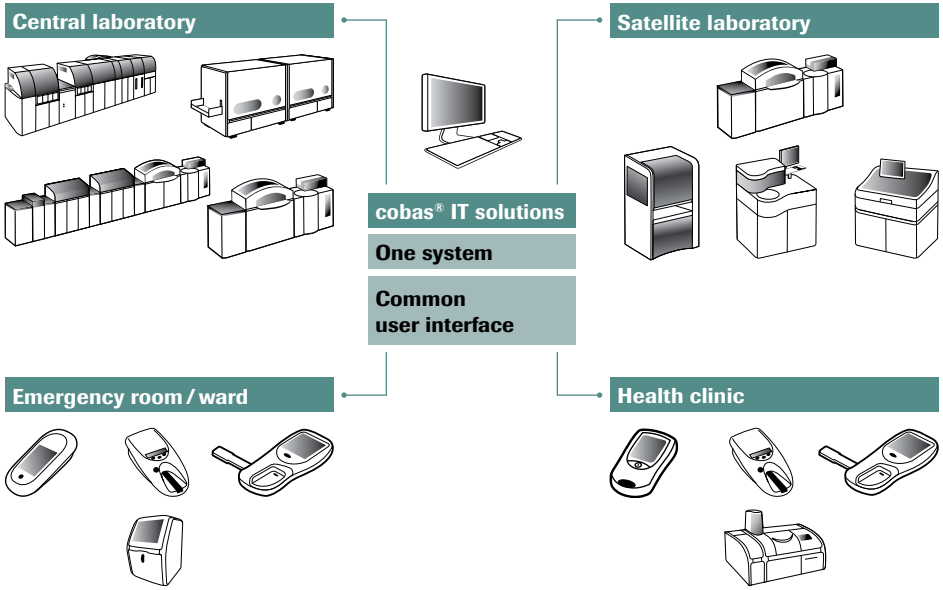
cobas® IT solutions
Centralized, decentralized and beyond

www.cobas.com

At Roche, IT is the nucleus of our diagnostics solutions. **cobas IT** solutions give you the control you need to ensure quality and efficiency across your IVD testing enterprise. For the laboratory, an integrated IT solution reduces complexity, improves efficiency and helps to streamline information to the respective recipients.

cobas IT solutions offer the flexibility to cover the specific needs of a healthcare enterprise today and in the future. Solutions range from workflow management in the core lab to complex, multi-discipline, multi-instrument and multi-site set-ups covering both workflow as well as LIS functionality where needed. Our POC IT solutions facilitate efficient and secure management of hospital point of care.

Enterprise management and control



cobas
Life needs answers

cobas® middleware solutions

Intelligent workflow management for your laboratory

www.cobas.com

cobas middleware solutions are the workflow manager for your laboratory, consolidating **cobas** 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 and **cobas IT** 3000 application).*

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

Your benefit

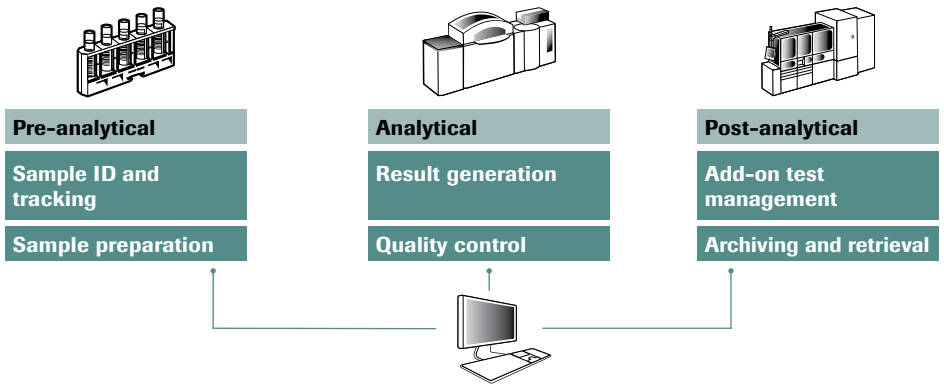
Effective use of your resources

- 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



cobas middleware solutions

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
Life needs answers

cobas® infinity IT solutions

More powerful than you can imagine

www.cobas.com

cobas infinity IT solutions are laboratory information solutions that go beyond workflow management of the core laboratory and cover information flows across various clinical disciplines. A modular architecture can serve as middleware, or add LIS (Laboratory Information System) functionality – depending on customers' needs. The fully web-based system along with modular architecture is designed to meet the specific needs of each institution and can grow together with the laboratory. To further enhance laboratory efficiency, this system integrates a consistent look-and-feel user interface and personalized work areas in which you can tailor information availability to select user groups.

Your benefit

Simplicity – see what is needed

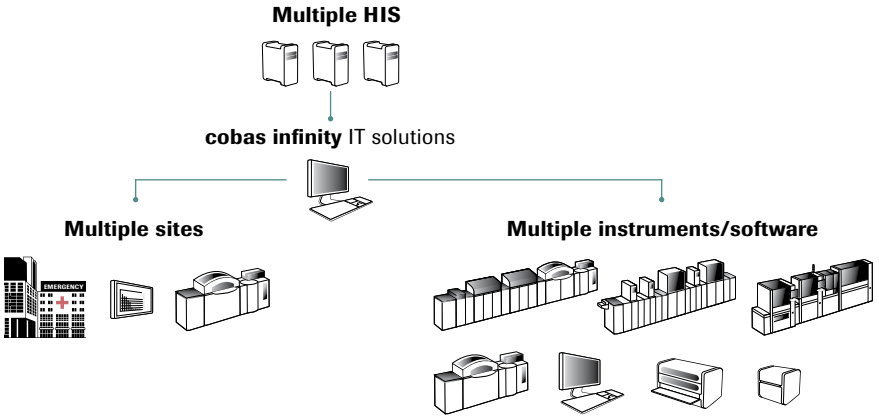
- Consistent look and feel across all user interfaces helps staff learn quickly and promotes better communication in and across your laboratories
- Personalized work area concept that enables information availability to be tailored to selected user groups, enhances efficiency and streamlines routine works in your laboratory

Flexibility – see what is possible

- Modular architecture supported by fully web-based technology gives you a scalable solution that meets your current and future needs
- Comprehensive coverage of multiple laboratory disciplines and expandability from a single site to multisite networks gives you great flexibility

Confidence – see what is important

- Dashboard shows you the key performance of the laboratory almost in real time. The visual display supports performance monitoring of your laboratory team
- Consistency through managed validation and workflow supported by intelligent rule engine aids quality management in your laboratory



Product characteristics

- **cobas® infinity** general lab module – Designed for core laboratory disciplines with personalized work areas offering specialized functionalities in Biochemistry, Immunology, Hematology, Serology and Urinalysis – includes Performance Dashboards for direct and clear monitoring of TAT.
- **cobas infinity** lab flow module – dedicated sample workflow module for efficient testing across integrated solutions.
- **cobas infinity** emergency lab module focuses on the management of emergency samples.
- **cobas infinity** microbiology module – Touch screen technology for ease of use and a paperless work environment.
- **cobas infinity** lab link module enabling ordering and result viewing across wards, physician offices, collection centers and satellite labs.
- **cobas infinity** total quality management – Maintain laboratory accreditation with document, audit, issue, indicator and equipment management – recording any issues and subsequent corrective actions.

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

cobas
Life needs answers

cobas® laboratory information systems

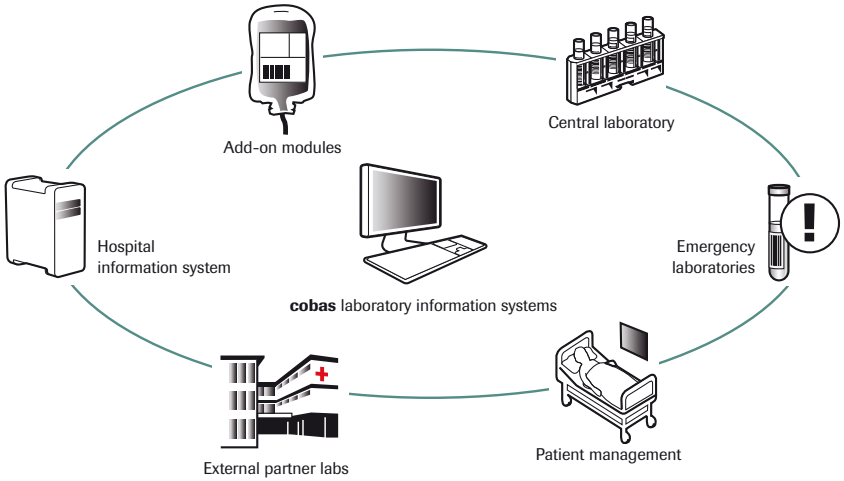
Streamline patient data and information flows

www.cobas.com

The **cobas** laboratory information systems goes beyond the core laboratory workflow management, streamlining patient data and information flows across various clinical disciplines to the Hospital Information System. Different IT solutions from Roche are available to meet regional customer needs (**cobas IT** 5000 application, SWISSLAB system and **cobas infinity** IT solutions).*

The software enhances laboratory operations by providing an end-to-end solution from orders to reports.

Data-mining capabilities allow you to explore your operational information to maximize medical value.



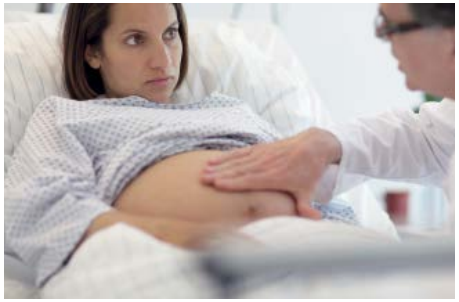
Your benefit

Allows a patient-centric approach

- Consolidated patient data across different clinical disciplines: chemistry, hematology, microbiology
- Access to results in any location
- Patient-based presentation of all results, including previous values
- Display of individual and cumulative findings
- Configurable plausibility data check for test results

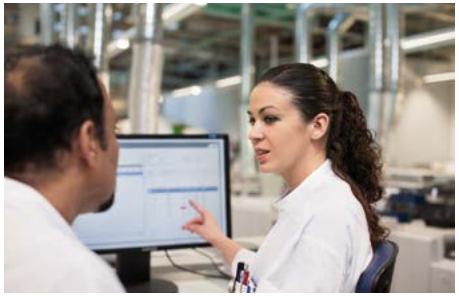
Provide decision support

- Guidance to enable clinical decision-making beyond just delivering results
- Support in-depth statistical analysis to manage laboratory efficiency in terms of KPI, such as turn-around times
- Dynamic access to data stored in the database in real time



Demonstrate working excellence

- Empowers the lab as a trusted partner for doctors
- Consistency of management across the elements of your Roche platform



Communicate with hospital information systems

- Automated, real-time download of patient orders and demographics
- Wide-ranging, flexible search and sort options
- Multi-site support

Modular design

- Dedicated modules designed for specific workflows in specific clinical disciplines
- Allows dedicated modular usage based on a common database

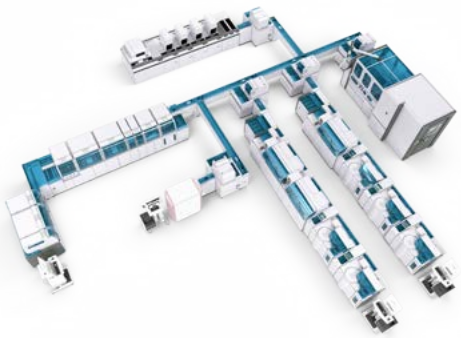
Please check with your local Roche representative for availability of the IT solution in your country.

cobas
Life needs answers

Standalone and connected automation
Personalized solutions for every lab

www.cobas.com

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



Connected Automation, besides having all the benefits of Standalone Automation, adds transportation by physically connecting pre-analytics, analytics and post-analytics

Your benefit

Quality comes first

At an early pre-analytical stage, automation solutions from Roche 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

- Improving patient care by offering reliable results within predictably short turn-around times, even during peak workflows

cobas p 312 pre-analytical system
The new dimension of laboratory automation

cobas p 312 pre-analytical is a standalone solution offering maximum efficiency with minimal space requirements. In less than 1 m², **cobas p** 312 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
- Throughput up to 450 samples / hour
- Registration of samples
- Selective decapping of samples
- Archiving of samples
- Flexible and freely definable input / output sorting area

cobas p 312 pre-analytical system

cobas
Life needs answers

cobas p 512 and cobas p 612 pre-analytical systems

Professional management of laboratory processes

www.cobas.com

cobas p 512 and **cobas p** 612 pre-analytical systems are standalone solutions for high-throughput laboratories.

cobas p 612 differs from **cobas p** 512 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

Comprehensive centrifugation

The **cobas** p 471 and **cobas p** 671 centrifuge units offer a extensive and flexible front-end automation solution.

- Spinning with high g-force
- Flexible parameters
- Self-balanced function
- Start timer

Convenient sample loading

- Single point of entry
- Optional bulk loading – Bulk loader module can be connected to the **cobas p** 471 single centrifuge or to the pre-analytical system
- No manual sample handling

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

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 1,100 samples / hour
- Registration of primary samples
- Orientation of barcode in a "good-to-read" position
- Tube type identification
- Sample volume and quality check
- Early detection and sorting of tubes with errors and issues
- Selective decapping of sample tubes
- **cobas p** 612 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

Complete configuration: cobas p 512 pre-analytical system with single centrifuge cobas p 471 and bulk loader module

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

cobas
Life needs answers

cobas p 501 and cobas p 701 post-analytical units

The automated archive

www.cobas.com

Product characteristics

- Can be operated as standalone or connected to **cobas**® 8100, **cobas** connection modules and **MODULAR**® *PRE-ANALYTICS* **EVO**
- Storage throughput: up to 400 tubes / hour
- Retrieval throughput: up to 40 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

cobas p 501 post-analytical unit

cobas p 701 post-analytical unit

MODULAR® *PRE-ANALYTICS* EVO

Pioneer in laboratory efficiency

MODULAR *PRE-ANALYTICS* **EVO** is a modular system for the fully automated processing of primary samples from centrifugation to archiving, including automated delivery of samples to **cobas**® 6000 analyzer series and **cobas** 8000 modular analyzer series. There are three models, plus options and upgrades to provide the greatest flexibility. Thus, **MODULAR** *PRE-ANALYTICS* **EVO** meets a wide range of demands with regard to sample throughput, laboratory layout, instruments connected and functionalities.

Your benefit

Full automation

- From sample entry to archive
- Reduced biohazard risks for personnel

Consolidation of analytics

- Reduced complexity with fewer analyzers and fewer process steps

Process organization

- Streamlining of processes by providing IT networking of all components along with complete data and workflow management

Integration by automation

- Shorter, predictable TAT
- Reduction of labor-intensive processes

cobas
Life needs answers

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 result, 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

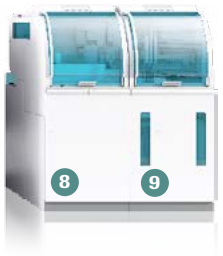
Product characteristics

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

Input station

Aliquot station



1. Restopper flex-cap / screw cap
2. Add-on / output buffer
3. Output buffer / sorter
4. Input buffer
5. Automatic centrifuge unit
6. Sample check module
7. Destopper
8. Barcode labeler / tube feeder
9. Aliquot module

cobas
Life needs answers

cobas® connection modules (CCM)

Everything designed to work together as one

www.cobas.com

cobas connection modules (CCM) 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

Convenient sample loading

- Single point of entry
- Optional bulk loading – Bulk loader module can be connected to **cobas p** 471 single centrifuge, or to the pre-analytical system
- No manual sample handling

Quality comes first

At an early pre-analytical stage, automation solutions from Roche 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 workflows

Multidisciplinary connectivity

- Molecular Diagnostics – **cobas** 6800 / 8800 system
- Serum Work Area – **cobas** 6000 analyzer series and **cobas** 8000 modular analyzer series
- Hematology – Sysmex
- Post-analytics – **cobas p** 501/ **cobas p** 701 post-analytical unit

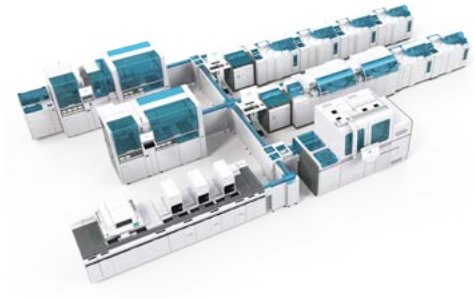
Please note that not all versions are distributed in all countries. For further details contact your local affiliate.

Possible solutions

The fast track to sample flow efficiency

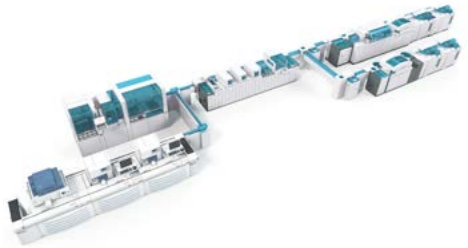
CCM is able to connect pre-analytical systems to multiple disciplines including Molecular Diagnostics.

CCM 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.



The flexible combination with MODULAR® PRE-ANALYTICS EVO

The connection of **cobas p** 512 or **cobas p** 612 pre-analytical system to **MODULAR** *PRE-ANALYTICS* **EVO** makes it possible to maximize the throughput of existing MPA systems. Additionally, this configuration allows you to integrate hematology connecting Sysmex® HST or XN hematology analyzers.



cobas
Life needs answers

Overview of Serum Work Area tests

www.cobas.com

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Anemia				
Ferritin		•	•	•
Folate			•	
Folate RBC			•	
Iron	•	•		•
Iron binding capacity – Unsaturated		•		•
Soluble transferrin receptor		•		•
Transferrin		•		•
Vitamin B12			•	
Lactate Dehydrogenase	•	•		•
Bone				
Calcium	•	•		•
N-MID Osteocalcin			•	
P1NP			•	
Phosphorus	•	•		•
PTH			•	
PTH (1-84)			•	
β-CrossLaps			•	
Vitamin D total			•	
Cardiac				
Apolipoprotein A1		•		•
Apolipoprotein B		•		•
Cholesterol	•	•		•
CK	•	•		•
CK-MB	•	•		•

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
CK-MB (mass)			•	
CK-MB (mass) STAT			•	
CRP hs	•	•		•
Cystatin C		•		•
D-Dimer	•	•		•
Digitoxin		•	•	•
Digoxin		•	•	•
HDL Cholesterol direct	•	•		•
Homocysteine	•	•		•
Hydroxybutyrate Dehydrogenase		•		•
LDL Cholesterol direct	•	•		•
Lipoprotein (a)		•		•
Myoglobin		•	•	•
Myoglobin STAT			•	
NT-proBNP			•	
NT-proBNP STAT			•[1]	
Troponin I			•[1]	
Troponin I STAT			•	
Troponin T hs			•	
Troponin T hs STAT			•	
Coagulation				
AT III		•		•
D-Dimer	•	•		•
Drugs of Abuse Testing				
Amphetamines (Ecstasy)		•		•
Barbiturates		•		•

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Barbiturates (Serum)				•
Benzodiazepines		•		•
Benzodiazepines (Serum)				•
Cannabinoids		•		•
Cocaine		•		•
Ethanol		•		•
Fentanyl		•[6]		
LSD		•[2]		•
Methadone		•		•
Methadone metabolites (EDDP)		•		•
Methaqualone		•		•
Opiates		•		•
Oxycodone		•[3]		•
Phencyclidine		•		•
Propoxyphene		•		•
Endocrinology				
Amylase – pancreatic	•	•		•
Amylase – total	•	•		•
ACTH			•	
Anti-Tg			•	
Anti-TPO			•	
Anti-TSH-R			•	
Calcitonin			•	
Cortisol			•	
C-Peptide			•	

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
FT3			•	
FT4			•	
hGH			•	
Hydroxybutyrate Dehydrogenase		•		•
IGF-1			•	
Insulin			•	
Lipase	•	•		•
PTH STAT			•	
T3			•	
T4			•	•
Thyreoglobulin (TG II)			•	
Thyreoglobulin confirmatory			•	
TSH			•	
T-uptake			•	•
Fertility				
Anti-Mullerian Hormone			•	
DHEA-S			•	
Estradiol			•	
FSH			•	
hCG			•	
hCG plus beta			•	
LH			•	
Progesterone			•	
Prolactin			•	
SHBG			•	

[1] *not on cobas e 411*
[2] *not on cobas c 311*
[3] *not on cobas c 701 and c 702*
[4] *in development*
[5] *launch in 2015*
[6] *only on cobas c 501 and c 502*

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

cobas® *Life needs answers*

	cobas c 111 analyzer	**cobas®** modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Testosterone			•	
Hepatology				
Alkaline phosphatase (IFCC)	•	•		•
Alkaline phosphatase (opt.)		•[3]		•
ALT/GPT with Pyp		•		•
ALT/GPT without Pyp	•	•		•
Ammonia	•	•		•
AST/GOT with Pyp	•	•		•
AST/GOT without Pyp	•	•		•
Bilirubin – direct	•	•		•
Bilirubin – total	•	•		•
Cholinesterase Acetyl		•[3]		
Cholinesterase Butyryl		•		•
Gamma Glutamyl Transferase	•	•		•
Glutamate Dehydrogenase		•		•
HBeAg			•	
HBsAg			•	
Lactate Dehydrogenase	•	•		•
Infectious diseases				
Anti-HAV			•	
Anti-HAV IgM			•	
Anti-HBc			•	
Anti-HBc IgM			•	
Anti-HBe			•	
HBeAg			•	
Anti-HBs			•	

	cobas c 111 analyzer	**cobas®** modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
HBsAg			•	
HBsAg confirmatory			•	
HBsAg quantitative			•	
Anti-HCV			•	
Chagas[4]			•	
CMV IgG			•	
CMV IgG Avidity			•	
CMV IgM			•	
HIV combi PT			•	
HIV-Ag			•	
HIV-Ag confirmatory			•	
HSV-1 IgG			•	
HSV-2 IgG			•	
HTLV 1 and 2[4]			•	
Rubella IgG			•	
Rubella IgM			•	
Syphillis			•	
Toxo IgG			•	
Toxo IgG Avidity			•	
Toxo IgM			•	
TPLA (Syphilis)		•[6]		
Inflammation				
Anti-CCP			•	
ASLO		•		•
C3c		•		•
C4		•		•

	cobas c 111 analyzer	**cobas®** modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Ceruloplasmin		•		•
CRP (Latex)	•	•		•
Haptoglobin		•		•
IgA		•		•
IgE			•	
IgG		•		•
IgM		•		•
Immunglobulin A CSF		•		
Immunglobulin M CSF		•		
Interleukin 6			•	
Kappa light chains		•		•
Kappa light chains free		•[6]		•
Lambda light chains		•		•
Lambda light chains free		•[6]		•
Prealbumin		•		•
Procalcitonin			•	
Rheumatoid factor		•		•
α1-Acid Glycoprotein		•		•
α1-Antitrypsin		•		•
Metabolic				
Bicarbonate (CO2)	•	•		•
Calcium	•	•		•
Chloride	•	•		•
Fructosamine		•		•
Glucose	•	•		•
HbA1c (hemolysate)	•	•[3]		•

	cobas c 111 analyzer	**cobas®** modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
HbA1c (whole blood)	•	•[3]		•
Insulin			•	
Lactate	•	•		•
Magnesium	•	•		•
Potassium	•	•		•
Sodium	•	•		•
Total Protein	•	•		•
Triglycerides	•	•		•
Triglycerides Glycerol blanked		•		
Vitamin D total			•	
Oncology				
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		•[6]		•
Lambda light chains free		•[6]		•
NSE			•	
proGRP			•	

[1] *not on cobas e 411*
[2] *not on cobas c 311*
[3] *not on cobas c 701 and c 702*
[4] *in development*
[5] *launch in 2015*
[6] *only on cobas c 501 and c 502*

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

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Life needs answers

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Oncology				
PSA free			•	
PSA total			•	
SCC[5]			•	
S-100			•	
Thyreoglobulin (TG II)			•	
Thyreoglobulin confirmatory			•	
β2-Microglobulin		•		
Renal				
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 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Therapeutic drug monitoring				
Acetaminophen (Paracetamol)		•		•
Amikacin		•		•
Carbamazepine		•		•
Cyclosporine			•	•
Digitoxin		•	•	•
Digoxin		•	•	•
Everolimus[5]			•	
Gabapentin[6]		•		
Gentamicin		•		•
Lidocaine				•
Lithium		•		**ISE**
Methotrexate[6]		•		
Mycophenolic acid		•		•
NAPA		•		•
Phenobarbital		•		•
Phenytoin		•		
Phenytoin free				•
Primidone				•
Procainamide		•		•
Quinidine		•		•
Salicylate		•		•
Sirolimus[5]			•	
Tacrolimus			•	

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
Theophylline		•		•
Tobramycin		•		•
Valproic acid		•		
Valproic acid free				•
Vancomycin		•		•
Women's health				
Anti-Mullerian Hormone			•	
AFP			•	
β-Crosslaps			•	
Estradiol			•	
FSH			•	
free ßhCG			•	
hCG			•	
hCG plus beta			•	
hCG STAT			•	
HE4			•	
LH			•	
N-MID Osteocalcin			•	
PAPP-A			•	
PlGF			•	
sFlt-1			•	
P1NP			•	
Progesterone			•	
Prolactin			•	

	cobas c 111 analyzer	**cobas**® modular platform: c module	**cobas** modular platform: e module	COBAS INTEGRA® ***400 plus***
SHBG			•	
Testosterone			•	
CMV IgG			•	
CMV IgG Avidity			•	
CMV IgM			•	
Rubella IgG			•	
Rubella IgM			•	
Toxo IgG			•	
Toxo IgG Avidity			•	
Toxo IgM			•	

[1] not on cobas e 411
[2] not on cobas c 311
[3] not on cobas c 701 and c 702
[4] in development
[5] launch in 2015
[6] only on cobas c 501 and c 502

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

cobas®
Life needs answers

ECL – unique immunoassay technology
Still light years ahead

www.cobas.com

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 superior 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

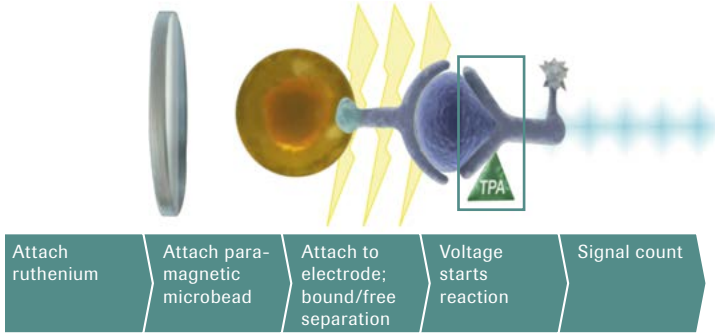
Precision and sensitivity
- Superior low-end detection limits
- Excellent precision over the entire measuring range

Product characteristics

ECL is an innovative technology with distinct advantages
- Extremely stable non-isotopic label for long onboard stability and economic use of reagents
- High sensitivity for patient-friendly low sample volumes and fast results due to short turnaround times
- Broad measuring range for fewer repeats and a streamlined workflow
- High precision over the entire measuring range for reliable results
- Applicable for the detection of all analytes for a broad assay menu including innovative markers

Elecsys® diagnostic markers with advanced assay design
- Robustness against interference (e.g. HAMA) due to a multidimensional approach: blocking proteins, fragmented catcher or tracer antibodies or chimeric antibodies
- Reference-traceable results with high lot-to-lot stability allow accurate long-term monitoring
- Unique reagent concept with ready-to-use, fail-safe and convenient reagent packs (**cobas e** pack) for consistent handling
- Consistently precise results across **cobas**® immunochemistry platforms based on standardized reagents and low inbuilt variability

ElectroChemiLuminescence (ECL) technology



cobas
Life needs answers

Turbidimetry – superior homogeneous immunoassay 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, immunoelectrophoresis 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

Consolidation without compromise

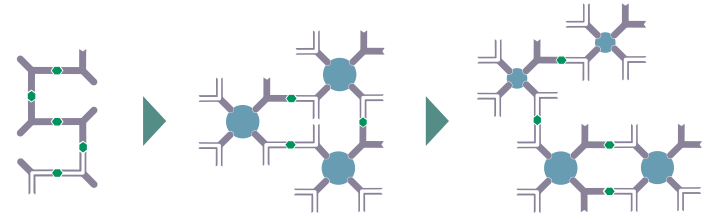
- Broadest specific protein menu on a fully consolidated platform including open channel offering
- Broad system platform portfolio for every lab size with standardized reagents across the platforms

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.

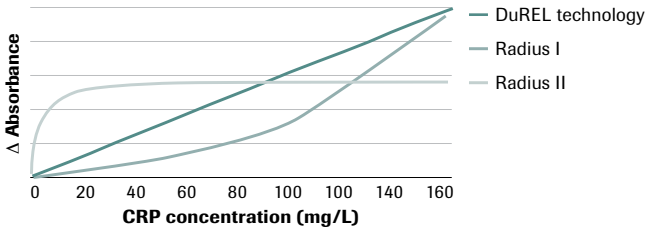
The use of bichromatic wavelengths in spectrophotometry in conjunction with the measurement of a sample blank minimizes interference effects.

Technological advances and future-oriented assay design



Classical HIA | Latex-enhanced HIA | DuREL

Differently-sized particles working together



cobas
Life needs answers

Elecsys® HBsAg II quant II
A powerful tool for therapy monitoring

www.cobas.com

Hepatitis B virus (HBV) accounts annually for 1 million deaths worldwide. After HBV infection, the surface antigen (HBsAg) is the first immunological marker detectable in serum. An important goal in therapy of HBV infections is the clearance of HBsAg, which is associated with complete and definitive remission of the activity of chronic hepatitis B and an improved long-term outcome. HBsAg levels decline under treatment with peginterferon α-2a in sustained viral responders but not in relapsers or nonresponders.

Your benefit

Optimized management of chronic hepatitis B patients
- Via the combination of HBV DNA and HBsAg quantification (see also Chapter Molecular Diagnostics)

Allows a response-guided therapy
- For interferon-based treatment (e.g. PEGASYS®) of chronic hepatitis B patients

Markers for risk prediction
- Of cirrhosis and hepatocellular carcinoma and accurate identification of inactive carriers

Enhanced convenience
- Minimization of retesting due to broad linear measuring range, onboard dilution, eight weeks onboard stability

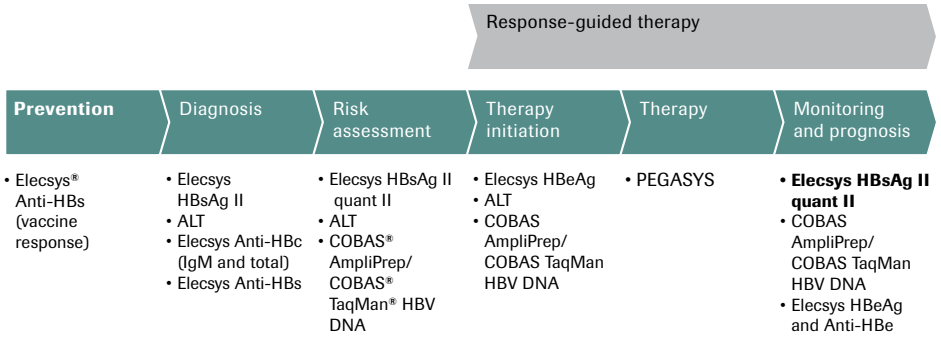
Maximal reliability
- Accurate results, elimination of pipetting errors, validated with all genotypes

Optimized for clinical decision making
- Linear range reflecting relevant HBsAg titers, excellent precision, traceable to WHO second international standard for HBsAg

Product characteristics

- Assay time: 18 min.
- Measuring range: 0.05 – 52,000 IU/mL
- Sample volume: 50 µL
- Intermediate imprecision:
  cobas e 411,
  E2010: 4.1 – 5.3 % (0.170 – 292 IU/mL)
  cobas e 601 / **cobas e** 602,
  E170: 3.3 – 5.3 % (0.164 – 286 IU/mL)
- Onboard stability: 8 weeks

The HBV portfolio: covering all stages of hepatitis B



EASL HBV management guidelines update 2012[1]

For the first time clinical practice guidelines have incorporated recommendations on HBsAg quantification in treated and non-treated chronic HBV patients:

Monitoring PEG-IFN

- **HBeAg-positive:** No decline in HBsAg level or levels >20,000 IU/mL at week 12 are associated with low probability of anti-HBe seroconversion (stopping rule)
- **HBeAg-negative:** No HBsAg decline and <2 log10 IU/mL decline in HBV DNA level at week 12 predicts non-response (stopping rule)

Untreated inactive carriers

- HBV inactive carriers identified by persistently normal ALT levels, HBV DNA <2,000 IU/mL and HBsAg levels <1,000 IU/mL

Monitoring NAs

- A decline of HBsAg in HBeAg-positive patients may predict subsequent HBeAg or HBsAg clearance

Please check availability with your local Roche representative.

1 European Association for the Study of the Liver. (2012). *J Hepatol 57,* 167–185.

cobas® Life needs answers

Elecsys® HIV combi PT
4th Generation (Ag+Ab test)
Designed for early detection of HIV infection

www.cobas.com

The human immunodeficiency virus (HIV), the causative agent of the acquired immunodeficiency syndrome (AIDS), belongs to the family of retroviruses. HIV can be transmitted through contaminated blood and blood products, through sexual contact or from an HIV infected mother to her child before, during and after birth. 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. This leads to improved sensitivity and, therefore, a shorter diagnostic window as compared to anti-HIV assays. 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. This includes an automated sample pretreatment step with incubation with a detergent agent in order to lyse HIV virions and maximize exposure of the HIV p24 antigen to increase sensitivity.

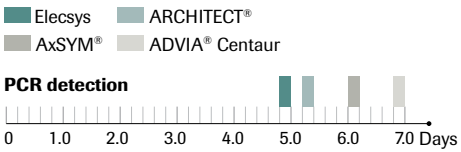
Your benefit

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 below < 2.0 IU/mL

Robust to viral change
- Multiple target concept to ensure excellent inclusivity: special detection of subtypes and group HIV2 antibodies

Cost efficiency
- High clinical specificity reduces the need for repeat testing



Mean seroconversion obtained using Ag/Ab assays across competitor systems

Comparison of the time required until acute infection can be detected using different HIV antigen/antibody combination immunoassays.[1,2]

Product characteristics

Elecsys® HIV combi PT test characteristics
- Indications: Diagnostic use and for screening of blood donations
- Fast results: 27 min.
- Analytical sensitivity: 2.0 IU/mL Human immunodeficiency virus type 1 (HIV-1 p24 antigen) – 1st International Reference Reagent 1992, code 90/636
- Sample material:
  - Serum, standard or separating gel tubes
  - Plasma, Li-heparin, K_2 EDTA, K_3 EDTA, sodium citrate, CPDA or Li-heparin plasma tubes containing separating gel
- Low 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 % CI: 99.77 – 99.94) (n = 7,343)
  - Samples from unselected daily routine, dialysis patients and pregnant women: 99.81 % (95 % CI: 99.47 – 99.90) (n=4,103)

1 Schmitt, U., van Helden, J., Hebell, T., Schennach, H., Mühlbacher, A., Bürgisser, P., Permpikul, P., Rodriguez, M.I., Eiras, A., Alborino, F., Cunningham, P., Andersson, S., Wetlitzky, O., de Sousa, G. (2011). Poster presented at 6th International AIDS Society Conference, Rome, Italy. Available at: http://pag.ias2011.org/EPosterHandler.axd?aid=2370.

2 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.

cobas® Life needs answers

The Syphilis test panel

Fully automated for complete assessment of the disease syphilis

Syphilis is mainly transmitted sexually caused by the intracellular Gram-negative spirochete bacterium *Treponema pallidum* subspecies pallidum. It 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 3 assays for efficient and reliable assessment of syphilis infections.

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
• Syphilis • TPLA • RPR	• Syphilis • TPLA • RPR	• RPR

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 Regin

Elecsys® Syphilis immunoassay

Confidence in all stages of treponemal infection

www.cobas.com

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

Your benefit

Designed for high sensitivity

- High sensitivity minimizes the probability of missing new infections

Cost efficiency

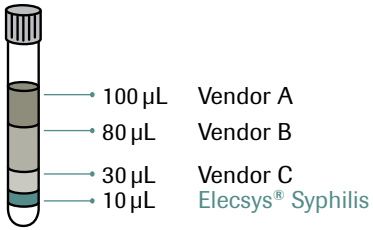
- High specificity reduces the need for re-testing

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



Product characteristics

- Sample material: Serum and plasma, Li-heparin, K_2 EDTA, K_3 EDTA, sodium citrate, CPDA or Li-heparin 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 = 8079)
  - Blood donors: 99.93 % (n = 4579)
  - Routine samples: 99.80 % (n = 3500)

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Life needs answers

Elecsys® TORCH panel

Reliable screening for early diagnosis

www.cobas.com

Infections with Toxoplasma gondii, rubella virus, cytomegalovirus (CMV) and herpes simplex virus (HSV) are especially risky 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.

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

- Due to highly specific assays

Fast reporting

- Results in less than 20 min.

Test principle: one-step double antigen sandwich (DAGS) assay (testing time 18 min.)

The double antigen sandwich format (DAGS) makes the Elecsys Toxo IgG and Elecsys CMV IgG highly sensitive even for the detection of very remote infections.

Product characteristics

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

Elecsys® CMV IgM, IgG and IgG Avidity

- Designed to detect all suspect primary infections
- Less sensitive to persistent IgM antibodies
- Prevents cross reactivity with other herpes viruses

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)

Rubella IgM and IgG

Clearly discriminates between an acute and a remote infection

- Rubella IgG test ultrasensitive to 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 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 detects past infections with superior accuracy therefore immediately ruling out non-relevant cases
- Combined use of the three assays allows accurate determination of primary infections

cobas® Life needs answers

Elecsys® Troponin T high sensitive (TnT hs)

Improved performance – better clinical decisions

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 Elecsys Troponin T hs test complies with the guidelines of ACC / ESC* and NACB/AACC** in achieving less than 10 % coefficient of variation (CV) at the 99 percentile upper reference limit of the reference population.

These requirements result in significant advantages in the diagnosis of acute coronary syndrome (ACS):

- Significantly earlier detection of a cTn increase during an acute myocardial infarction (AMI)
- Earlier rule-out and rule-in of AMI
- Increasing the number of patients correctly diagnosed with AMI, thanks to the greater sensitivity and better analytical precision
- Improving risk stratification of patients with elevated cTn levels without acute cardiac event

Your benefit

Guideline compliant

- Test complies with the guidelines of ACC / ESC* and NACB/AACC**

Safe and reliable results

- Particularly at lower levels

Earlier diagnosis

- Greater sensitivity allowing the detection of more patients at risk

High prognostic value for cardiac events

- In patients with renal failure

Early identification

- Of acute and chronic myocardial damage that would be not discovered at all or only later with conventional cTn assays

Consistent correlation

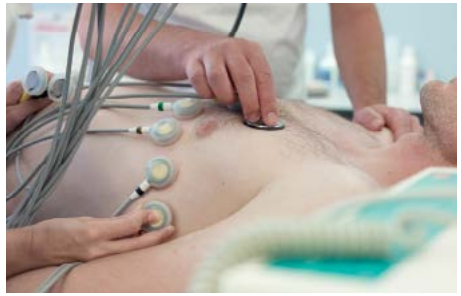
- Between POC devices for emergency testing and all **cobas**® immunoassay analyzers in the central lab

* *ACC/ESC: American College of Cardiology/European Society of Cardiology*

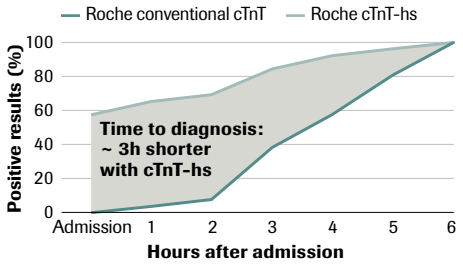
** *NACB/AACC: National Academy of Clinical Biochemistry/Academy of the American Association for Clinical Chemistry*

Product characteristics

- Fully automated test
- Sample material: Heparin, EDTA plasma and serum
- STAT test: 9 min.
- 99th percentile upper reference limit*: 14 ng/L (pg/mL)
- 10 % CV precision: 13 ng/L (pg/mL)



Key benefit: Earlier diagnosis of AMI



Using the cTnT-hs assay, results in NSTEMI compared with the conventional cTnT test report:

- Time to diagnosis shorter by almost three hours
- 20 % more patients identified with a final diagnosis of NSTEMI

* *Elecsys® Troponin T high sensitive package insert.*

cobas
Life needs answers

Elecsys® NT-proBNP

A leap forward in the diagnosis and stratification of cardiovascular disease

www.cobas.com

Heart failure (HF) is a global health problem associated with high morbidity and mortality. Detection in its early stages and appropriate treatment are key objectives in improving 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 an innovative marker to improve clinical decisions. It delivers accurate data to help rule-out, rule-in, risk-stratify or monitor patients.

Your benefit

Simplified testing process and improved efficiency of testing

- NT-proBNP provides 72 hour room temperature stability without additional processing
- Test tube requirements allow one tube solution for all cardiac markers

Consistent correlation

- Between all **cobas**® immunoassay analyzers and POC devices

Fast diagnosis

- In cases of dyspnea; differentiation between cardiac or pulmonary causes

Suspicion of acute heart failure because of symptoms and signs

Examination, ECG, X-ray and NT-proBNP

Patient age (Years)	NT-proBNP values (pg/mL)		
< 50 50 – 75 >75	< 300	300 – 450 300 – 900 300 – 1800	> 450 > 900 > 1800
Interpretation	Acute HF unlikely	Acute HF less likely, alternative causes must be considered	Acute HF likely, consider confounding factors
	NPV = 98 %		PPV = 92 %

Early diagnosis of HF

- Even in early stages without symptoms

Objectivity

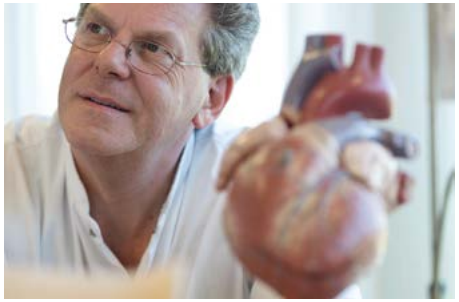
- NT-proBNP concentration correlates with severity of disease

Strong prognosis

- High predictive value in cardiology risk patients

Improved therapy

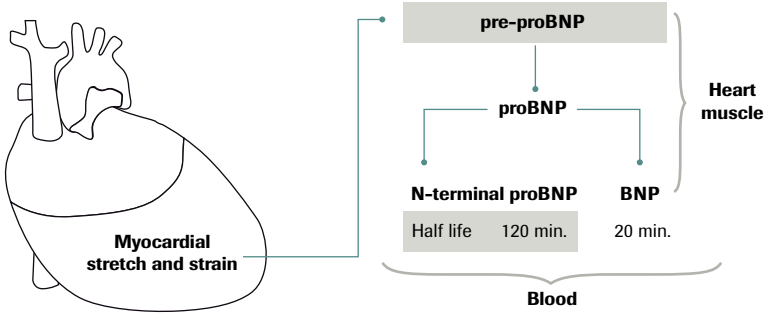
- Aids in the evaluation of the clinical situation and optimization of therapy



Product characteristics

- Fully automated quantitative assay
- Low sample volume: 50 µL
- Fast results: 9 min. as STAT assay
- Longer sample stability: 3 days at room temperature and even longer at 4°C
- High test precision (CV 2.9 to 6.1 %) coupled with a wide dynamic measuring range (5 – 35,000 ng/L)
- Sample material: standard serum and heparin / EDTA plasma

NT-proBNP is formed by cleavage of proBNP



cobas®
Life needs answers

NEW

Lp(a), hsCRP and Homocysteine

Improving cardiovascular risk assessment – allowing better treatment decisions

www.cobas.com

Cardiovascular disease (CVD) is a major health burden: a high proportion of patients are not classified correctly or even missed entirely for cardiovascular (CV) risk assessment

- Up to 70 % of those who develop coronary events have only one, or even none of the traditional risk factors, and more than half have either normal or mildly increased lipid values[1] (figure 1)
- Official guidelines recommend using Lp(a), hsCRP and Homocysteine, in combination with conventional risk analysis to aid in the evaluation of CV risk assessment.[2–4] This leads to a more accurate categorization of individuals at increased risk for CV disease[5] (figure 2)

Figure 1: Only up to 70 % of cases can be identified

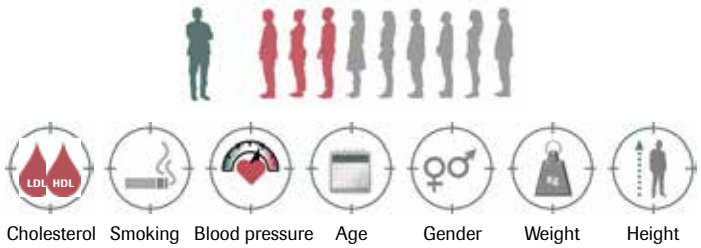
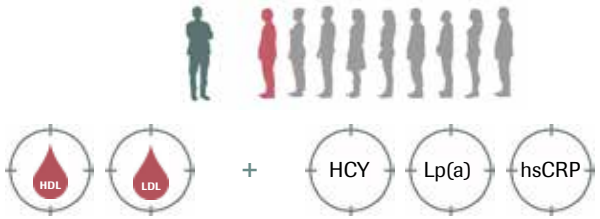


Figure 2: 90 % of cases can be identified



Your benefit

Testing efficiency

- Cost-effective, fast, robust, easy to perform with excellent accuracy and precision due to advanced assay design

Standardization

- Consistent patient results across all care settings due to standardized reagents on all Roche systems
- Excellent correlation to the reference method / material

Consolidation

- Accurate and reliable measurement on a fully consolidated platform

1 Young, I., Rifai, N. (2009). *Clin Chem. 55,* 201–2.
2 Nordestgaard, B.G. et al. (2010). *Eur Heart J. 31*(23), 2844–53.
3 Perk, J. et al. (2012). *Eur Heart J. 33*(13), 1635–701.
4 Refsum, H. et al. (2004). *Clin Chem. 50*, 3–32.
5 Montgomery, J.E., Brown, J.R. (2013). *Vasc Health Risk Manag. 9*, 37–45.

Product characteristics

Assay	Tina-quant® Lipoprotein (a) Gen. 2	Homocysteine enzymatic	Cardiac C-Reactive Protein High Sensitive
Sample material	Serum, Plasma	Serum, Plasma	Serum, Plasma
Sample volume	2 µL	14 µL	6 µL
Assay time	10 min.	10 min.	10 min.
Measuring range	7–240 nmol/L	3–50 µmol/L	0.15–20 mg/dL
Onboard stability	42 days	28 days	84 days
Calibration frequency	With every lot	With every lot	With every lot
Precision (**cobas c** 501 module) - Repeatability - Intermediate precision	 0.8–5.6 % 1.1–8.0 %	 1.4–2.0 % 1.8–2.3 %	 0.4–1.6 % 2.1–8.4 %
Traceability	SRM2B for nmol/L	NIST SRM 1955	BCR470/CRM470

cobas®
Life needs answers

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. With 18 million global cases annually, it is a major burden on healthcare.

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.

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

Acute inflammatory episode	Clinical indication of sepsis	Differential diagnosis	Severe sepsis/shock
	Suspicion/treatment	characterization of infection*	Therapy stewardship
• **IL-6**	• Temperature • Heart rate • Breathing rate • Leukocytes • **CRP**	• Blood culture – **PCT** – **IL-6** – **CRP**	• **PCT** • **IL-6**

** Rapid identification of sepsis pathogens is possible with LightCycler® SeptiFast Test.*
Please see on page 198 for more details.

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	CRPL3 on cobas c analyzers
Sample material	Serum, Li-heparin and K_3-EDTA plasma	Serum, Li-heparin and K_2- and K_3-EDTA plasma	Serum, Li-heparin and K_2- and K_3-EDTA plasma
Sample volume	30 µL	30 µL	2 µL
Assay time	18 min.	18 min.	10 min.
Measuring range	0.02 – 100 ng/mL	1.5 – 5,000 pg/mL	0.3 – 350 mg/L
Analytical sensitivity	<0.02 ng/mL	1.5 pg/mL	0.3 mg/L
Functional sensitivity	<0.06 ng/mL	5 pg/mL	0.6 mg/L
Traceability	Standardized against BRAHMS PCT LIA	WHO Standard NIBSC 1st IS 89/548	IRMM reference preparation CRM470 (RPPHS)

cobas
Life needs answers

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 continual 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 monitoring based on the individual base levels before and after primary treatment. An excellent long-term assay accuracy and precision is crucial for the reliable evaluation of significant differences in tumor marker levels in cancer patients.

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[1]
- 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 > 210 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 menu in Tissue Diagnostics, Elecsys tumor markers and the oncology portfolio in Molecular Diagnostics

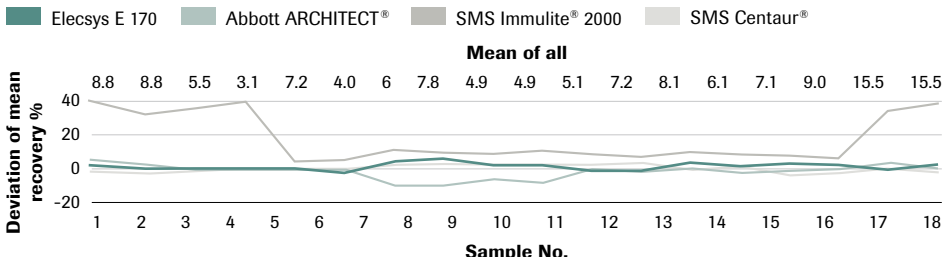
1 Bolstad, N. et al (2011). Heterophilic antibody interference in commercial immunoassays. *Clin Chem Lab Med 49*(12), 2001-2006.

Roche reagent and application portfolio for consolidated tumor marker testing

Test	Cancer indications (primary and secondary)	Roche/Hitachi systems	COBAS INTEGRA	cobas e systems	MODULAR *ANALYTICS* EVO	cobas c 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			●	●	
CEA	Colorectal, lung			●	●	
CYFRA 21-1	Non small cell lung, bladder			●	●	
Ferritin	Tumor related anemia	●	●	●	●	●
HCG	Chorion			●	●	
ß2 Microglobulin	Multiple myeloma (non-Hodgkin)	●	●		●	●
NSE	Small cell lung			●	●	
proGRP	Small cell lung			●	●	
SCC*	Small cell lung			●	●	
Free PSA	Prostate			●	●	
Total PSA	Prostate			●	●	
S100	Malignant melanoma			●	●	
Anti-TG	Medullary, thyroid carcinoma			●	●	
Tg II (hs)	Medullary, thyroid carcinoma			●	●	

**in development*

External longitudinal recovery monitoring shows high lot-to-lot consistency



cobas
Life needs answers

Elecsys® HE4

An oncological biomarker improving ovarian cancer care

www.cobas.com

Worldwide, ovarian cancer is the second leading cancer in women and the fourth most common cause of death from cancer. It is a gynecological disease with one of the highest mortality rates.

The more the disease has progressed, the lower the survival rate is and unfortunately most cases of ovarian cancer are detected in later stages where the chances of cure are rather low.

In the early stages of ovarian cancer, symptoms are unspecific and cause little, if any, discomfort. Therefore, new methods and biomarkers which can help in diagnosing this disease at an earlier stage are highly desirable. The biomarker HE4 (human epididymal protein 4) together with the marker CA125 can play a very important role here.

Your benefit

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

- As a single tumor marker, HE4 had the greatest sensitivity (at a specificity of 75 %) in detecting of EOC, especially in the early non-symptomatic stage

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

Improved monitoring of ovarian cancer recurrence and progression

HE4 correlates with the recurrence status in women with a diagnosis of EOC and is an earlier marker for recurrence than CA 125.

Reliable results with efficiency

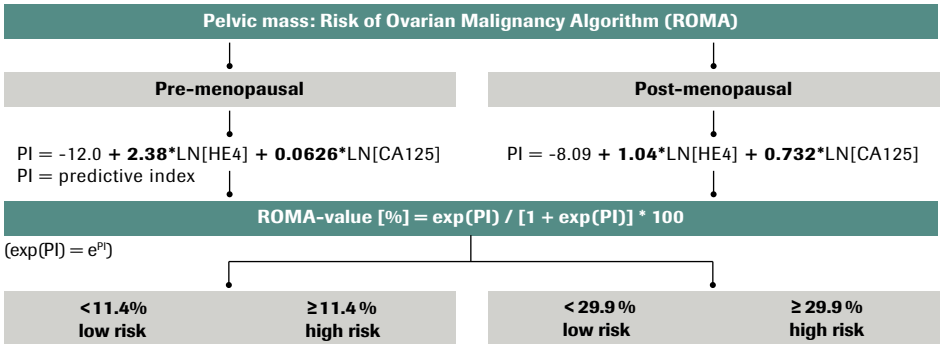
- Excellent precision and lot-to-lot consistency
- Comprehensive tumor marker menu available on all **cobas**® platforms

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.[1] This high accuracy in stratifying women with low or high risk for EOC contributes to better diagnosis, treatment and outcome.

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 %



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.

1 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.

cobas Life needs answers

Elecsys® ProGRP

Crucial information for differential diagnosis in lung cancer

www.cobas.com

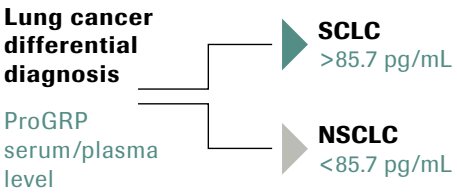
Pro-gastrin releasing peptide (ProGRP) is a tumor marker with benefits for the management of lung cancer patients.

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.

ProGRP is the tumor marker of choice for SCLC as it aids in quick and decisive discrimination between SCLC and NSCLC for 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.

Your benefit

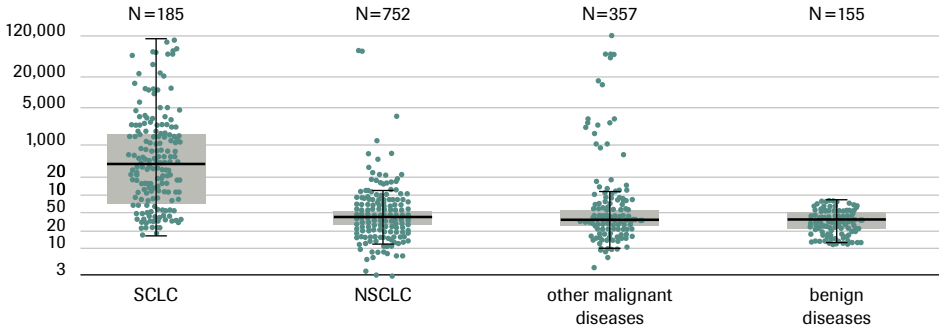
- High sensitivity and discrimination aiding the accurate differential diagnosis of SCLC
- Excellent precision across the entire measuring range for reliable results
- Lung cancer biomarkers available on a single automated platform – CEA, CYFRA 21-1, NSE, ProGRP and SCC*
- Equivalent performance between plasma and serum for flexibility and convenience, thus offering advantages over existing assays[1]



The 85.7 pg/mL cut-off value is based on the 95 % specificity of the NSCLC collective.

Product characteristics

- Assay time: 18 min.
- Sample material:
  - Serum collected using standard sampling tubes or tubes containing separating gel
  - Li-heparin plasma, K_2-EDTA and K_3-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



Other malignant diseases include breast, ovary, prostate, renal, liver, pancreas, colorectal, gastrointestinal, carcinoid, cervical, medullary carcinoma of the thyroid, mesothelioma, neuroendocrine tumors, lymphoma, and stomach cancer. Benign diseases contain liver-, metabolic-, autoimmune and inflammatory diseases, as well as the benign lung diseases pneumonia, asthma, chronic obstructive pulmonary disease and tuberculosis.

** in development*

1 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.

cobas® Life needs answers

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.

Elecsys® Calcitonin – excellent precision at low concentrations

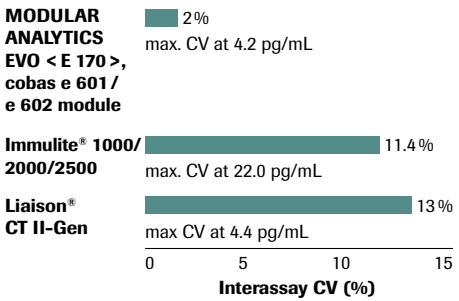


Figure 2: Comparison of interassay CVs (coefficient of variation) at the lowest concentrations tested. Source: package inserts; March 2013.

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

Product characteristics

- Assay time: 18 min.
- Sample material: Serum, Li-heparin plasma, K_2-EDTA plasma, K_3-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/**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

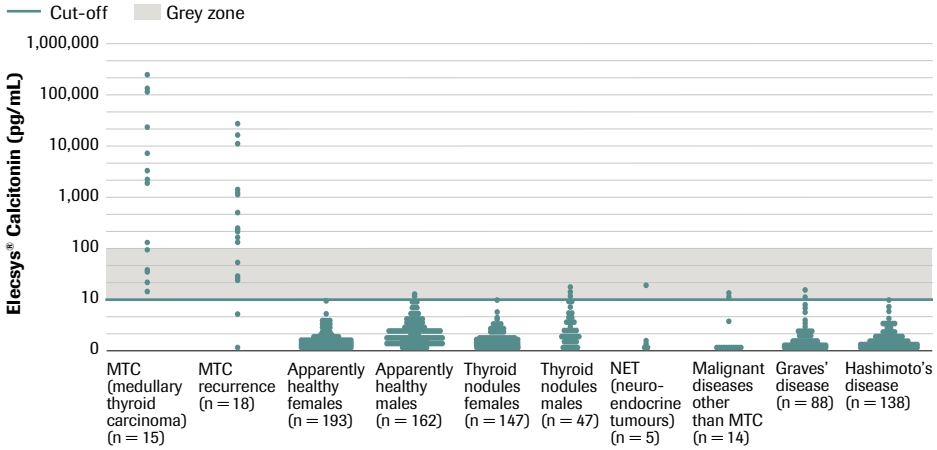


Figure 1: Calcitonin is a highly specific marker for MTC, allowing early and specific diagnosis and reliable monitoring. Source: Performance Evaluation Study 2013, data available upon request.

cobas®
Life needs answers

Elecsys® Tg II

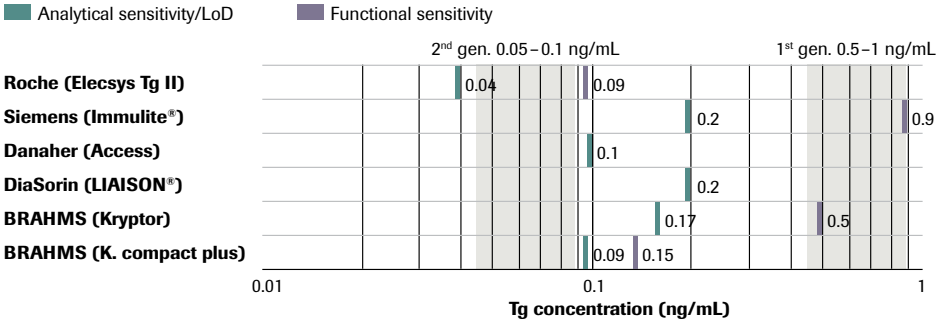
The power to offer more for differentiated thyroid cancer (DTC) management

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.

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
- Patients with a basal Tg below the functional sensitivity of a sensitive Tg assay have a high chance of being free of disease



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_2-EDTA plasma, K_3-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/**e** 602 modules: 4.0 – 5.9 %

** LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation with a total allowable error of ≤ 20 %*

cobas
Life needs answers

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
- Assessing the risk of developing fetal hyperthyroidism in the last trimester of pregnancy

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

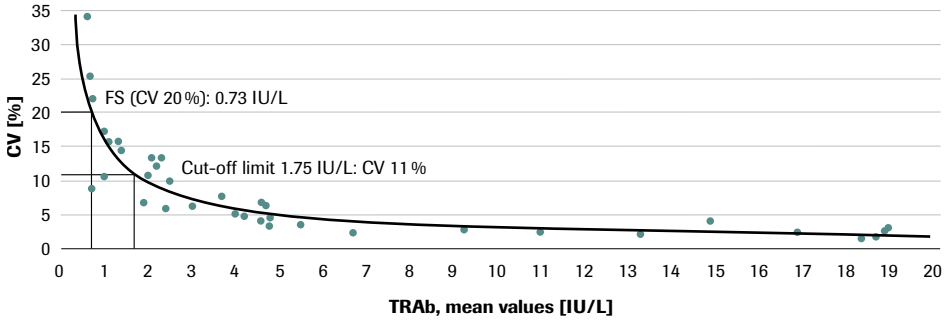


Figure 2: The functional sensitivity of Elecsys Anti-TSHR at approx. 0.9 IU/L is significantly below the cut-off (≥1.75 IU/L), allowing clear differentiation of pathological results.

Product characteristics

- Assay time: 27 min.
- Sample volume: 50 µL
- 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 1st IS 90/672

High clinical accuracy of Elecsys® Anti-TSHR

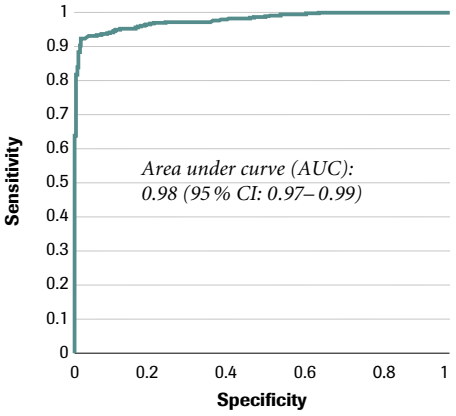


Figure 1: Clinical accuracy of Elecsys Anti-TSHR

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.

Hermsen, D. et al. (2009). Technical evaluation of the first fully automated assay for the detection of TSH receptor autoantibodies. *Clin Chim Acta,* 84 – 89.

cobas® Life needs answers

Elecsys® Vitamin D total

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 assay aids in the assessment of vitamin D sufficiency.

Your benefit

- Standardized against LC-MS/MS (traceable to NIST) 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, β-CrossLaps, P1NP, Osteocalcin and PTH testing on one fully automated platform

Traceability and standardization

National Institute of Standards & Technology (NIST)

Standard reference material (SRM) 2972
Ethanolic solutions of vitamin D2 (25-OH) and vitamin D3 (25-OH)

SRM 972
Four levels of serum with different concentrations of vitamin D (25-OH), value assignment by LC-MS/MS

▲

LC-MS/MS

Liquid chromatography tandem mass spectrometry
NIST SRM2972 used for calibration, NIST SRM972 for quality control

▲

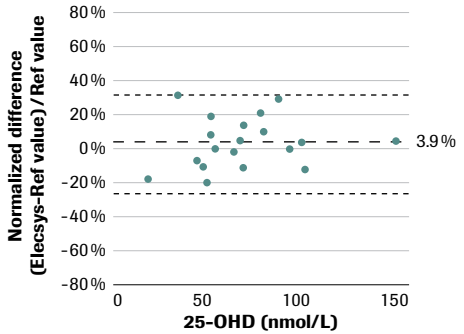
Elecsys Vitamin D total

Fully automated protein binding assay
calibrators based on serum matrix, standardization against LC-MS/MS

Product characteristics

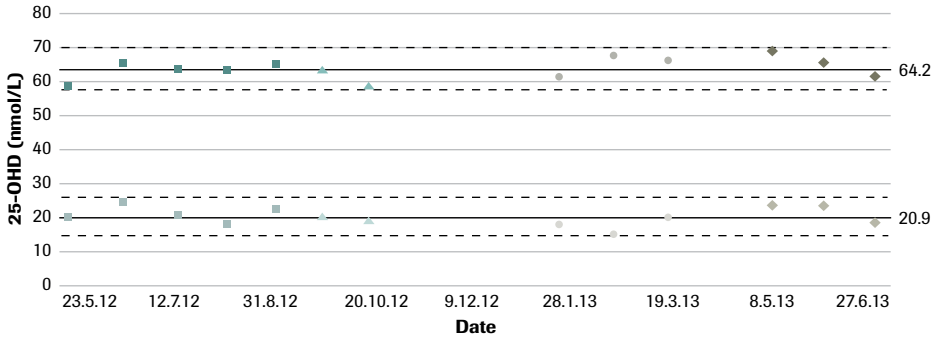
- Assay time: 27 min.
- Sample material: Serum and plasma
- Sample volume: 15 µL
- Functional sensitivity: 4.01 ng/mL (10.0 nmol/L) (CV 18.5%)
- Repeatability: Within-run precision:
  <15 ng/mL: SD ≤1 ng/mL,
  >15 ng/mL: ≤6.5%
- Reproducibility: Intermediate precision:
  <15 ng/mL: SD ≤1.7 ng/mL,
  >15 ng/mL: ≤11.5%

Proven accuracy with certified Vitamin D Reference Panel



Assessment of Vitamin D Reference Panel, certified by University of Ghent LC-MS/MS reference measurement procedure.

Consistent results from lot to lot



Long-term recovery of serum pools over 4 different reagent lots.

Wielders et al. (2014). *J Clin Lab Anal*, Epub ahead of print DOI 10.1002/jcla.21793.

cobas®
Life needs answers

NEW

Elecsys® Anti-Mullerian Hormone (AMH)

Providing clinical confidence in the assessment of ovarian reserve

www.cobas.com

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-Mullerian 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.

AMH assists in assessment of ovarian reserve, for example identifying in patients at risk of having diminished ovarian reserve. AMH can also add prognostic information to the counseling and planning process for infertile couples seeking treatment.

There is also growing scientific evidence linking between the level of AMH and Polycystic ovary syndrome (PCOS), prediction of time to menopause, disorders of sex development in children, and ovarian function in cancer patients under chemotherapy.

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

Product characteristics

- Assay time: 18 min.
- Traceability: Standardized against BCI AMH Gen II ELISA (unmodified)
- Sample material: Serum and Li-heparin plasma
- Sample volume: 50 µL
- LoB, LoD, LoQ*: 0.007 ng/mL, (0.05 pmol/L), 0.010 ng/mL, (0.071 pmol/L), 0.030 ng/mL, (0.214 pmol/L)
- Measuring range: 0.01 – 23 ng/mL (0.071 – 164.2 pmol/L)
- Intermediate imprecision:
  - **cobas e** 411 analyzer: 2.9 – 4.4 %
  - **cobas e** 601/**e** 602 modules: 2.7 – 3.5 %
  - Lowest conc. measured: 0.232 ng/mL

LoB = Limit of Blank, LoD = Limit of Detection, LoQ = Limit of Quantitation

Precision and sensitivity

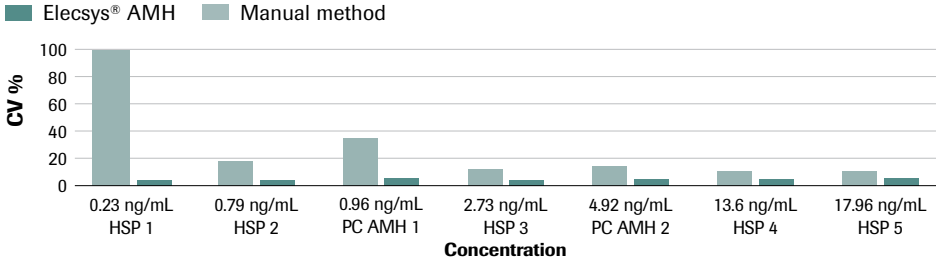


Figure 1: Precision comparison between Elecsys and a manual method on the market as part of a method comparison study conducted. The study has been run according to CLSI Protocol (CLSI-EP5).
HSP – Human Serum Pool, PC AMH – PreciControl AMH

Agreement and low variability in results vs. AFC

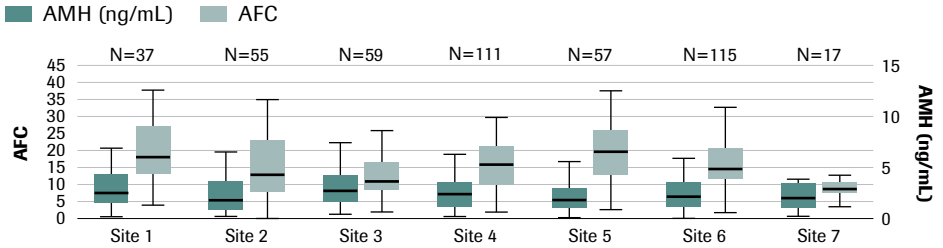


Figure 2: Distribution of AFC and AMH in 7 site multicenter evaluation. Multiple technicians performed AFC at each site.

cobas® Life needs answers

Elecsys® sFlt-1 / PlGF

Short term prediction and diagnosis of preeclampsia

www.cobas.com

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 PlGF) 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

- Elecsys sFlt-1 and PlGF 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 / PlGF 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 pre-eclampsia leads to effective clinical management and improves the outcome for both mother and child

Product characteristics

Technical assay features on Elecsys® sFlt-1 and PlGF	sFlt-1	PlGF
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 Elecsys sFlt-1/ PlGF ratio can improve the management of suspected preeclampsia patients allowing short-term prediction and diagnosis. An improved prediction and diagnosis of preeclampsia can allow a reduction of inappropriate discharges as well as a reduction of unnecessary hospitalizations, therefore a reduction of the health care burden.

Early onset preeclampsia – gestational week 20 – 34

sFlt-1/ PlGF ≥ 85	Diagnosis	**99.4 % specificity** the patient has preeclampsia Sensitivity: 88.0 %
sFlt-1/ PlGF < 85 ≥ 38	Prediction rule-in in the next 4 weeks	**38.6 % PPV** the patient is at high risk to develop preeclampsia within the next 4 weeks
sFlt-1/ PlGF < 38	Prediction rule-out for the next 1 week	**99.1 % NPV** the patient will not develop preeclampsia in the next 1 week

Late onset preeclampsia – gestational week 34 to end of pregnancy

sFlt-1/ PlGF ≥ 110	Diagnosis	**95.5 % specificity** the patient has preeclampsia Sensitivity: 58.2 %
sFlt-1/ PlGF < 110 ≥ 38	Prediction rule-in in the next 4 weeks	**38.6 % PPV** the patient is at high risk to develop preeclampsia within the next 4 weeks
sFlt-1/ PlGF < 38	Prediction rule-out for the next 1 week	**99.1 % NPV** the patient will not develop preeclampsia in the next 1 week

Verlohren, S., Herraiz, I., Lapaire, O., Schlembach, D., Moertl, et al. (2012). *Am J Obstet Gynecol. 206*(1),58.e1–8.
Verlohren, S., Herraiz, I., Lapaire, O., Schlembach, D., Zeisler, H., et al. (2014). *Hypertension. 63*(2),346–352.
Schnettler, W.T., Dukhovny, D., Wenger, J., Salahuddin, S., Ralston, S.J., Rana S. (2013). *BJOG 120*(10),1224–123.

cobas® Life needs answers

Tina-quant® Hemoglobin A1c

Efficiency for the diagnosis and monitoring of diabetes

www.cobas.com

HbA1c is viewed as a significant and accepted diabetic marker. For most people with diabetes, the target HbA1c is below 48 mmol/mol (6.5% HbA1c), since evidence shows that this can reduce the risk of developing diabetic complications.

In 2009 an international expert committee recommended HbA1c as a test for the diagnosis of type 2 diabetes and prediabetes. The Tina-quant assay provides a fast and precise routine HbA1c measurement for the comprehensive care of your diabetes patient.

Your benefit

One test for diagnosis and monitoring

- First HbA1c assay on the market that can be used for the diagnosis of diabetes and to identify persons at risk of developing diabetes, and for monitoring (FDA/CE)

Reliable diabetes management

- With excellent precision and accuracy

Uncompromised performance

- With no interference from HbAS, HbAD, HbAD and HbAE or acetylated, carbamylated Hb and labile HbA1c

Efficiency, cost and workflow improvements

- Easy integration into routine testing for efficiency, cost and workflow improvements. Without post-analytical data review (e.g. interpretation of chromatograms)

Product characteristics

- Twin test reaction technology
- Reagent lot-specific calibration
- NGSP certified and traceable to the IFCC and DCCT reference method
- Dual reporting in mmol/mol and %
- Intermediate precision (CV) <1.5%
- Whole blood and hemolysate application
- 70% immersion depth into the primary tube for correct and reproducible recovery of fast settling whole blood samples
- FDA approved/CE

Epitope of Roche antibody

Glycated (HbA1c) N-terminal hexapeptide and epitope recognition of the Roche HbA1c antibody for measuring the "true" HbA1c as defined by the IFCC reference system.

cobas
Life needs answers

Tina-quant® Cystatin C Gen. 2

Assess renal function earlier and more reliably

www.cobas.com

Chronic kidney disease (CKD) is an insidious disease with a dramatically increasing prevalence across the globe accompanied by a huge impact on healthcare budgets. Detecting chronic kidney disease at early stages allows for early intervention and thus has the potential to delay or even prevent the development of end-stage renal disease and related complications.

Creatinine, which has been widely used to date to assess renal function, is subject to variation due to a number of factors including age, gender, race, chronic illness, diet, and muscle mass. In addition, it doesn't detect mild kidney insufficiency since serum levels only begin to rise in CKD stage 3 when approximately 50 % of renal function is already lost ("creatinine-blind area").

Cystatin C is a marker with the ability to detect mild kidney insufficiency through subtle changes in the glomerular filtration rate (GFR). Cystatin C therefore offers additional medical value versus the use of creatinine, contributing to better patient care.

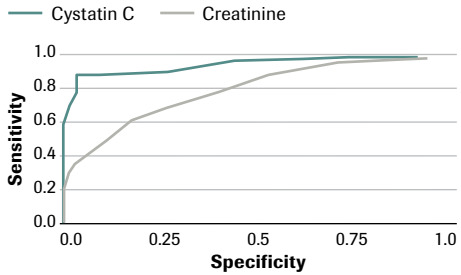
Your benefit

- **Early detection of CKD** by determination of subtle changes in GFR due to high sensitivity and specificity
- Tina-quant Cystatin C is not influenced by gender, muscle mass or inflammation and therefore provides **reliable results**
- Tina-quant Cystatin C, together with creatinine measurement, provides **detection of CKD across the complete range of renal function**
- In patients with limited renal function, it **allows exact dosing of medications** eliminated by the kidneys
- **Easy and efficient testing** due to fully automated testing on all clinical chemistry analyzers from Roche and availability of a comprehensive renal diagnostics marker menu
- Traceable to ERM-DA71/IFCC

Product characteristics

- Cystatin C can detect impairment of renal function in a GFR range of approx. 40 – 80 mL / min. / 1.73 m²
- Sample material: Serum and plasma
- Measuring range: 0.4 – 6.8 mg/L
- Precision (**cobas c** 501 module):
  Intraassay: CV 0.6 – 1.0 %
  Interassay: CV 0.7 – 1.2 %
- Expected values: 0.61 mg / L – 0.95 mg / L

Highly sensitive and specific, unaffected by physical factors



ROC analysis of cystatin C and creatinine.[1]

Determination of subtle changes in GFR is crucial in the early detection of CKD

Cystatin C		Creatinine		
Creatinine-blind area →				
GFR mL/in/1.73m² >89	60 – 89	30 – 59	15 – 29	<15
Stage 1 Kidney damage with normal/elevated GFR	Stage 2 Mild kidney insufficiency	Stage 3 Moderate kidney insufficiency	Stage 4 Severe kidney insufficiency	Stage 5 End stage renal disease (ESRD)

Stages of chronic kidney disease according to NKF KDOQI.[2]

1 Stevens, L.A., Coresh, J., Greene, T., Levey, A.S. (2006). Assessing kidney function – measured and estimated glomerular filtration rate. *N Engl J Med 354,* 2473-83.

2 National Kidney Foundation Kidney Disease Outcomes Quality Initiative, www.kidney.org/professionals/kdoqi – access date July 2012.

cobas® Life needs answers

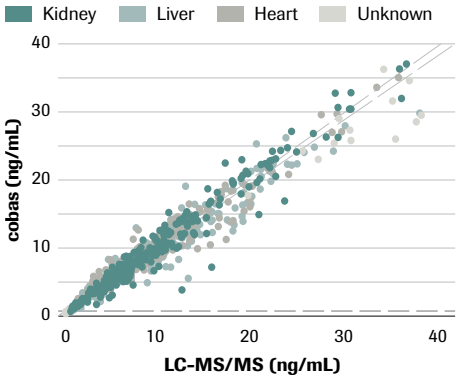
Immunosuppressive Drug Monitoring

Trusted and consistent results for organ transplant patients

www.cobas.com

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.

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

High precision for confidence in results

- High precision at low drug concentrations and across a wide measuring range

Consistent results for life-long monitoring

- Consistent results across all **cobas®** platforms
- High comparability with well-established and validated LC-MS / MS methods

Consolidation of relevant monitoring needs

- The full ISD menu available on one platform*
- Outstanding possibilities for consolidation of parameters, including those highly relevant for transplant patients (e.g. mycophenolic acid (MPA), infectious diseases, diabetes, kidney and liver function)

Universal manual sample pretreatment for Elecsys ISDs

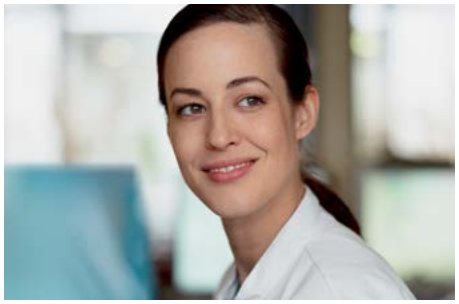
As the analytes are largely distributed in red blood cells and bound to proteins, a one-step manual pretreatment is performed to release them from the proteins. The pretreatment reagent and the one step procedure are universal for all Elecsys ISD assays.

**Sirolimus and Everolimus in development*

Product characteristics

	Tacrolimus	Cyclosporine	Sirolimus*	Everolimus*
Assay time	18 min.			
Sample material	EDTA whole blood			
Sample volume	300 µL			
Sample pretreatment	Identical sample pretreatment			
Sensitivity LoB**	0.3 ng/ml	20 ng/mL	0.4 ng/mL	0.4 ng/mL
LoD**	0.5 ng/mL	30 ng/mL	0.5 ng/mL	0.5 ng/mL
LoQ**	1.0 ng/mL	50 ng/mL	2.0 ng/mL	1.5 ng/mL
Measuring range	0.5 – 40 ng/mL	30 – 2,000 ng/mL	0.5 – 30 ng/mL	0.5 – 30 ng/mL
Total imprecision				
cobas e 411 analyzer	2.1–14.2 %	4.2 – 9.2 %	in development	in development
cobas e 601/e 602 modules	2.4 –10.4 %	3.1 – 6.4 %		

*** LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation with a total allowable error of ≤ 20 %*



cobas
Life needs answers

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 and www.roche-multiplate.com

NEW

cobas t 411 coagulation analyzer

For maximum efficiency

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.

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 and random access pipetting arm for prioritization of STAT samples

cobas t 411 coagulation analyzer

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
- Menu for routine and thrombophilia assays, followed by anti-Xa and fibrinolysis assays

Test principle

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

Software

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

Multiplate® analyzer

Platelet function testing with best-in-class 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 results[1] 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[1-4] following percutaneous coronary interventions. Multiplate delivers best-in-class predictivity[5] and evidence is available demonstrating that Multiplate guided anti-platelet therapy has the potential to improve patient outcome.[6-8]

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.[9-10]

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 Bonello, L. et al. (2010). *J Am Coll Cardiol. Sep 14;* 56(12):919-33.
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 Straub, N. et al. (2013). *Thromb Haemost. Oct 24;* 111(2). [Epub ahead of print]

Your benefit

Cost-effective therapies
- in cardiac surgery[10]
- in coronary interventions[11]

Fast and easy assessment
- of platelet function from small volumes of whole blood

Best 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 400 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 IIbIIIa 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

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.

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

cobas®

Life needs answers

Urinalysis from Roche

Expertise coming from a long tradition of more than 50 years

www.cobas.com

Combur-Test®

cobas u pack

Urisys 1100®

Sediment terminal

cobas u 411 urine analyzer

cobas® 6500 urine analyzer series

Urine diagnostics portfolio

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

Combur-Test® strip

A quality choice for professional use

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

Efficiency

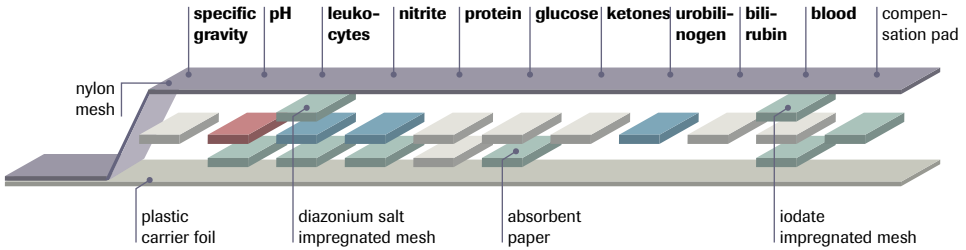
- Avoidance of retesting and false-negative results in glucose and blood even with high levels of ascorbic acid (up to 400 mg/L) with the application of an iodate impregnated mesh layer

Safety

- Independence interference from of glued components as a result of a unique sealing technology
- Test area colors prevented from running 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.
** For instrument tests only.*

cobas®
Life needs answers

Urisys 1100® analyzer

Connected, compact and intuitive solution for urinalysis

www.cobas.com

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.

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
- Throughput: approx. 50 test strips / hour
- Combur-Test® is resistant to ascorbic acid interference
- Control-Test M for weekly calibration
- Test strips*: Combur[10] Test® UX
- Memory capacity: 100 results
- Printer: Thermal printer
- Connectivity to the **cobas** POC IT solution

Strips										
Urine test strips	Combur-Test strips									
Parameters	SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BIL	BL
Combur[10] Test UX	•	•	•	•	•	•	•	•	•	•
Calibration	Control-Test M calibration strip									

** Combur[7] Test®, Combur[5]Test® are not available in all countries.*

cobas®
Life needs answers

cobas u 411 urine analyzer

The compact solution for the semi-automated urine work area

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.

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

Safe and hygienic handling of strips

- Due to netsealing technology

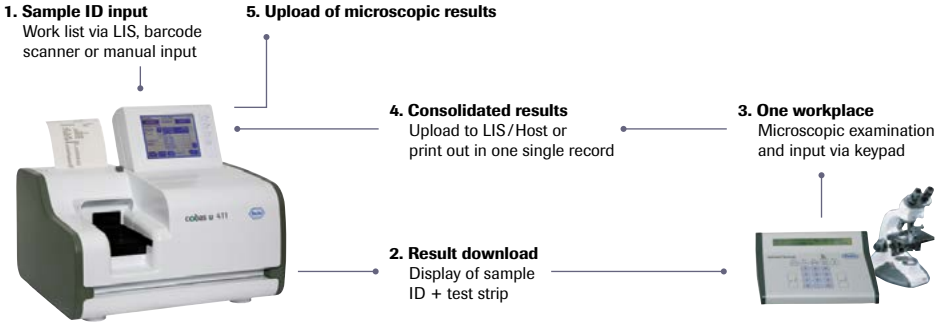
cobas u 411 urine analyzer

Product characteristics

- Workloads: 30 – 100 samples per day
- Throughput: 600 tests / hour
- Continuous loading of test strips without requiring a measurement cycle
  - optional barcode reader simplifies manual worksteps
- 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.

cobas®

Life needs answers

cobas® 6500 urine analyzer series

Fully automated urine work area on a modular platform

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

- Reagent free cassette concept
- Automated sieve testing – microscopy test only if needed, efficient cost management

cobas 6500 urine analyzer series

Product characteristics

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® strips
  - two weeks on-board stability (humidity protected)
- New photometer technology for the strip result reading
- Detecting the intact and lysed erythrocytes

cobas u 701 microscopy analyzer

- Fully automated urine microscopy system
- Reagent-free system
- Throughput: 116 samples / hour
- 400 cuvettes in one package (**cobas u** cuvette)
- Parameters:
  - Erythrocytes
  - Leukocytes
  - Bacteria
  - Non-squamous epithelial cells
  - Epithelial cells
  - Hyaline cells
  - Pathological casts
  - Crystals
  - Yeasts
  - Mucus
  - Sperm
  - Leukocytes

cobas u 601 urine analyzer

cobas u 701 microscopy analyzer

cobas®

Life needs answers

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 and www.CoaguChek.com

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Overview of point-of-care diagnostic tests

www.cobas.com

	Combur (visual strips)	TROP T sensitive (visual strip)	**cobas h** 232	Accu-Chek® Inform II	CoaguChek® XS, XS Plus and XS Pro	Accutrend® Plus	Urisys 1100®	**cobas b** 101	Reflotron® Plus and Reflotron® sprint	**cobas b** 123*	**cobas b** 121*	**cobas b** 221*
Anemia												
Bilirubin							•		•	•		•
Bilirubin neonatal										•		•
Hemoglobin total	•						•		•	•	•	•
Hematocrit										•	•	•
Oxygen saturation (sO_2)										•	•	•
Blood gas												
pH										•	•	•
pCO_2										•	•	•
pO_2										•	•	•
Electrolytes												
Ca^{2+}										•	•	•
Cl^-										•	•	•
K^+										•	•	•
Na^+										•	•	•
CO-oximetry												
tHb-COOX										•		•
O_2Hb										•		•
HHb										•		•
COHb										•		•
MetHb										•		•
sO_2 COOX										•		•
Bilirubin neonatal										•		•
Barmetric pressure (Baro)										•		•
Cardiac												
Troponin T		•	•									
CK-MB			•									

	Combur (visual strips)	TROP T sensitive (visual strip)	**cobas h** 232	Accu-Chek® Inform II	CoaguChek® XS, XS Plus and XS Pro	Accutrend® Plus	Urisys 1100®	**cobas b** 101	Reflotron® Plus and Reflotron® sprint	**cobas b** 123*	**cobas b** 121*	**cobas b** 221*
Myoglobin			•									
D-dimer			•									
HDL cholesterol (or HDL-C)								•	•			
LDL cholesterol (or LDL-C)								•	•			
NT-proBNP			•									
Coagulation												
D-dimer			•									
PT (INR/% Quick/sec.)					•							
Metabolic												
Ca^{2+}										•	•	•
Cl^-									•	•	•	•
Glucose				•		•	•		•	•		•
HbA1c								•				
HDL cholesterol (or HDL-C)								•	•			
Ketone	•						•					
LDL cholesterol (or LDL-C)								•				
Lactate						•			•	•		•
Potassium									•	•	•	•
Sodium										•	•	•
Total cholesterol (or CHOL)						•		•	•			
Triglycerides (or TG)						•		•	•			
Hepatology												
Alkaline phosphatase									•			
Bilirubin									•			
Creatine kinase									•			
GGT									•			
GOT (AST)									•			

** in addition several calculated parameters are available*

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cobas® POC IT solution
Bringing it all together

	Combur (visual strips)	TROP T sensitive (visual strip)	**cobas h** 232	Accu-Chek® Inform II	CoaguChek® XS, XS Plus and XS Pro	Accutrend® Plus	Urisys 1100®	**cobas b** 101	Reflotron® Plus and Reflotron® sprint	**cobas b** 123*	**cobas b** 121*	**cobas b** 221*
Hepatology												
GPT (ALT)									•			
Pancreatic amylase									•			
Urobilinogen	•											
Renal and urine												
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, provide you with 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
- Most efficient customizable online e-learning with automatic operator recertification saves a significant amount of time

Innovative functionality

- Over a decade of collecting user input and workflows has resulted in a high level of innovation that are firsts on the market

Open connectivity at its best

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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

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, Coagu-Chek XS Plus and Pro, **cobas h** 232, **cobas b** 101, Urysis 1100, **cobas b** 121 system, **cobas b** 123 POC system and **cobas b** 221 system.

cobas academy

- With **cobas** academy you can customize eLearning courses and deploy training content on your intranet, and also allow user re-certification automatically – the system will also automatically lock out users who are not certified until they have completed the required training.

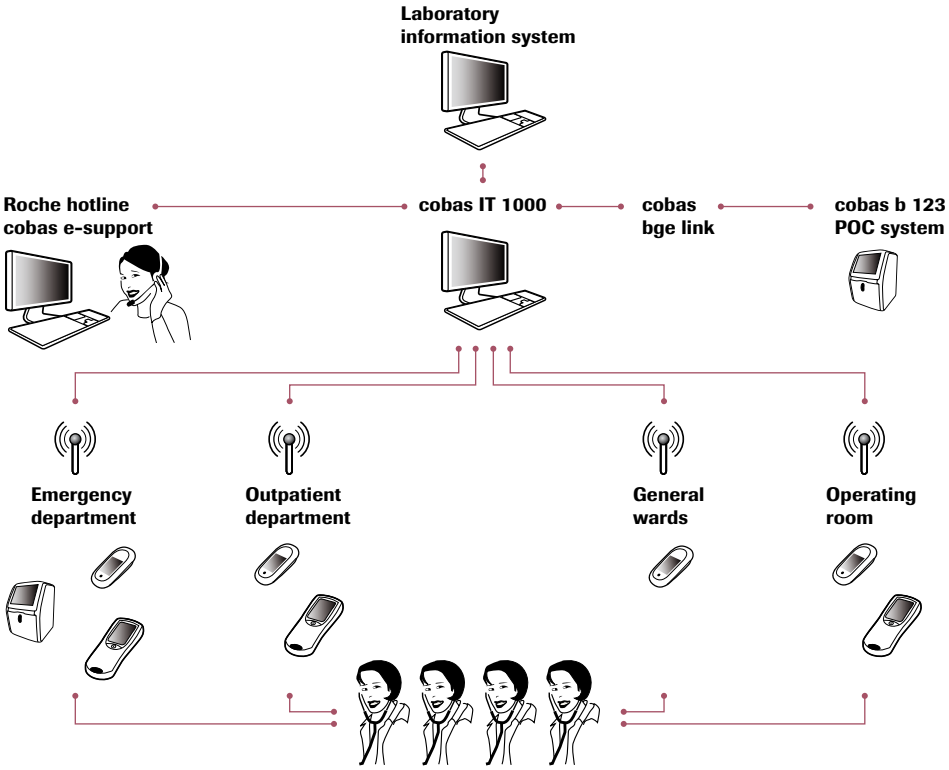
cobas bge link

- 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 eServices

- 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



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cobas® bge link software

Central control of your Roche blood gas and electrolyte analyzers

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

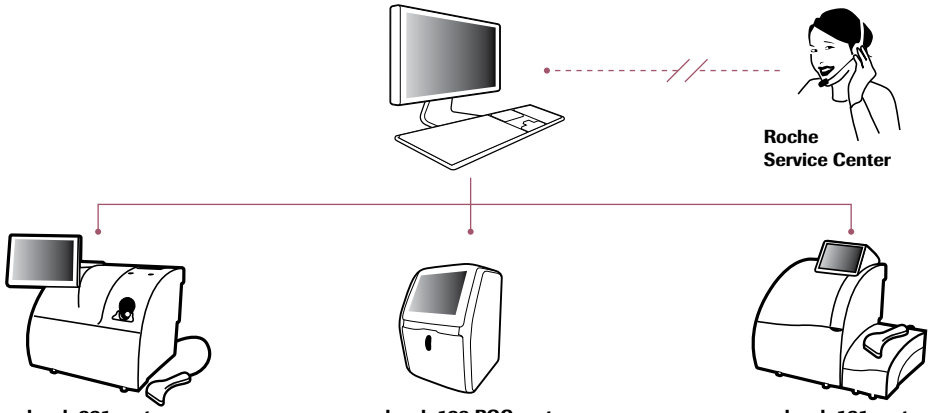
- By not having to walk to each analyzer, with continuous remote status monitoring of your blood gas and electrolyte systems, from the laboratory

Improve analyzer uptime

- With effective remote troubleshooting and remote control of analyzer functions (e.g. calibrations, QC, cleaning cycles, test functions)

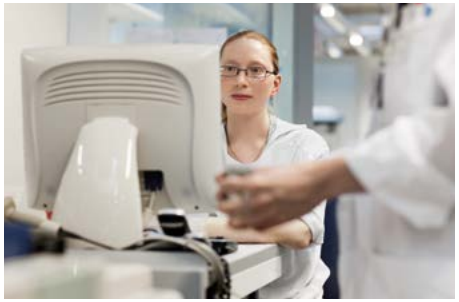
Increase confidence and security

- 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®
Life needs answers

cobas b 121 system

Quick and efficient testing in critical care

www.cobas.com

In critical care settings, fast test results mean rapid patient care. You can get valuable information on ten of the most important parameters, all measured on the **cobas b** 121 system. The parameter profile can be customized to meet your individual requirements. In addition, this instrument offers easy handling and low maintenance, yet performs as well as larger, more complex systems.

Your benefit

Meets varied testing needs

- Of different departments through the broad parameter menu

Increased security and confidence

- Providing you with laboratory-quality results at the Point of Care

Highest quality and full traceability

- Automated quality control with documentation software for certification requirements

cobas b 121 system

Product characteristics

- Throughput: 30 samples / hour
- Low sample volume: 60 µL, allows use in the neonatal setting
- Barcode scan prevents patient data mix-up
- Low maintenance electrodes
- Graphical user interface ensures ease of operation
- Liquid calibration for more convenience
- Connectable to network via the **cobas**® **bge link** software for remote control and to the **cobas** POC IT solution for comprehensive data management

Extended blood gas profile

Parameters:

- Blood gases pH, PO_2, PCO_2
- Total hemoglobin tHb
- Oxygen saturation SO_2
- Hematocrit Hct

Extended emergency profile

Parameters:

- Blood gases pH, PO_2, PCO_2
- Electrolytes Na^+, K^+, Ca^{2+}, Cl^-
- Total hemoglobin tHb
- Oxygen saturation SO_2
- Hematocrit Hct

cobas b 121 system versions	b 121	b 121 ‹bge›
pH / blood gas (pO_2, pCO_2, pH) / Co-oximetry	•	•
Electrolytes (Na^+, K^+, Ca^{2+}, Cl^-) / Hematocrit	•	•
tHb/sO_2	•	
Auto QC	•	

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cobas b 221 system

Convenience for your critical care testing

www.cobas.com

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

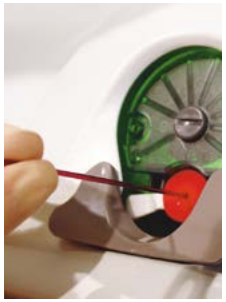
- Lab-quality results where and when you need them

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_2, PCO_2, pH)/CO-oximetry	•	•	•
Electrolytes (Na^+, K^+, Ca^{2+}, Cl^-)/hematocrit		•	•
Metabolites Glu/Lac			•
Metabolites Glu/Lac/Urea (BUN)			•
Bilirubin	•	•	•

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cobas b 123 POC system

Allowing you to focus on patient critical care

www.cobas.com

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

Medical Design Excellence Awards 2011 WINNER

** 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** academy

- 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_2, pCO_2, pH)	•	•	•	•
Electrolytes (Na^+, K^+, Ca^{2+}, Cl^-)/Hematocrit	•	•	•	•
Metabolites Glu/Lac	•	•	•	•
Bilirubin			•	•
Co-oximetry (tHb, O_2Hb, HHb, COHb, MetHb, SO_2)			•	•
Auto QC		•		•

Plus an extensive range of calculated parameters.

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Accu-Chek® Inform II system

Professional glucose testing for the wireless age

www.cobas.com

The Accu-Chek Inform II system helps nursing staff to do the right glucose test on the right patient at the right time.

It is a user-friendly hand-held system for point-of-care glucose testing and monitoring in hospitals. The **cobas**® POC IT solution maintains all information, allowing central management of all meters and data. Accu-Chek Safe-T-Pro Plus lancing devices enhance safety and hygiene for both patient and healthcare provider.

Accu-Chek Inform II system

Your benefit

Improves workflow and regulatory compliance

- Real-time result transfer to hospital network with optional wireless connection (WLAN)
- Bidirectional data exchange with point-of-care networking software
- Enhanced patient identification using patient ID, name and date of birth
- Comprehensive quality control functions
- Easier and more hygienic blood sample application through improved Y-capillary at the tip of the test strip

Precise, accurate, reliable results

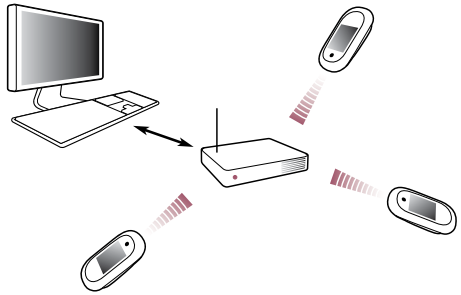
- Strips with advanced chemistry to avoid maltose interference
- Calibration according to the newest standard (IFCC plasma)

Reliable prevention of cross-infections and needlestick injuries:

- Lancet protected from contamination by removable sterile cap
- Sterilized lancet, safely contained in the housing – No direct needle contact possible
- Lancet locked by a dedicated safety mechanism after use – Multiple use excluded

Product characteristics

- Cutting-edge technology with a WLAN-enabled measuring device
- Data entry via touchscreen and / or 2D-barcode reader
  - User-ID and patient ID / case number
  - Password
  - Lot numbers for test strips and controls
- Watertight construction for easy cleaning and better infection control



The Accu-Chek® Inform II test strips

- Speed and accuracy for professional use
- Fast measuring time: only 5 seconds
- Small sample volume: 0.6 µL
- Approved for use with capillary, venous, arterial and neonatal blood
- Not dependent on partial oxygen pressure

The Accu-Chek Safe-T-Pro Plus

- Ergonomic T-shaped design for easy handling
- Trigger button gives resistance thus preventing unintended activation
- Special cut and diameter of the needle to minimize pain

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Life needs answers

cobas h 232 POC system

Expedite your cardiac decisions with rapid results

www.cobas.com

Thanks to its compact, portable design, the **cobas h** 232 POC system can be easily deployed near the point of patient care where space is tight, be it at the bedside, in triage bays or in a designated lab area. The instrument is intended to be used in emergency care settings or CCU* for patients presenting with acute chest pain, dyspnea and other symptoms suggestive of acute cardiovascular disease. Studies have proven the effectiveness of cardiac marker testing with the **cobas h** 232 POC system in physician office settings, in particular where the use of NT-proBNP aids the diagnosis and assessment of heart failure. The system can also be used in pre-hospital settings such as ambulances or helicopters.

cobas h 232 POC system

Optional integrated barcode scanner and external printer for greater safety and record keeping

Your benefit

Highly versatile

- Suitable for use in different clinical settings, e.g. emergency room, GP office and ambulances

Allows fast patient stratification

- Via a broad menu of individual tests
- Results available in a maximum of 15 min.

Easy handling and portability

- No sample preparation
- Automatic calibration
- No complicated setup procedures: intuitive, icon-based interface
- Maintenance-free
- Allows near-patient use at various locations

Reliable quantitative measurements

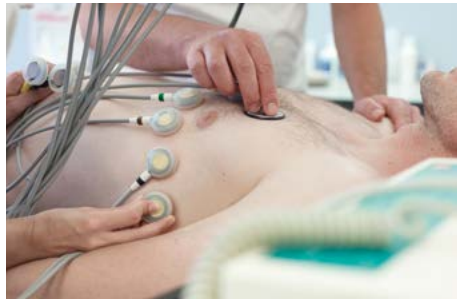
- Roche CARDIAC® assays are validated by clinical studies and are comparable to Roche laboratory methods

Safety

- Patient and operator ID entry and lockout
- Quality control lockout

Control and traceability

- 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



Product characteristics

- Offers a wide range of parameters to help in the rapid diagnosis of acute coronary syndrome, heart failure, and venous thromboembolism (DVT and PE):

Parameter	Time to result
Myoglobin	8 min.
D-dimer	
Troponin T	12 min.
NT-proBNP	
CK-MB	

** Cardiac care unit.*

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Life needs answers

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.

The Trop T Sensitive 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 mycardial infarction.

Results from a large prospective clinical trial* 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

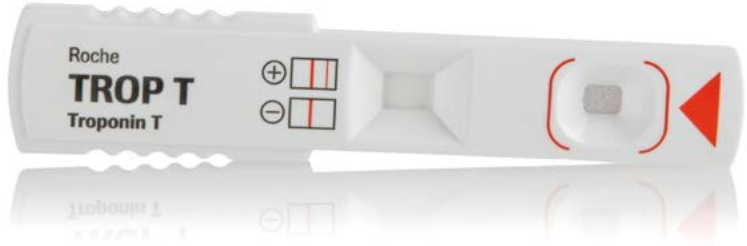
- Requires no external measurement system
- Requires no special training

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

Product characteristics

- Qualitative detection of troponin in anticoagulated (EDTA or heparin) venous whole blood
- 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 is available in 5 and 10 pack sizes



** 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*

cobas®
Life needs answers

CoaguChek® XS system
Coagulation self-testing made easy

www.CoaguChek.com

The CoaguChek® XS system is a convenient, portable and user-friendly instrument for monitoring oral anticoagulation 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 on vacation.

Your benefit

Fast, reliable results
- Accurate PT / INR results in one minute
- Built-in quality control checks every strip automatically
- Lab-equivalent accuracy precision[1]

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[3]

Improved patient outcomes
- Frequent testing allows side effects to be minimized and increases the time spent within the therapeutic range[2]

Product characteristics
- Test principle: Electrochemical determination of the PT time after activation of coagulation with human recombinant thromboplastin
- User interface: Icon-based LCD display; on/off, mem and set buttons
- Memory capacity: 300 test results with date and time
- Sample types: Fresh capillary or anticoagulant-free venous whole blood
- Easy blood application: top- or side dosing
- Measuring range:
  INR: 0.8 – 8.0
  %Quick: 120 – 5
  Seconds: 9.6 – 96
- Data transfer: Infrared interface

1 Kitchen, D.P., Munroe, S., Kitchen, S., Jennings, I., Woods, T.A.L., Walker, I.D. (2008). Results from the first year of an external quality assessment programme for the users of CoaguChek XS and CoaguChek XS Plus for monitoring INRs. *British Journal of Haematology,* Volume 141 Supplement 1: P188.

2 Heneghan, et. al (2006). *Lancet, 367;* 404-411.

3 Woods, K., Douketis, J.D., Schnurr, T., Kinnon, K., Powers, P. et al. (2004). Patient preferences for capillary vs. venous INR determination in an anticoagulation clinic: a randomized controlled trial. *Thromb Res 114(3)*, 161-165.

CoaguChek®
Because it's my life

CoaguChek® XS Plus system
CoaguChek XS Pro system
Coagulation monitoring for healthcare professionals

www.CoaguChek.com

The CoaguChek XS Plus and the CoaguChek XS Pro systems are convenient, portable and user-friendly systems for monitoring oral anticoagulation therapy. They determine the INR value (International Normalized Ratio) from a drop of capillary whole blood – simple, precise and reliable. CoaguChek XS Plus and Pro systems have been developed exclusively for professional use.

They produce results equivalent[1] to those obtained with reference laboratory methods; results are also comparable to those obtained with the patient's device, the CoaguChek XS system, as they use the same technology and the same strips.

Your benefit

Safety and confidence

- Onboard control on every strip plus optional liquid controls
- Optional operator and QC lockouts
- Integrated barcode scanner with the CoaguChek XS Pro, for safe, easy patient identification
- Over 20 years' experience from Roche in INR monitoring

Improved workflow and convenience

- Approx. 1 min. to get an accurate INR result from 8 µL whole blood
- Easy blood application: top- or side dosing

CoaguChek XS Plus system *CoaguChek XS Pro system*

1 Kitchen, D.P., Munroe, S., Kitchen, S., Jennings, I., Woods, T.A.L., Walker, I.D. (2008). Results from the first year of an external quality assessment programme for the users of CoaguChek XS and CoaguChek XS Plus for monitoring INRs. *British Journal of Haematology,* Volume 141 Supplement 1: P188.

Product characteristics

- Test principle and measuring range is the same as on the CoaguChek® XS system
- User interface: large TFT color touchscreen; screen icons allow intuitive operation
- Memory capacity: 2,000 test results with date and time
- Liquid control available for dedicated QC requirements
- Extended data management capabilities:
  - industry standard POCT1-A or Roche internal protocol (to the **cobas IT** 1000 application)
  - complete documentation of results including patient and operator identification
- Automatic code chip identification to match lot-specific information with test strips in use

CoaguChek®
Because it's my life

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

This cost-effective, all-in-one device provides rapid, yet accurate results.

Accutrend Plus system

Your benefit

On the spot results

- Point-of-care lipid testing can substantially improve identification and management of dyslipidemic patients in primary care
- Make immediate recommendations regarding lifestyle or treatment, leading to improved patient compliance and loyalty

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 • 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 • Use of heparin-coated pipettes possible	10 – 40 µL	18° – 30°C
Lactate	0.8 – 22 mmol/L		60 sec	• Fresh capillary blood • Use of heparin-coated pipettes possible	15 – 50 µL	5° – 35° or 15° – 35°C depending on concentration of analyte

cobas®

Life needs answers

Reflotron® Plus system and Reflotron® Sprint systems

Flexible testing to support your clinical decisions

www.cobas.com

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

Reflotron Sprint system

Your benefit

Reliability

- Test results, correlating well with standardized laboratory methods and validated in a number of clinical studies even from capillary samples
- No storage concerns due to excellent test strip stability
- Little waste and almost no maintenance

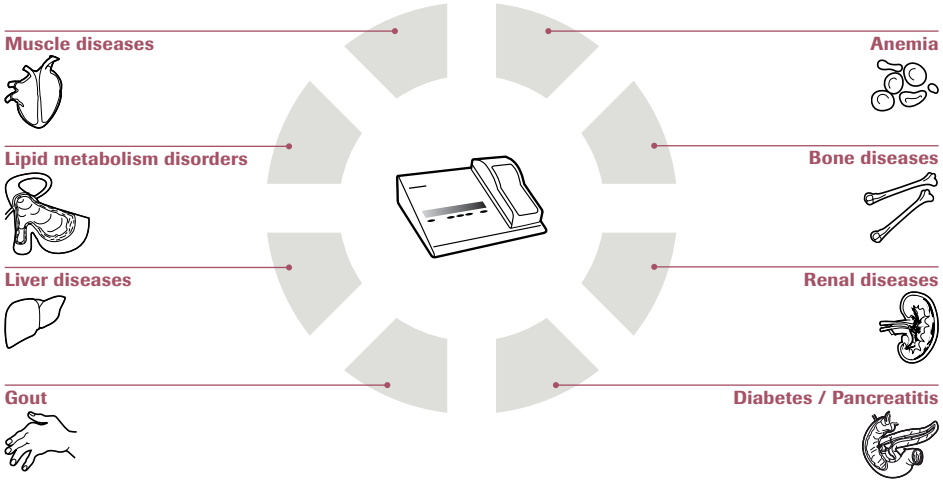
Faster clinical decision making

- Quick time to result
- No reagent preparation

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®
Life needs answers

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 (CHOL, HDL, LDL, TG) on one device at the Point of Care. Capillary blood, whole blood and 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

Test precision and guideline compliant

- **cobas b** 101 system complies with all relevant standards and methods (IFCC, DCCT/NGSP and NCEP)[1]

Easy and safe operation

- Both tests can be performed from one finger prick
- No calibration needed, checking sample integrity, full process control, configurable display of results

Fast turnaround time

- An intuitive 15 min. workflow from patient preparation to result 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.*

1 Roche internal verification data (multi-center evaluation).

Product characteristics

- User-friendly with a large touchscreen, full keyboard, and multiple language 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

- Sample volume easily from one finger stick, fast and easy with direct sample application (no capillaries, tubes or pipettes are needed)
  - HbA1c ≤ 2 µL in ≤ 340 sec
  - Lipids ≤ 19 µL in ≤ 385 sec
- Discs are color-coded and clearly labelled to support correct use. Flap for high operator safety
- Shelf life of more than 13 months
- Both capillary and venous whole blood can be used for lipids and HbA1c testing. Lipid testing can also be done with plasma

** calculated*

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*

cobas®
Life needs answers

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 molecular testing point of care segment to better serve customers needs with after-hours and STAT testing within the primary care segment. These solutions are designed to provide information that allows healthcare professionals to diagnose diseases and monitor patients' response to therapy. 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

cobas®

Life needs answers

Molecular diagnostics solutions from Roche

Innovative, reliable and efficient

www.molecular.roche.com

Meeting the requirements for safe, high-quality PCR diagnostics, Roche has developed the concept of flexible, easy to combine system modules. Depending on test requirements and sample volumes, these modules can provide a customized, efficient solution for every laboratory.

Your benefit

- Efficient workflow
- Innovative real-time PCR technology meets international guidelines for sensitivity and linear measurement range
- Reliable results due to AmpErase prevention of enzyme contamination, use of internal controls and automation

Workflow solutions for molecular diagnostics

Laboratory needs	Sample purification	PCR system
Women's health and genetic/oncology parameters		
• **Low to high throughput**	**cobas**® 4800 System	
		
	cobas x 480 Instrument	**cobas z** 480 analyzer
		
• **Pre-analytic sample processing**	**cobas p** 480 Instrument	
		
Microbiology and special virology assays and customizable assay protocols		
• **Low and medium throughput** • **Customizable assay protocols**	High Pure or MagNA Pure LC 2.0 System	LightCycler® 2.0 System
		

Workflow solutions for molecular diagnostics

Laboratory needs	Sample purification	PCR system
Infectious diseases/virology		
• **Very high throughput** • **Full automation** • **Unmatched flexibility**	**cobas**® 8800 System, **cobas** 6800 System (Infectious disease, Virology, Blood screening), **cobas p** 680 Instrument (optional for blood screening)	
		
• **High throughput**	**cobas s** 201 System (Blood screening)	
		
• **High throughput** • **Full automation**	**cobas p** 630 Instrument, COBAS® AmpliPrep/COBAS® TaqMan® System	
		
• **High throughput** • **Back-up system** • **Flexibility**	COBAS® AmpliPrep Instrument	3x COBAS® TaqMan® 48 Analyzer
		
• **Medium throughput**	Manual or COBAS AmpliPrep Instrument	COBAS TaqMan 48 Analyzer
		
• **Low throughput**	Manual	COBAS TaqMan 48 Analyzer
		
• **Single sample testing** • **Point of care** • **Full automation**	**cobas** Liat System	
		

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Test overview

Parameter	Test kit	Detection	cobas® Liat System	cobas 6800 / 8800	cobas s 201 System	LightCycler® 2.0 Analyzer	cobas x 480 / cobas z 480 / cobas 4800 System	COBAS® Amplicor / Amplicor Analyzer	COBAS® TaqMan® Analyzer
Viruses									
Cytomegalovirus	COBAS® AmpliPrep/COBAS® TaqMan® CMV Test	quant.						●	
	LightCycler® CMV quant Test						●		
Epstein Barr	LightCycler® EBV quant Test						●		
Hepatitis A	LightCycler® Hepatitis A Virus quantification Kit						●		
Hepatitis B	COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0							●	
	COBAS® TaqMan® HBV test for use with High Pure System							●	
Hepatitis C	COBAS® AmpliPrep/COBAS® TaqMan® HCV qualitative Test, v2.0	qual.						●	
	COBAS® AmpliPrep/COBAS® TaqMan® HCV quantitative Test, v2.0	quant.						●	
	COBAS® TaqMan® HCV Test for use with High Pure System, v2.0							●	
	LINEAR ARRAY HCV genotyping Test	genot.							●
Herpes	LightCycler® HSV 1 and 2 qual Test	qual. and diff.					●		
	cobas® HSV 1 and 2 Test					●			
Human immunodeficiency	COBAS® AmpliPrep/COBAS® TaqMan® HIV Test, v2.0	quant.						●	
	COBAS® TaqMan® HIV Test for use with High Pure System, v2.0							●	
	COBAS® AmpliPrep/COBAS® TaqMan® HLA-B*5701 screening Test	qual.						●	
	COBAS® AmpliPrep/COBAS® TaqMan® HIV qualitative (for research only)							●	
Human Papillomavirus	**cobas**® HPV Test	qual./genot.				●			
	LINEAR ARRAY HPV genotyping Test	genot.							●
	AMPLICOR® Human Papillomavirus Test	qual./genot.							●
Parvo B 19	LightCycler® Parvo B19 quantification Kit (for research only)	quant.					●		
Varicella-Zoster	LightCycler® VZV qual Test	qual.					●		
Other pathogens									
Chlamydia tracho-matis / Neisseria gonorrhoeae	**cobas**® 4800 CT/NG Test	qual.				●			
	COBAS® AMPLICOR CT/NG								●
Chlamydia trachomatis	COBAS® TaqMan® CT Test	qual.						●	
Chlostridium difficile	**cobas**® Cdiff Test					●			
Methyllicin resistant staphy-lococcus aureus	LightCycler® MRSA advanced Test	qual. and diff.					●		
	cobas® MRSA/SA Test					●			
Mycobacteria Tuberculosis	COBAS® TaqMan® MTB Test	qual.						●	

Parameter	Test kit	Detection	cobas® Liat System	cobas 6800 / 8800	cobas s 201 System	LightCycler® 2.0 Analyzer	cobas x 480 / cobas z 480 / cobas 4800 System	COBAS® Amplicor / Amplicor Analyzer	COBAS® TaqMan® Analyzer
Vancomycin resis-tant enterococcus	LightCycler® VRE	qual.					●		
Sepsis pathogens									
Bacteria/Fungi	LightCycler® SeptiFast Test MGRADE	qual. and diff.					●		
	LightCycler® SeptiFast mecA Test MGRADE	qual. and ident.					●		
Blood screening									
HIV-1*, HIV-2, HCV, HBV	**cobas**® MPX	qual./diff.						●	
	cobas® **TaqScreen** MPX Tests						●		
B19V/HAV	**cobas**® DPX							●	
	cobas® **TaqScreen** DPX Test						●		
West Nile virus	**cobas**® WNV	qual.						●	
	cobas® **TaqScreen** WNV Test						●		
HEV	**cobas**® WNV	qual.						●	
Influenza A/B									
Influenza A/B	**cobas**® Influenza A/B	qual.							●
Influenza A/B-RSV	**cobas**® Influenza A/B-RSV	qual.							●
Bacteria									
Strep A	**cobas**® Strep A	qual.							●
Oncology									
BRAF	**cobas**® 4800 BRAF V600 Mutation Test	qual. (mutation detection)			●				
KRAS	**cobas**® KRAS Mutation Test				●				
EGFR	**cobas**® EGFR Mutation Test				●				
PIK3CA	**cobas**® PIK3CA Mutation Test (research use only)	qual. and ident.			●				
BCR-ABL	LightCycler® t(9;22) quantification Kit (for research only)	relative quant.					●		
Genetics									
Factor V Leiden	Factor V Leiden Kit	qual. (mutation detection)					●		
Factor II	Factor II (Prothrombin) G20210A Kit						●		
HLA-B*5701	COBAS® AmpliPrep/COBAS® TaqMan® HLA-B*5701 screening Test	qual.							●

** Groups M and O*

qual. = qualitative; quant. = quantitative, genot. = genotyping; diff. = differentiation; ident. = identification

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

cobas®

Life needs answers

NEW

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 four **cobas p** 680 Instruments to the **cobas**® 6800 / 8800 Systems to meet your lab's needs.

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

cobas p 680 Instrument

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.

NEW

cobas® 6800 / 8800 Systems

Own the future

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 microbiology 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

Your benefit

Unparalleled Performance

Rapidly complete daily testing requirements with trusted and reproducible results.

- Produce up to 384 and 960 tests respectively in an eight-hour shift, with the first 96 test results available in less than 3.5 hours

Absolute Automation

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

- Minimal and intuitive user interactions result in eight and four hours of "work-away" time* respectively, while also reducing the potential for human error

Unmatched Flexibility

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

- Perform up to three molecular tests simultaneously, without batching or pre-sorting samples. Run high-priority samples through a dedicated priority lane. Continuously load samples onto the system and perform up to three tests from a single sample

**may vary based on workflow demands*

Product characteristics

Advanced automation

- Ready-to-use reagents do not require thawing, mixing or pouring
- Automated onboard storage and refrigeration system enable ready access and maintain inventory of consumables and reagents
- Radio-frequency identification (RFID) and barcodes ensure full traceability from sample in to results out
- Uni- and bi-directional LIS interface simplifies order and result handling
- System connectivity: up to five analytic systems and four **cobas p** 680 instruments managed by a single instrument gateway

Consolidated menu

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

Blood screening today	Viral load monitoring	Diagnostic testing tomorrow
MPX*	HIV-1†	CT/NG
WNV	HBV	HPV
DPX	HCV††	MTB/MAI
HEV	CMV	HIV ual

* Dual-target for HIV-1 and dual-probe for HCV
† Dual-target
†† Dual-probe

Virus
Bacteria

The cobas® 6800/8800 Systems are not available in all markets, including the United States.

cobas®
Life needs answers

cobas p 630 Instrument

The pre-analytics solution that makes life easier

The **cobas p** 630 Instrument offers in combination with the COBAS® AmpliPrep / COBAS® TaqMan® System a fully automated pre-analytical solution for primary tube handling. The system automatically pipettes primary and secondary tubes and controls into sample input tubes for the COBAS AmpliPrep Instrument.

The **cobas p** 630 Instrument can be combined with up to three COBAS AmpliPrep Instruments and AmpliLink® software to ensure full traceability of workflow.

Your benefit

Efficiency

- Automated handling of primary and secondary tubes

Flexiblility

- Compatible with a variety of sample tubes
- Modular design

Full traceability

- Barcode tracking from patient tube to result

Process surveillance

- Monitors liquid handling

cobas p 630 Instrument

Product characteristics

- Uncapping and recapping of the sample tube
- Pipetting Roche controls from control tubes to sample tubes
- Pipetting samples from primary and secondary tubes to sample tubes
- Multiple tests can be ordered on a single primary tube
- Only one LIS interface required

Unit dimensions

- 112 cm wide, 101 cm deep, 90 cm high

Sample processing throughput

- 320 samples on board
- 154 tubes per hour for 650 µL samples
- 149 tubes per hour for 1.0 mL samples
- 157 tubes per hour for 500 uL samples

cobas®
Life needs answers

cobas p 480 Instrument

Automating your primary vial preprocessing steps

The **cobas p** 480 Instrument reduces laboratory hands-on-time, and offers a fast, reliable way to uncap and recap PreservCyt® and SurePath liquid based cytology vials as well as **cobas**® PCR Media tubes. The instrument allows primary vials to be loaded directly onto the **cobas** 4800 System, without a need to aliquot into a secondary vial. It provides significant workflow and sample integrity advantages improving lab workflow and eliminating repetitive motions.

Your benefit

Improve laboratory efficiency

- Allows multiple vial types to be loaded in a single decapping operation
- Process four vials simultaneously
- High throughput operation allows a single instrument to support more than one analytic system

Reduce hands on time and eliminate repetitive motion

- Automated uncapping, recapping and vortexting
- Minimizes the risk of sample mix-up or user error

cobas p 480 Instrument

- Compatible with BD SurePath, Hologic PreserCyt and **cobas**® PCR media vials
- Intuitive interface requires minimal training
- Barcode quality checks prevents costly delays in downstream processing

Improve sample reproducibility and process reliability

- Automated vortexing processes specimens consistently from first to last, regardless of throughput
- Precision movements reduce opportunity for cross contamination
- Helps ensure reliability of the test results
- No LIS or data connection required

Replacement caps ensure a quality seal

- Quality seal ensures that the sample are well protected for transport, storage or other testing needs
- New replacement caps packaged for easy loading and automated recapping
- Replacement caps available for all compatible vial types
- Offers better seal integrity compared to parafilm or cellophane over pierced or open vial containers

cobas®
Life needs answers

cobas® 4800 System v2.0

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 (the detection of *C. trachomatis (CT), N. gonorrhoeae (NG),* HPV (human papillomavirus) 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

Reliable results
- Proprietary kinetic algorithm software provides clear and precise answers reducing the need for retesting or interpretation

Efficiency
- By fully automated sample preparation and PCR set-up (for HPV and CT/NG)
- By bidirectional connectivity with your LIS for automated results reporting

Flexibility
- Possibility to use multiple primary vial types
- User defined workflow software for free programmable PCR applications

Load-and-go reagents
- Save time and labor
- Low daily maintenance requirements

cobas x 480 Instrument

cobas z 480 analyzer

Test menu

cobas® 4800 HPV Test
- Only FDA approved, CE-marked hr HPV DNA test for cervical cancer primary screening; simultaneously detects 14 high-risk HPV genotypes, including individual identification of HPV genotypes 16 and 18

cobas 4800 CT/NG Test
- Test is designed to run as CT only, NG only or as CT/NG combination
- Highest specificity for NG and detection of Swedish CT mutant and other variants due to dual target detection

Oncology tests
- **cobas** 4800 BRAF V600 Mutation Test
- **cobas** KRAS Mutation Test
- **cobas** EGFR Mutation Test
- **cobas** PIK3CA Mutation Test (for research use only)

Please see details on page 170.

Hospital aquired infections
- **cobas** MRSA/SA Test
- **cobas** Cdiff Test

Please see details on page 172.

Viral infections
- **cobas** HSV 1 and 2 Test

Product characteristics

- Processes up to 376 samples in 10 h
- Bidirectional connectivity to LIS
- Easy to use software
- Automated result interpretation for HPV and CT/NG

Components:

cobas x 480 Instrument
- Fully automated nucleic acid purification
- Automated PCR set up
- Dimensions: 166 cm width, 90 cm depth, 101 cm high

cobas z 480 analyzer
- Based on LightCycler® 480 technology (see page 194)
- 6 detection channels
- 96 well plate format
- Dimensions: 57 cm width, 59 cm depth, 50 cm high

cobas®
Life needs answers

The cobas® HPV Test
Know the risk

www.hpv16and18.com

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 „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 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 of the patients at the highest risk

Report with confidence
- Internal control for assurance of sample integrity
- No cross reactivity with low risk HPV genotypes

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

Product characteristics

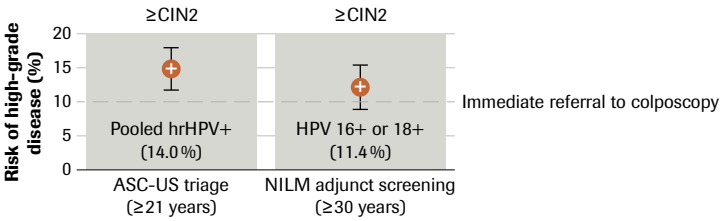
Coverage:
- Identifies (types) HPV 16 and HPV 18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) at clinically relevant infection levels

Sample material:
- Cervical cells collected in **cobas**® PCR cell collection media (Roche Molecular Systems, Inc.), PreservCyt® solution (Cytyc Corp.) and SurePath® preservative fluid (not approved in the US) (BD Diagnostics-TriPath)
- Sample volume of 1 mL is sufficient

Test principle:
- Multiplex assay to detect 12 pooled high risk genotypes, with simultaneous individual genotyping for highest risk HPV 16 and 18
- Beta-globin acts as control for extraction and amplification

Throughput:
- Up to 282 tests in less than 12 hours

Absolute risk of ≥ CIN2 by screening strategies assessed in ATHENA at baseline



1 in 10 women ≥30 years of age with negative cytology who tested positive for HPV 16/18 using the cobas HPV test had underlying precancerous lesions. Women with negative pap cytology who are HPV 16+ and/or HPV 18+ and women with ASC-US who are pooled hrHPV+ share a similar absolute risk of precancer and should be managed similarly with immediate referral to colposcopy.

cobas®
Life needs answers

The cobas® Oncology Tests

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 clinically validated companion diagnostics help physicians make therapy decisions for patients suffering from metastatic melanoma, colorectal cancer, and non-small cell lung cancer. Due to the short testing time physicians can make decisions in hours instead of days when using alternative methods.

Your benefit

Reliable results

- Complete and controlled IVD System consisting of **cobas** DNA sample Preparation Kit, **cobas** BRAF, KRAS, EGFR, and PIC3CA (RUO) Mutation Tests, and the **cobas** 4800 System, v2.0

Consistent, objective and reproducible results

- Automated result interpretation and test reporting provide from laboratory to laboratory

Fast result reporting

- Delivering patient results in < 8 h

Test menu

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 (< 5 % mutant copies in formalin-fixed, paraffin-embedded tissue [FFPET]); also sensitive to V600K and V600D
- 24 reportable results from a single test kit
- Only requires one 5 µm tissue section with > 50 % tumor area for the PCR reaction

cobas KRAS Mutation Test (CE-IVD)

- Offers broad mutation coverage of KRAS codons 12, 13 and 61 to identify colorectal cancer patients not likely to respond to anti-EGFR monoclonal antibody therapies, e.g., Erbitux, Vectibix
- Detects all of the reported mutations in codons 12, 13 and 61 of the EGFR gene (< 5 % mutant copies in FFPET)
- 24 reportable results from a single test kit
- Only requires one 5 µm tissue sections with ≥ 10 % tumor area for the PCR reaction

cobas EGFR Mutation Test

- Identifies patients with non-small cell lung cancer who benefit from anti-EGFR TKI therapy, e.g. Tarceva®

- Specific detection of 41 mutations (insertions and deletions) in exons 18, 19, 20 and 21* of the EGFR gene (≤ 5 % mutant copies in FFPET)
- 24 reportable results from a single test kit
- Only one 5 µm tissue section with ≥ 10 % tumor area for the PCR reaction

cobas DNA Sample Preparation Kit

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

Assay specific analysis packages

- Software package containing cycling conditions, algorithms and calculations for automated interpretation and report of results

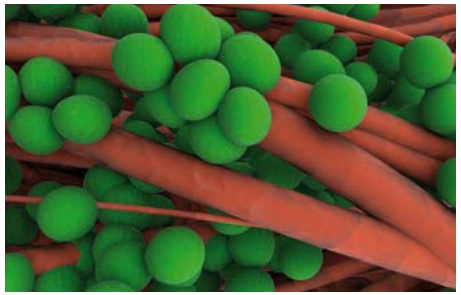
** In US, coverage is Exon 19 and 21 only*

cobas®
Life needs answers

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

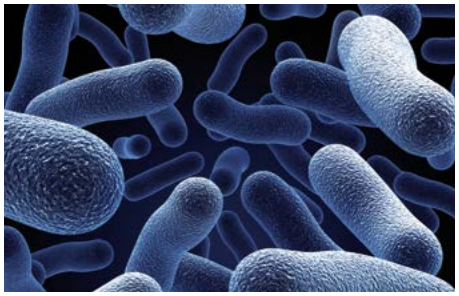
Automated efficiency

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

cobas® 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 toxino-types 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

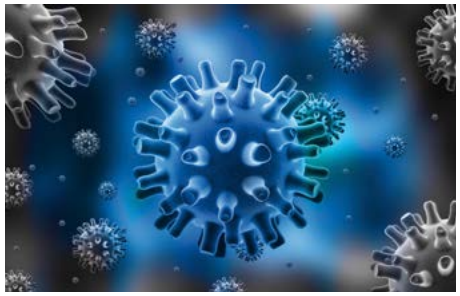
- Run as few as 6 or as many as 94 samples
- Process different tests and sample types simultaneously

cobas®
Life needs answers

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

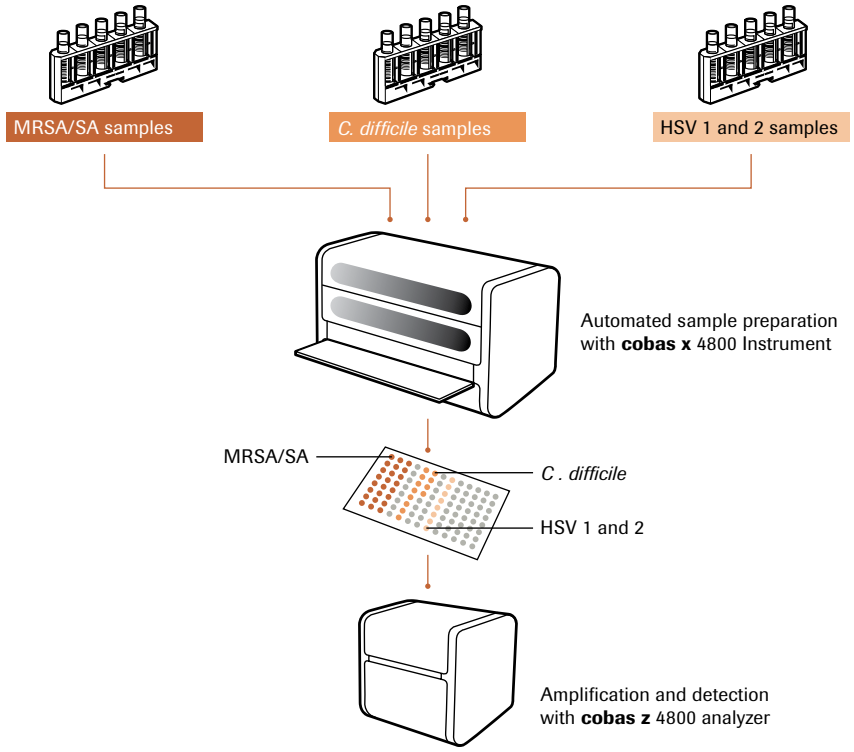
Reduced hands-on time

- 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

Mixed batch testing on cobas® 4800 System



Parallel sample processing offers the flexibility to run different tests and sample types, including:

- Stool (**cobas** Cdiff test)
- Nasal (**cobas** MRSA/SA Test)
- Anogenital lesions (**cobas** HSV 1 and 2 Test)

cobas®
Life needs answers

NEW

cobas® Liat System

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

www.cobasliat.com

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 less than 20 minutes.

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

cobas® Lab in a tube Liat

Your benefit

Accuracy
- Roche PCR technology
- Definitive, reproducible, objective

Speed
- Analysis in less than 20 minutes, 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

Product characteristics

- No complex set up
- Runs single assays on single patient samples
- All assay components fully enclosed – no direct operator contact with reagents or other solutions
- Easy, 3-step process
- Definitive, objective results
- Over 20 controls including comprehensive real-time monitoring
- Touchscreen options allow viewing of real-time PCR curve
- 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
Additional assays in development

** Not available in all markets including the US*

cobas®
Life needs answers

COBAS® AmpliPrep Instrument

Nucleic acid purification made simple

The COBAS AmpliPrep Instrument automates purification of DNA and RNA using magnetic bead technology. Elimination of time-consuming and fault-prone manual sample preparation increases efficiency and safety in the laboratory. The COBAS AmpliPrep Instrument can be combined with the COBAS TaqMan® or COBAS TaqMan 48 Analyzer and thereby offer a custom solution for each PCR laboratory.

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
- Additional generic sample preparation for other PCR systems increases the versatility of the instrument

COBAS® AmpliPrep Instrument

Product characteristics

- Ready-to-use reagents in barcoded cassettes
- Detection of liquid level and clots
- Controllable via data station with AmpliLink® software, for laboratory integration with LIS
- Barcoded data input

Unit dimensions

- 165 cm wide, 75 cm deep, 95 cm high

Capacity

- 72 samples; up to 144 purifications per day

Throughput

- approx. 15 – 24 samples/hr

cobas®
Life needs answers

COBAS® TaqMan® Analyzer and COBAS® TaqMan® 48 Analyzer

Easy begins here – Innovation for routine PCR

The COBAS TaqMan 48 Analyzer is a compact benchtop instrument that minimizes manual steps and shortens analysis times with innovative real-time PCR technology. Two independent thermocyclers allow two parameters to be processed in parallel. For higher throughput needs, a higher-capacity COBAS TaqMan 96 Analyzer provides automated real-time amplification and detection of DNA or RNA for up to 96 samples and four assays at the same time. Samples can be prepared automatically on the COBAS AmpliPrep Instrument. The combination of innovation and flexibility ensures efficient workflow in routine PCR laboratories with low to medium throughputs. The COBAS TaqMan Analyzer combined with the COBAS AmpliPrep Instrument and docking station is the solution for higher throughput PCR.

Your benefit

Efficiency and 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® TaqMan® 48 Analyzer

COBAS® TaqMan® Analyzer

Product characteristics

COBAS TaqMan 48 Analyzer

- Compact desktop model
- two independent thermocyclers, each with 24 positions
- Real-time PCR assays using hydrolysis probes
- 48 samples in 2,5 to 3,5 hours (depending on parameters)

COBAS TaqMan Analyzer

- A docking station can combine COBAS AmpliPrep Instrument and COBAS TaqMan Analyzer into a single, fully automated system that can perform sample preparation, PCR set-up and amplification / detection
- Four independent thermocyclers, each with 24 positions
- Run time: 2.5 – 3.5 hours
- 192 samples in 24 hours

Test menu

With manual sample preperation

- HCV quantitative
- HBV quantitative
- HIV-1 quantitative
- *Chlamydia trachomatis* qualitative
- *Mycobacterium tuberculosis* qualitative

With automated sample preparation

- HCV qualitative and quantitative
- HBV quantitative
- CMV quantitative
- HIV-1 quantitative
- HLA – B*5701
- HIV-1 qualitative*

** Not commercially available in all countries*

cobas®
Life needs answers

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

Empowering change in HCV

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

The version 2.0 tests are developed with a lower input volume, and innovative dual-probe design provides improved sensitivity and precise detection across all genotypes for the new era of direct acting antiviral agents (DAAs) to distinguish true signal from background noise.

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

The test completes the molecular diagnostic tools in HCV diagnosis. It is indicated for patients who have clinical and / or biochemical evidence of liver disease and antibody evidence of HCV infection, and who are suspected to be actively infected with HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.

Your benefit

- Reliable results by enhanced mismatch tolerance and coverage of all genotypes
- Economic sample usage
- Excellent sensitivity to meet guidelines

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
- Diagnostic sensitivity 100 %
- Specificity 99.9 %

Workflow

- Confirm active infection and monitor HCV viral load on the same system
- Flexible batch size with continuous loading
- Interleave with other COBAS TaqMan Tests (HIV-1, HBV)

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

The test can be used to assess the probability of a sustained viral response early in a course of antiviral therapy and to assess viral response to antiviral treatment as measured by changes in serum or plasma HCV RNA levels.

Your benefit

- Precisely distinguish true signals from background noise for more accurate viral load results
- Reliable results by enhanced mismatch tolerance and coverage of all genotypes
- Perfect tool to aid in response-guided therapy with excellent sensitivity and specificity delivering accurate results
- Economic sample usage required which provides laboratory with enough left over sample for other laboratory testing

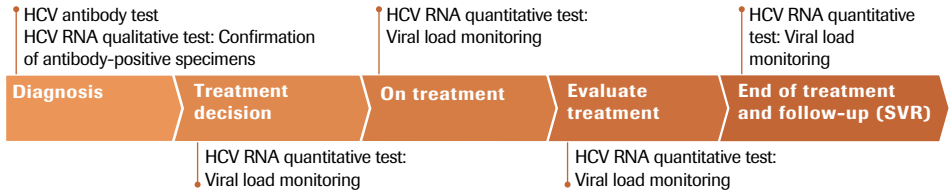
Product characteristics

- Kit configuration 72 tests / kit
- Sample types EDTA plasma and serum
- Sample input volume 650 µL
- Limit of detection 15 IU/mL
- Linear range 15 IU/mL – 1E108 IU/mL
- Genotype inclusivity genotypes 1 through 6
- Diagnostic sensitivity 100 %
- Specificity 100 %

Workflow

- Confirm active infection and monitor HCV viral load on the same system
- Flexible batch size with continuous loading
- Interleave with other COBAS TaqMan Tests (HIV-1, HBV)

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®
Life needs answers

NEW

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 greater 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. The test provides diagnostic accuracy in test results even if mutations occur in one of the two regions.

This test uses the COBAS® AmpliPrep Instrument to automate specimen processing and the COBAS® TaqMan® Analyzer or COBAS TaqMan 48 Analyzer to automate amplification and detection.

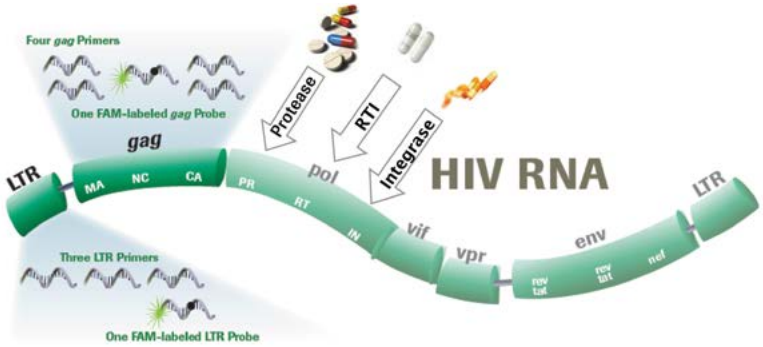
Your benefit

Dual-targeted approach for greater security against the unexpected:

- Provides diagnostic accuracy of test results even if mutations occur in one of the two regions
- Compensates for the possibility of mismatch occurring with a primer / probe region
- Ensures enhanced reliability of test results and more confidence in assessing viral loads
- Offers increased sensitivity and linear range for accurate measurement of viral suppression

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
- Offers increased sensitivity and linear range for accurate measurement of viral suppression
- 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



cobas®
Life needs answers

NEW

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

cobas®
Life needs answers

NEW

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.

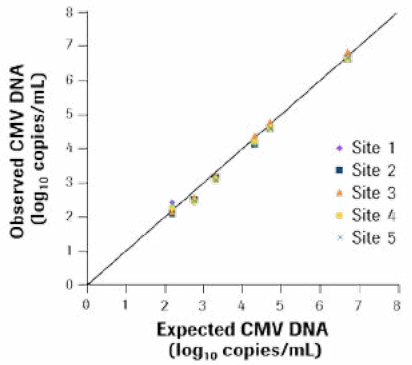
Your benefit

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

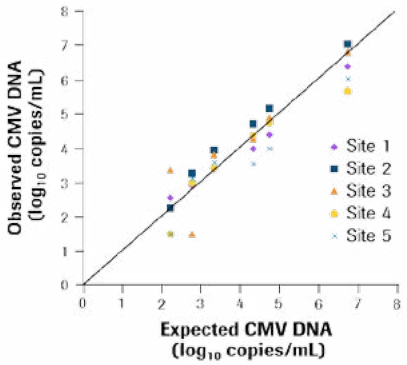
- A test that fulfils international guideline recommendations – demonstrating co-linearity to the WHO international standard and reports results in IU/mL, as recommended by the international consensus guidelines for CMV management in solid organ transplant patients[1,8]
- A test that is clinically validated – Used in key clinical studies, demonstrating clinical utility of CMV viral load monitoring[3,9]
- 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.[6] The first standadized CMV viral load test with CE and FDA approval[8]

CMV viral load test standardization enables improvement in CMV infection management[4,5]

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®
Life needs answers

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 AMPLICOR respiratory specimen preparation kit

COBAS TaqMan 48 Analyzer and MTB kits

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®
Life needs answers

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.

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
- Most comprehensive assays on the market with ready-to-use reagents
- Built-in viral target resolution through multi-dye technology makes confirmation testing obsolete

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

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 tests

- Covers 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

cobas®

Life needs answers

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 format or tube based formats.

For additional information see lifescience.roche.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

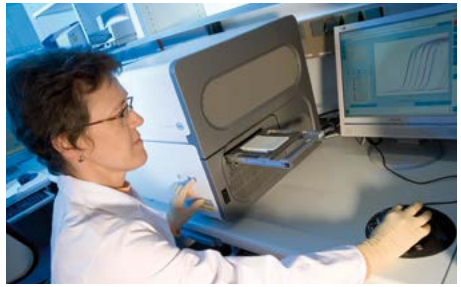
*LightCycler 96 System**

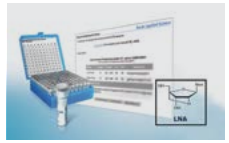
LightCycler 2.0 Instrument (IVD)

*LightCycler 480 System**

** For life science research only. Not for use in diagnostic procedures.*

Available reagents
- Generic kits for PCR and RT-PCR
- Parameter-specific kits Research Use Only
- Parameter-specific kits IVD
- Ready to use custom assays and panels for all available LightCycler Systems (e.g., Universal ProbeLibrary and RealTime ready)





Universal ProbeLibrary

RealTime ready

Product characteristics

	LightCycler® 2.0 Instrument	LightCycler 480 System (96/384)	LightCycler 96 System
Throughput	1–32 reactions	1–96 or 1–384 reactions	1–96 reactions
Hardware	6 detection channels	5 excitation and 6 detection filters	
Disposable	Capillaries	96 or 384 multiwell plates	96 multiwell plates or tube strips
System features	• Excellent temperature homogeneity in all wells/vessels • No need for passive reference dyes • 40 cycles are possible in 40 minutes • Freely programmable protocols, data import and export, creation of macros and templates.		
Assay formats	SYBR Green I, hydrolysis and hybridization probes	SYBR Green I, hydrolysis and hybridization probes	SYBR Green I, hydrolysis probes
Reagents	• Generic kits for PCR and RT-PCR • Ready-to-use custom assays • Parameter-specific kits	• Generic kits for PCR and RT-PCR • Ready-to-use custom assays and panels • Parameter-specific kits	• Generic kits for PCR and RT-PCR • Ready-to-use custom assays and panels • Parameter-specific kits

LightCycler® 2.0 Instrument is available as IVD in many countries. Information about the low throughput LightCycler® Nano System and the high-throughput LightCycler® 1536 System is available on request.

cobas®
Life needs answers

LightCycler® 2.0 Instrument

High performance that meets the needs of IVD

The LightCycler 2.0 System is an innovative real-time PCR platform that uses a fluorescence detection system and high-quality reagents for a wide range of applications in *in vitro* diagnostics and in medical research.

It offers a multitude of innovative features, ranging from optimized validated software to six different detection channels.

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

LightCycler 2.0 Instrument (IVD)

Product characteristics

- Compact desktop model
- 35 cycles in about fast 40 min.
- 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
- Online display of the PCR kinetics

Test kits, validated for IVD

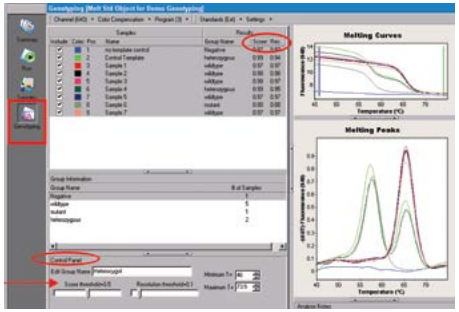
- CMV quantification
- EBV quantification
- HSV 1/2 detection and differentiation
- VZV detection
- MRSA advanced detection
- Septi*Fast* identification of bacteria and fungi
- Septi*Fast* mec A resistance screening
- Factor V mutation detection
- Factor II mutation detection

For medical research

- HAV quantification
- Parvo B19 quantification
- VRE resistance screening
- Translocation (9;22) quantification

Include	Color	Pos	Name	Calls: Combined	Calls: Target	Calls: Control
☑		1	no template control	Success	Negative	Success
☑		2	Negative Control	Success	Negative	Success
☑		3	Positive Control	Success	Positive	Success
☑		4	Sample 1	Positive	Positive	Success
☑		5	Sample 2	Positive	Positive	Success
☑		6	Sample 3	Negative	Negative	Success
☑		7	Sample 4	Positive	Positive	Success
☑		8	Sample 5	Positive	Positive	Success

Data display for a qualitative detection analysis



Genotyping analysis

cobas®
Life needs answers

LightCycler® Septi*Fast* Test

Rapid identification of sepsis pathogens

Sepsis is a leading, infectious complication for critically ill patients. It represents about 15 % of all nosocomial infections. Despite improvements in medical care, sepsis is still a challenge for internal medicine. Any delay in the management of infection is deleterious, especially in patients whose illness is severe. Shortening this delay is of paramount importance. In the LightCycler Septi*Fast* test, Roche offers a molecular test that detects the presence of microorganisms responsible for approx. 90 % of all sepsis cases seen on intensive care units.

Your benefit

Broad coverage of sepsis pathogens

- Approx. 90 % of all potential sepsis pathogens are detected in a single PCR

Fast results with minimal sample volume

- Detection within 6 hours starting with just 1.5 mL of whole blood

Broad application

- DNA detection also possible during antibiotic therapy
- Resistance screening possible with the LightCycler SeptiFast mecA Test

25 different pathogens can be identified with dem LightCycler Septi*Fast* Test

Gram (-) bacteria	Gram (+) bacteria	Fungi
• Escherichia coli • Klebsiella (pneumoniae/oxytoca) • Serratia marcescens • Enterobacter (cloacae/aerogenes) • Proteus mirabilis • Pseudomonas aeruginosa • Acinetobacter baumannii • Stenotrophomonas maltophilia	• Staphylococcus aureus* • CoNS (Coagulase negative Staphylococci) • Streptococcus pneumoniae • Streptococcus spp • Enterococcus faecium • Enterococcus faecalis	• Candida albicans • Candida tropicalis • Candida krusei • Candida glabrata • Candida parapsilosis • Aspergillus fumigatus

** If positive, resistance can be tested with LC SeptiFast mecA test.*

LightCycler® MRSA Advanced Test

Enabling improved infection control

The incidence of hospital-associated methicillin-resistant *Staphylococcus aureus* (MRSA) is on the rise around the globe. Studies in Europe and the United States suggest that 28 – 34 % of patients infected with MRSA will even die from their infection. These findings have serious implications for patients, physicians, and hospitals. The increased rates of MRSA also have significant economic implications.

The LightCycler MRSA Advanced test offers a simple, flexible and reliable way to incorporate MRSA surveillance into your hospital's infection control program.

Your benefit

- Fast results: Results available within 100 min.
- Simple: Sample preparation procedure involves no pipetting steps
- Flexible: Validated for use with 3 different swabs and provided in a convenient, ready-to-use format
- Reliable results: The only rapid MRSA test containing the Roche AmpErase® enzyme, able to prevent carry-over amplicon contamination that lead to false positive results

Ensure fast and simple operation




cobas®
Life needs answers

MagNA Pure Systems
Accelerate your lab workflow

For 10 years, MagNA Pure Systems represent safe, contamination-free, and reproducible isolation of highly pure nucleic acids. Hence MagNA Pure Systems are the optimal solution for sample preparation in each molecular biology lab.

With the MagNa Pure 96 System, this technology is now also available for high throughput labs.

Your benefit

Efficiency
- Walk-away systems with simple handling and standardized purification protocols

Reliability
- Proven isolation method based on magnetic bead technology

Safety
- Cross-contamination-minimized sample preparation; closed housing, use of UV light, and convenient liquid waste discard

Flexibility
- Isolation of highly pure DNA and RNA from pro- and eukaryotic organisms and different sample materials

*MagNA Pure Compact System**

*MagNA Pure LC 2.0 System**

MagNA Pure 96 System

** For general lab use.*

Product characteristics

	MagNA Pure Compact System	MagNA Pure LC System	MagNA Pure 96 System
Throughput	1–8 samples in about 30 min.	1–32 samples in about 60 min.	8–96 samples in about 50 min.
Hardware setting instrument	Benchtop with integrated PC	Benchtop with integrated PC. Automated PCR setup integrated	Options for benchtop or continuous mode and sensors for load check
Run setup	Easy and convenient with single packaged, barcoded reagents	High flexibility multipack concept	Convenience and error prevention with prepacked, barcoded reagents
Run tracking	Barcoded tracking of individual samples and reagents	Barcoded tracking of sample plate	Barcoded tracking of sample plate and reagent trays
Flexible sample and elution volumes	100–1000 µL / 50–200 µL elution into single tubes	20–100 µL / 25–200 µL elution into plate	100–1000 µL / 50–200 µL elution into plate or single tubes

MagNA Pure 96 system is available as IVD in many countries.

cobas®
Life needs answers

Ventana

Innovative diagnostic instruments

High-value assays

Digital pathology and workflow

Companion diagnostics

Consultative services

Tissue diagnostics

Ventana Medical Systems, Inc., a member of the Roche Group, 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 founder of Ventana, 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.

Ventana 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.

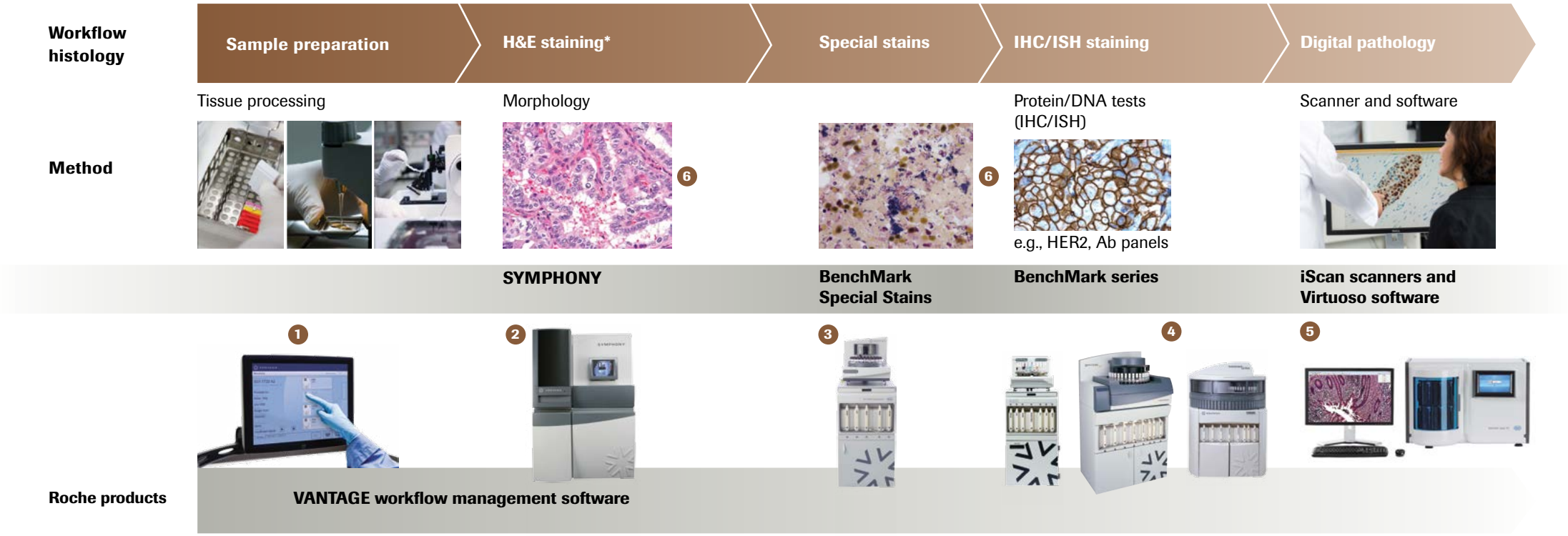
In addition, Ventana offers premier workflow solutions specially designed to improve laboratory efficiency and protect patient safety.

Recognizing the world's increasing medical needs, Ventana 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

VENTANA®

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 SYMPHONY platform
- Fully automated H&E staining
- Capacity up to 500 slides
- Integrated coverslipper

3 BenchMark Special Stains instrument
- Fully automated special stains from baking to staining
- Capacity up to 20 slides per run
- Individual heater pads
- Pre-packed complete detection kits

4 BenchMark IHC / ISH automated staining series
- Fully automated IHC* and ISH* systems, driven by easy-to-use barcoded slides and reagents
- Systems with different capacity available to fit small to large laboratories
- Open systems for antibodies

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®

SYMPHONY system
Rethink H&E

Histology laboratories face a critical challenge – even in today's high-tech world, H&E slide preparation continues to be a labor intensive process. Each step requires significant time and effort, and can result in variable stain quality. The process also presents dangers that may compromise safety for patients through possible tissue cross contamination and lab technicians by exposing them to harmful chemicals.

The SYMPHONY system enables the only fully automated, one-touch H&E process that can minimize these issues and equip your lab with new levels of productivity, safety and quality.

Thanks to the SYMPHONY system, a technician can load slides on the system and walk away. When the automated process is complete, finished slides are coverslipped and ready for immediate presentation to the pathologist.

SYMPHONY system

Your benefit

Reduction of errors and mitigation of risk

- Helps ensure positive patient identification and chain of custody by integrating the SYMPHONY system with the VANTAGE workflow solution
- Helps protect against cross-contamination with individual slide staining for every patient slide
- Reduce technician exposure to toxins with xylene-free SYMPHONY Clear

Accurate and reproducible results

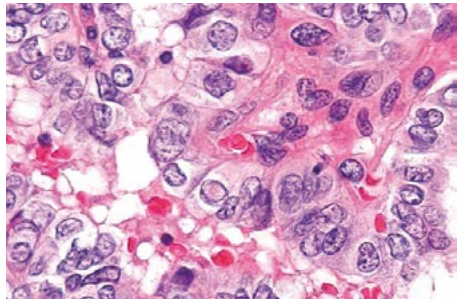
- Individual slide staining means no reagent carryover and stain degradation
- Application of fresh reagent on each slide produces exceptional clarity and enhanced visibility of microanatomic detail
- Excellent visualisation of microanatomic detail through the exceptional quality of high-definition H&E

Faster turnaround times and greater efficiency

- Free your technicians to focus on additional value-added work with fully automated one-touch H&E slide processing
- Optimise lean workflow opportunities by integrating the SYMPHONY staining platform with the VANTAGE workflow solution

Product characteristics

- Throughput: 160 – 200 slides per hour with continuous loading of up to 500 slides at a time
- Slide tray: universal tray holds up to 20 individual slides and can be stacked or "nested" for pathologist review
- "Slide Detect" ID: slide tracking supporting multiple barcode formats
- Workflow: simultaneous processing of multiple slide trays including drying, deparaffinisation, staining and coverslipping
- Reagents: solutions are sealed, prepackaged, ready-to-use and monitored with RFID for inventory management
- LIS connectivity through the VANTAGE workflow solution
- CareGiver remote support is an automated remote monitoring and diagnostics solution that enables continuous monitoring and remote service for SYMPHONY instruments



Gastric biopsy (above), Prostate biopsy (below).

VENTANA®

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.

Your benefit

Superior 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

BenchMark Special Stains

Reduced risk

- Individual slide staining mitigates risk for cross contamination
- Ready to use reagents reduces technician risk due to 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
- Modularity: 1–8 BenchMark Special Stains and BenchMark ULTRA systems may be controlled from one host PC

Special Stains reagents

The new BenchMark Special Stains system brings reproducible, high quality staining capabilities by providing ready-to-use, quality controlled reagents.

Special Stains menu:

- AFB III
- Alcian Blue
- Alcian Blue for PAS
- Alcian Yellow
- Congo Red
- Diastase
- Elastic
- Giemsa
- GMS II
- Gram
- Iron
- Jones Light Green
- Jones Hematoxylin
- Light Green for PAS
- Mucicarmine
- PAS
- Reticulum II
- Steiner II
- Trichrome Blue
- Green for Trichrome

VENTANA®

BenchMark IHC / ISH platform

Automated slide staining systems

Minimize diagnostic lead time, maintain consistent high quality and streamline workflow in the histology laboratory with the BenchMark IHC / ISH instruments.

The BenchMark GX, BenchMark XT and BenchMark ULTRA instruments automate all slide preparation steps of immunohistochemistry (IHC), fluorescent IHC, *in situ* hybridisation (ISH) and Dual Color Silver tests. They have the flexibility you need to expand your test menu, process more slides and improve your turnaround time.

Your benefit

Fully automated
- Standardised IHC and ISH staining
- Dual and triple stains

Flexibility
- Select from over 250 available Ventana antibodies, or use your own antibodies
- Independent and simultaneous processing

Optimal quality
- Independent protocols for each slide
- Barcoded slides and reagents for case identification and traceability

Workflow
- Higher throughput and faster turnaround times
- Increased laboratory productivity and reduced rework

BenchMark GX system

BenchMark XT system

BenchMark ULTRA system

BenchMark system features

Unique and innovative technology for best patient care by kinetically optimized reaction
- Individual heater pads
- Liquid coverslip controls evaporation and integrity
- Full slide coverage with 100 µL
- Air vortex mixing

BenchMark GX system
- 20 slide positions
- 25 reagent positions
- Low to medium throughput
- Complete batching IHC and ISH diagnosis system

BenchMark XT system
- 30 slide positions
- 35 reagent positions
- Medium to high throughput
- Independent or simultaneous processing of IHC and ISH steps

BenchMark ULTRA system
- 30 slide positions
- 35 reagent positions
- Flexibility to add/remove slides without impacting workflow
- Ability to add or remove reagents without interrupting cases in process

- Immediately process STAT and late-arriving samples
- Simultaneous IHC/ISH testing on a single platform

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

VENTANA®

Primary antibodies

Over 250 ready-to-use clinical reagents, optimized for use on Ventana staining platforms

Ready-to-use antibodies

Ventana antibodies, including a world-class breast panel, cover the pathology world's diagnostic requests. Ventana 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

- Calponin-1 (EP798Y)
- Cytokeratin 14 (SP53)
- Cytokeratin 5/6 (D5/16B4)
- E-cadherin (36), CONFIRM
- E-cadherin (EP700Y)
- Estrogen Receptor (ER) (SP1), CONFIRM
- FoxA1 (2F-83)
- GATA3 (L50-823)
- GCDFP-15 (EP1582Y)
- HER2 Dual ISH DNA Probe Cocktail assay, INFORM
- HER-2/neu (4B5), PATHWAY
- HER-2/neu (4B5), Ventana
- Ki-67 (30-9), CONFIRM
- p120 (98)
- p53 (DO-7), CONFIRM
- Progesterone Receptor (PR) (1E2), CONFIRM
- Topoisomerase IIa (JS5B4), CONFIRM

Cervical

- CINtec® PLUS p16/Ki-67 dual stain (Cytology) (E6H4™ and 274-11 AC3)
- CINtec® p16 Histology (E6H4)

Colorectal and Gastrointestinal

- Beta-catenin (14)
- BRAF-V600E (VE1)
- c-KIT (9.7), PATHWAY
- Cadherin 17 (SP183)
- CEA (TF3H8-1)
- CEA (CEA31)
- CDX-2 (EPR2764Y)
- COX-2 (SP21)
- Cytokeratin 7 (SP52), CONFIRM
- Cytokeratin 19 (A53-B/A2.26)
- Cytokeratin 20 (SP33), CONFIRM
- DOG1 (SP31)
- Glutamine Synthetase (GS-6)
- Helicobacter pylori (SP48), Ventana
- MLH-1 (M1)
- MSH2 (G219-1129)
- MSH6 (44), CONFIRM
- MUC1 (H23)
- MUC2 (MRQ-18)
- 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 (NKI/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
- 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)

Lung

- ALK (D5F3), Ventana
- c-MET Total (SP44), CONFIRM
- Calretinin (SP65), CONFIRM
- Carcinoembryonic Antigen (CEA) (TF3H8-1)
- CD56 (123C3), CONFIRM
- CEA (CEA31)
- CD56 (MRQ-42)
- 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)
- p63 (4A4), Ventana
- SOX-2 (SP76)
- Synaptophysin (MRQ-40)
- Synaptophysin (SP11), CONFIRM
- TAG-72 (B72.3)
- Thyroid Transcription Factor-1 (SP141)
- WT1 (6F-H2)

Prostate

- Androgen Receptor (SP107)
- Basal Cell Cocktail (34ßE12+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)

IHC detection

Meet your needs and everything beyond

IHC / ISH detection

Ventana offers a comprehensive menu of optimized detection systems for use with our Ventana BenchMark IHC/ISH automated slide stainers, allowing for the identification of targets by IHC and ISH.

IHC detection offerings

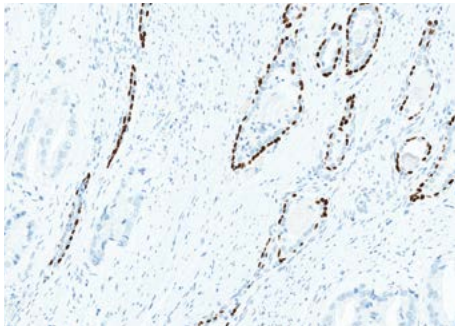
Choose from a comprehensive menu of detection chemistries (biotin and biotin-free based systems) and stains (DAB and Red) for high-quality IHC results:

- iVIEW DAB Detection Kit (biotin streptavidin)
- *ultra*View Universal DAB Detection Kit
- *ultra*View Universal Alkaline Phosphatase Red Detection
- OptiView DAB IHC Detection Kit

ISH detection offerings

Our comprehensive menu of indirect, biotin-free detection systems and stains (Blue, Silver and Red) provides the options you need for high-quality ISH results:

- ISH iVIEW Blue Plus Detection Kit
- *ultra*View SISH Detection Kit
- *ultra*View SISH DNP Detection Kit
- *ultra*View Red ISH Detection Kit



Ventana p63 stained with OptiView DAB IHC detection.

The OptiView DAB IHC Detection Kit offers advancements in detection technology, using a proprietary non-endogenous, biotin-free hapten technology that allows for exceptional range in sensitivity with extremely low background. Using Ventana OptiView detection software with the BenchMark IHC/ISH platform provides the ability to optimise testing to achieve a desired level of sensitivity and improved turnaround times, with flexible protocols and workflow enhancements.

VENTANA®

Your benefit

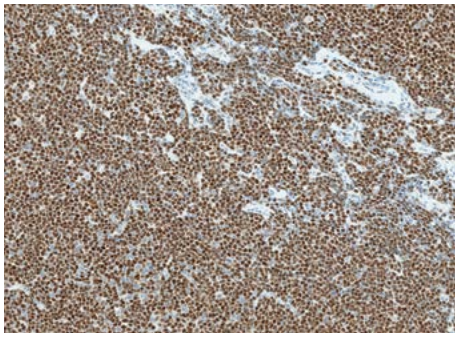
OptiView DAB IHC detection

Increased sensitivity
By increasing the numbers of HRP enzymes at each primary antibody site, OptiView provides unparalleled signal intensity, empowering you to achieve the level of intensity you desire for even the low-expressing antigens.

Enhance stain quality
Our synthetic, non-endogenous hapten system virtually eliminates background, even as signal intensity increases, to create the perfect view.

Customize intensity
Unique chemistry and flexible software enable greater control to meet preferred staining intensity.

Improve turnaround time
Amazing sensitivity and software flexibility allows you to reduce turnaround time by 30 minutes or more for most assays.



Cyclin D1 (SP4) on mantle cell lymphoma with OptiView DAB IHC Detection Kit.

Breast cancer diagnostics
Empowering clinical confidence

Roche 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 BenchMark IHC/ISH staining platforms that reduce the time to result and resources required compared to manual or semiautomated solutions.

Your benefit

Clinical superiority
- High accuracy and clinical confidence in a short turnaround time to identify patients other assays can miss

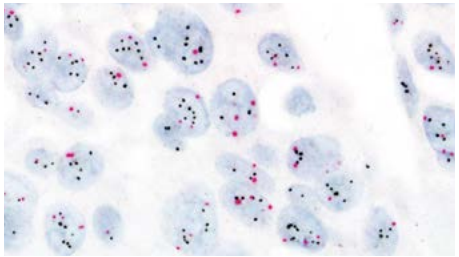
Analytical superiority
- Specific and sensitive rabbit monoclonal antibodies, best-in-class probes and powerful detection systems

Testing efficiency
- Comprehensive breast cancer solution
- Fully automated assays, with digital pathology and workflow solutions

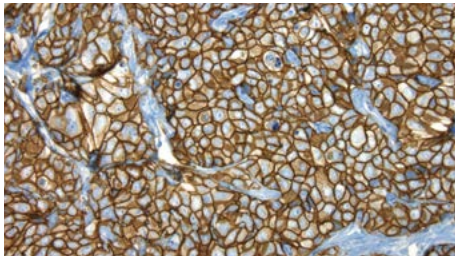
Product characteristics

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 INFORM HER2 Dual ISH DNA Probe Cocktail non-amplified; magnification: 40X.



Breast carcinoma HER2 (4B5) positive Score: 3+; magnification: 40X.

VENTANA®

NEW

Cervical disease diagnostics

The Roche and Ventana Medical Systems, Inc. (Ventana) cervical cancer portolio helps protect women from cervical cancer and from overtreatment. CINtec® products, available exclusively from Roche and Ventana are the only IVD (in vitro diagnostics) products to detect the overexpression of the cellular protein $p16^{INK4a}$ (p16) in cervical cytology and tissue specimens. Used adjunctively with available clinical information, the CINtec® products empower you to make informed, confident decisions.

The over-expression of p16 (a cyclin-dependent kinase inhibitor) in cervical specimens, detected by CINtec® immunohistochemistry products, is highly correlated with oncogenic transformation caused by persistent high-risk HPV (hrHPV) infections

CINtec® p16 Histology – Seeing beyond H&E in cervical cancer diagnostics

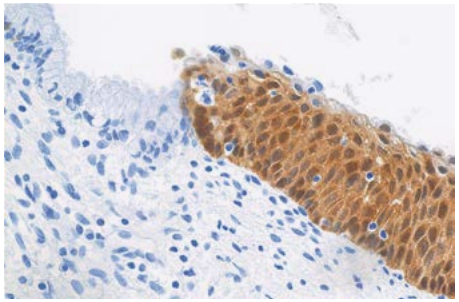
The CINtec® p16 Histology product is part of a fully automated immunohistochemistry (IHC) assay for the qualitative detection of the p16 protein on slides prepared from formalin-fixed, paraffin-embedded cervical biopsies.

Over 100 publications, medical society recommendations[1] as well as a major Pan-European clinical study[2] support the scientific and medical value of the CINtec® p16 Histology product for use in cervical biopsy specimens.

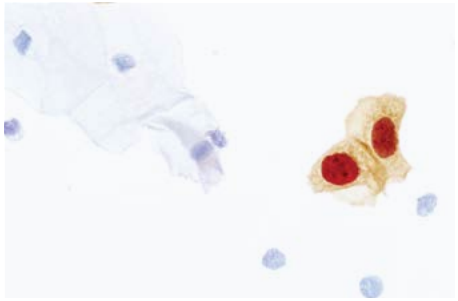
CINtec® *PLUS* – Improving accuracy for detecting high-grade disease in cervical cancer screening

The CINtec® *PLUS* Cytology immunocytochemistry assay provides simultaneous qualitative detection of p16 and Ki-67 proteins in cervical cytology preparations. This advanced combination of biomarkers provides high sensitivity and high specificity in a single test. CINtec® *PLUS* Cytology identifies underlying high-grade cervical disease in cytology specimens and helps identify women with transforming cervical lesions (p16/Ki-67 positive) who need colposcopy.[3,4,5]

**CINtec® PLUS Cytology is a CE/IVD product, intended for clinical use. CINtec® PLUS Cytology is not available for this use in the United States, Canada, China or Japan. Check with your local Roche representative for the availability of products in your region and the applicable intended use.*



Diffuse p16 immunostained cervical specimen demonstrating a positive CINtec® p16 Histology result



Co-expression of $p16^{INK4a}$ (brown cytoplasmic immunostain) and Ki-67 (red nuclear immunostain) within the same cell demonstrates a positive CINtec® PLUS Cytology result

1 Darragh, T. M., et al. (2012). *Archives of pathology & laboratory medicine, 136*(10), 1266-1297. doi:10.5858/arpa.LGT200570.

2 Bergeron, C., et al. (2010). *Am J Clin Pathol.133*(3), 395-406.doi:10.1309/AJCPXSVCDZ3D5MZM.

3 Petry, K.U., et al. (2011). *Gynecol Oncol. 121*(3), 505-509. doi: 10.1016/j.ygyno.2011.02.033.

4 Schmidt, D., et al. (2011). *Cancer Cytopathol. 119*(3), 158-166. doi:10.1002/cncy.20140.

5. Wentzensen, N., et al. (2012). *Clin Cancer Res. 18*, 4154-4162. doi: 10.1158/1078-0432.CCR-12-0270.

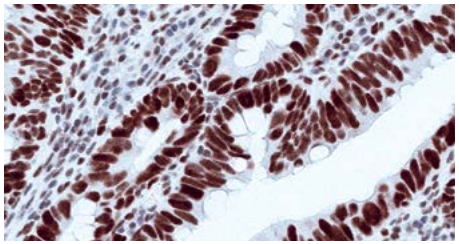
Colorectal diagnostics

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.

Ventana 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 BenchMark series IHC/ISH platforms.

The Ventana 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.



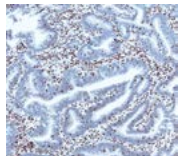
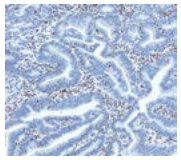
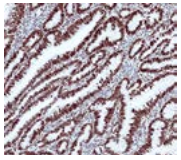
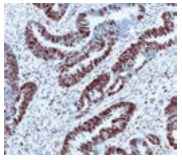
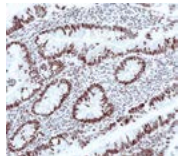
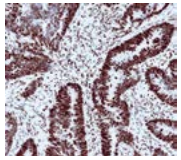
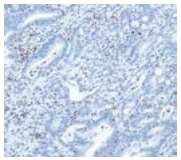
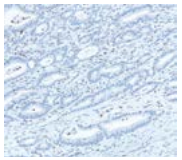
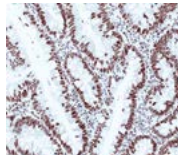
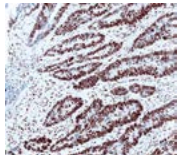
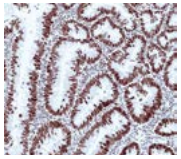
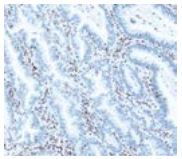
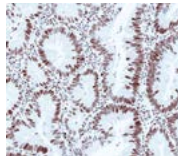
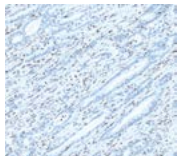
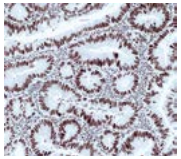
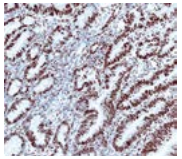
MSH2 (G219-1129) Mouse Monoclonal Antibody, colon carcinoma, 150x

Informing clinical decisions

Ventana 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** 	**Loss** 	Preserved 	Preserved 
MSH2 mutation	Preserved 	Preserved 	**Loss** 	**Loss** 
MSH6 mutation	Preserved 	Preserved 	Preserved 	**Loss** 
PMS2 mutation	Preserved 	**Loss** 	Preserved 	Preserved 

Powered by the OptiView DAB IHC detection system.

NEW

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.[1] Ventana Medical Systems, Inc. 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, only from Roche, are the right solution to empower you to deliver the highest-quality diagnostic information for patients – today and in the future.

Partner of choice for companion diagnostics

A global leader 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, Ventana and pharma increase the efficiency and speed of developing patient selection biomarkers.

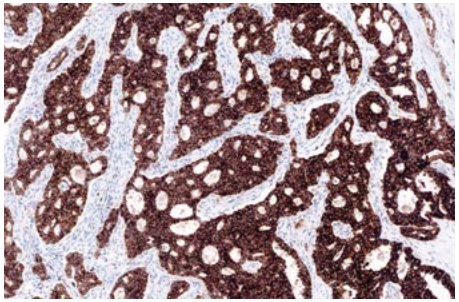
- Brings 180+ biomarker projects with a strong track record – reliably on time and on budget
- Provides global access through the Ventana and Roche commercial network and installed base
- Offers a differentiated, broad instrument and reagent portfolio

Helping to deliver the promise of Personalized Healthcare

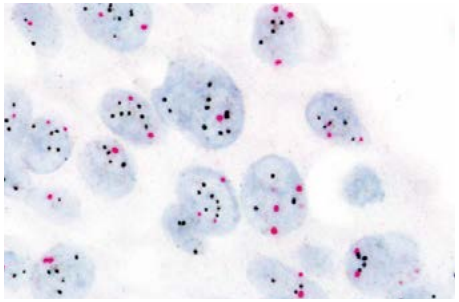
Tissue diagnostics: no other technology captures the anatomical context that helps determine patient outcomes and enables Personalized Healthcare:

- 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 ALK (D5F3) Rabbit Monoclonal Primary Antibody is a CE / IVD product. It is not available or approved for this use in the United States. Check with your local Account Manager for the availability of products in your region and the applicable intended use.*



VENTANA ALK (D5F3) Rabbit Monoclonal Antibody



INFORM HER2 Dual ISH DNA Probe Cocktail Assay

1 Source: Roche Personalized Healthcare brochure, 2011.

VENTANA®

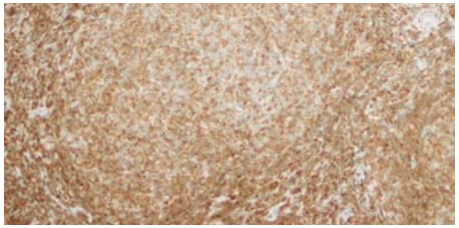
Hematopathology diagnostics

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 unparalleled 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 IHC/ISH series of instruments to maximize quality and laboratory efficiency.

Comprehensive menu to aid in diagnosis and subtyping

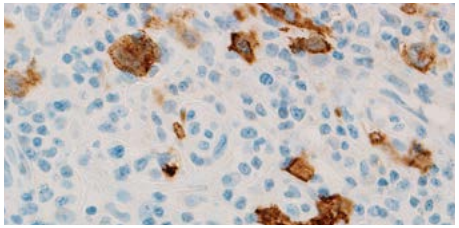


bcl-2 (SP66) Rabbit Monoclonal Primary Antibody

Ventana 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 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."[1]

Our portfolio of products, which includes rabbit monoclonal antibodies, novel biomarkers and detection kits, delivers the high sensitivity and specificity needed from diagnostic assays.

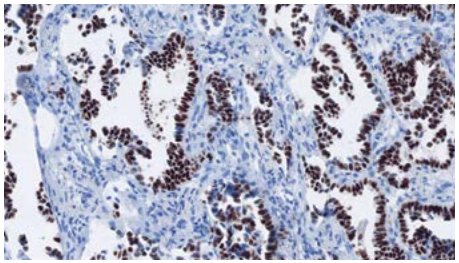
Our antibodies are ready to use on the fully automated Ventana BenchMark IHC/ISH staining platforms, reducing the time-to-result and resources required with manual or semi-automated solutions.

Differentiating between adenocarcinoma and squamous cell carcinoma

Confidently differentiate between lung adenocarcinoma (ADC) and squamous cell carcinoma (SCC) with four key markers, including the Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody.

TTF-1 (SP141) detects lung carcinoids and was validated by third parties versus the SPT24 clone, demonstrating equal or better detection. "The TTF-1 (SP141) has a cleaner background and stronger staining intensity compared to clone 8G7G3/1."*

The combination of napsin-A, TTF-1, CK5/6 and p63 has been identified in some studies as the best IHC panel for differentiating ADC from SCC of the lung.[2]

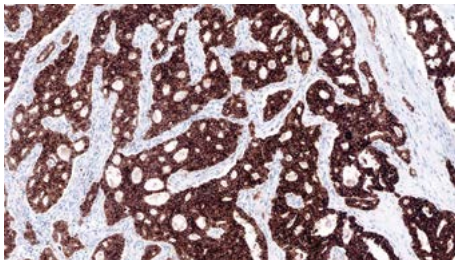


Adenocarcinoma stained with TTF-1 (SP141) Magnification 20X

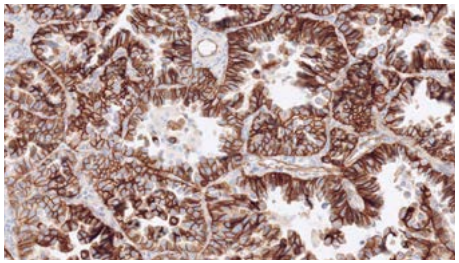
** Dr. Shalini Singh, Ventana Medical Systems, Inc.*

1 Tacha D, Yu C, Bremer R, Qi W, Haas T. (2012). *Appl Immunohistochem Mol Morphol 20:*201-207.
2 Kim M.J, Shin H.C, Shin K.C, Ro J.Y. (2013). *Ann Diagn Pathol. 17:*85-90.

Gain a clear view by detecting ALK and c-MET protein expression



Adenocarcinoma stained with Ventana ALK (D5F3), and OptiView DAB IHC detection with AMP, Magnification 20X



Adenocarcinoma stained with CONFIRM Total c-MET (SP44), Magnification 20X

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.[3]

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.[4]

CONFIRM Total c-MET (SP44) Rabbit Monoclonal Primary Antibody

CONFIRM Total c-MET (SP44) is directed against a membranous and/or cytoplasmic epitope present in human normal epithelial or tumour cells. This antibody may be used to aid in the identification of normal and neoplastic c-MET expressing cells.

"The pre-clinical evaluation demonstrated excellent specificity and sensitivity of the SP44 antibody and its suitability for determining Met protein expression on FFPE tissue."[5]

3 Shaw et al. (2011). *J Natl. Compr. Canc. Netw. 9:*1335-1341.
4 Minca et al. (2013). *J Mol Diagn. 15*(3).
5 Koeppen, H., Januario, T., Filvaroff, E. (2012). *Mod. Pathol. 25;* 480A.

VENTANA®

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 BenchMark IHC/ISH series of automated platforms for efficient, reproducible staining quality. 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.

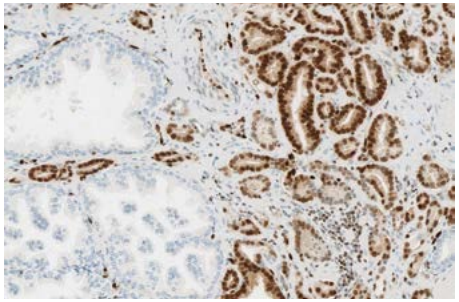
ERG (EPR3864) Rabbit Monoclonal Primary Antibody

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 34βE12, p63 is specific and sensitive for basal cells in the prostate gland

Ventana Basal Cell Cocktail 34βE12+p63

Our Basal Cell Cocktail combines p63 (4A4) with 34βE12 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

NEW

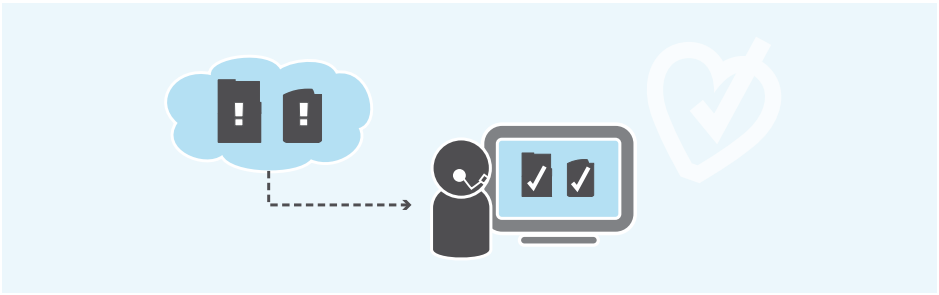
Work confidently with Connectivity Solutions from Ventana that help you optimize lab efficiency, patient safety, and equipment uptime through direct connections to your Ventana platforms. From remote support to Laboratory Information Systems (LIS) connectivity, we have you covered.

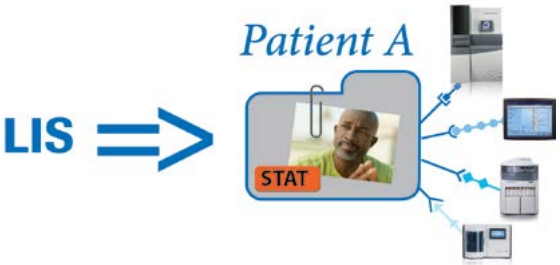
CareGiver Remote Support

Monitoring your lab's Ventana instruments in real-time, the Ventana 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 software solution

Ventana Connect software moves critical information between multiple LIS systems and Ventana instruments enabling more efficient workflow. Discover Ventana Connect software.





VENTANA®

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

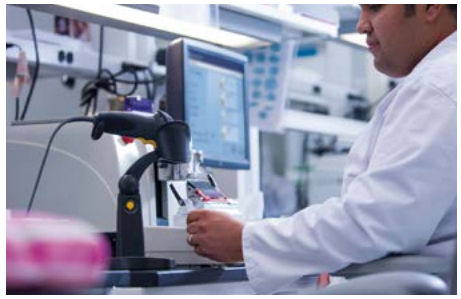
- Locate any specimen, block or slide immediately
- Ask the VANTAGE system to locate any patient's slide, on any instrument, at any point in your process – and count on immediate, accurate results

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



Digital pathology

Remote consultation, second opinions, image analysis and education

Ventana Digital Pathology is transforming the practice of pathology by developing innovative technologies that deliver medical value, inform decision making and improve cancer care. The comprehensive 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

Remote consultation
- Maximize pathologist time
- Enable flexibility for tumor boards, case sharing and collaboration

Second opinions
- Enable fast turnaround time for expert opinions
- Provide access to sub-specialists

Image analysis
- Build clinical confidence with FDA 510(k)-cleared and CE IVD companion algorithms
- 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

Digital pathology

Product features

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

Companion Algorithm image analysis software
- FDA 510(k)-cleared and CE IVD 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

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 educational 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)

**In the US, the Ventana iScan HT slide scanner is for research use only. Not for use in diagnostic procedures.*

VENTANA®

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

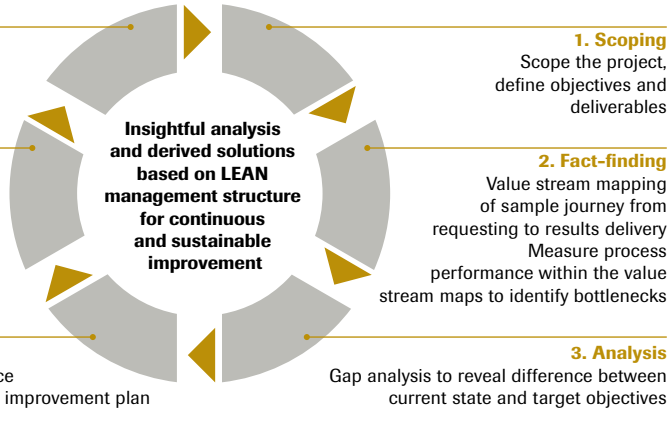
- Empower your people to embrace continuous performance improvement
- Co-derived sustainable solutions with optimized workflow
- Rapid implementation according to fact based concept
- Increase operational efficiency and effectiveness
- A working environment with harmonised prosperity and performance
- 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



Clinical research

DNA sequencing

Innovation

Sequence capture

GS Junior

Sequencing solutions

Roche Sequencing provides researchers with innovative tools for next-gen sequencing workflow, including instruments, reagents and target enrichment products. This portfolio of next-generation sequencing products is driving research advances in cancer, infectious diseases, inherited genetic diseases, immunogenetics, drug discovery, agriculture, environmental ecology and more.

Roche's 454 Sequencing Systems spearheaded the post-Sanger era with the first next-generation sequencing system. The GS FLX+ System andbenchtop GS Junior System offer a unique combination of powerful next-generation sequencing throughput and long, accurate read lengths (up to 1,000 bp). The systems allow you to move quickly from sample to result with easy-to-interpret data and dedicated analysis software.

NimbleGen SeqCap Target Enrichment Systems are designed to enrich target DNA regions for a variety of next-generation sequencing platforms. This portfolio of products allows researchers to selectively sequence the human exome, human disease-associated genes, or genomic regions of interest in a wide range of non-human species. The broad portfolio of products with complete customization enables researchers to achieve best-in-class target enrichment efficiency and uniform coverage in variant detection.

Roche Sequencing offers researchers a clearer understanding of genomic structure and function in order to understand the impact of genes on biological processes. As pioneers in sequencing with a rich heritage in diagnostics, the Roche Sequencing Unit is committed to a future that fosters innovation to provide solutions that enable scientific discovery and deliver clinical value – We are Changing Science and Changing Lives.

For more information please visit www.roche-sequencing.com

For life science research only.
Not for use in diagnostic procedures.

Genome Sequencer FLX+ System

Sanger-like read lengths – the power of next-generation throughput

Roche's portfolio of proven DNA sequencing and target enrichment solutions are advancing research in human health, agriculture, evolutionary biology, and more. The GS FLX+ System and benchtop GS Junior System offer the unique combination of powerful next-generation sequencing throughput and the familiarity of long Sanger-like read lengths (up to 1,000 bp).

NimbleGen SeqCap Target Enrichment Systems prepare DNA samples for a variety of next-generation sequencing platforms, allowing researchers to selectively sequence specific human exome and disease-associated regions. The broad portfolio of products with complete customization enables researchers to minimize sequencing costs in variant discovery studies.

For life science research only.
Not for use in diagnostic procedures.

Your benefit

Fast results

- Generate 700 million bases per 23 hours run

More comprehensive data

- Take advantage of the Sanger-like read length up to 1 kb
- Includes powerful and easy-to-use Data Analysis SW

Widest application range and flexibility

- Cover all applications
- Gain project flexibility by utilizing different plate formats, gaskets and multiplex identifiers

The Genome Sequencer FLX+ System – sequence with confidence

Up to 1,000 bp read length – get all the benefits of Sanger capillary sequencing with the power of next-gen throughput to take your research to the next level. Trusted results in over 1,300 publications:

- Identification of a novel arenavirus responsible for a series of fatal transplant-associated diseases in Australia
- Generation of the first complete genome and exome sequences from the hunter-gatherer people of southern Africa
- Sequencing of rearranged VDJ immune receptor loci tracks immune diversity and clonal lymphocyte population

Product characteristics

Throughput	700 Mb per 23 hours run
Read length	Up to 1,000 bp
Consensus accuracy	99.997 %
Data processing and bioinformatics	Perform data analysis without the need for enterprise scale IT solutions with preinstalled, easy-to-use software tools: • GS De Novo Assembler • GS Reference Mapper-GS Amplicon Variant Analyzer
Applications	• De novo sequencing • Re-sequencing • Sequence capture/targeted resequencing • Transcriptome analysis • Gene regulation studies • Epigenetic changes • Metagenomes and microbial diversity • Ancient DNA

GS Junior System

The power of next-generation sequencing on your benchtop

The 454 GS Junior System brings the power of next-generation sequencing technology directly to your benchtop, opening the door to a new revolution in genomic research sequencing for every day and everyone. Access to next-generation sequencing will no longer be limited to large facilities with the budget and infrastructure previously required to accommodate the high demands of the emerging technology.

Your benefit

Integrated next-generation sequencing

- Established easy-to-use technology and Roche sequencing expertise

Increased lab productivity

- Reproducible data, short run times and complete data analysis solutions

Broad application versatility

- Due to read length, throughput, sensitivity and read accuracy

For life science research only.
Not for use in diagnostic procedures.

Product characteristics

Research application

- Unambiguously resolve highly complex genomic regions (e.g., HLA, IgH)
- Discover germline or somatic mutations in oncology (e.g., EGFR, KRAS, BRAF, PI3K, BRCA), hematology (e.g., TET2, CBL, RUNX1, RAS), and metabolic diseases (e.g., CFTR, MODY)
- Detect low-frequency variants such as rare drug-resistant viral mutations (e.g., HIV*)
- Throughput: >35 million high-quality, filtered bases per run
- Run time: 10 hours sequencing, 2 hours data processing
- Read length: ≈400 bp
- Accuracy: 99 % accuracy at 400 bases
- Reads per run: 100,000 reads (on average)
- Sample input: gDNA, amplicons, cDNA, or BACs depending on the application
- Computing: HP desktop computer; All software is point-and-click

GS Junior applications

- Zoom into critical genomic regions using amplicon sequencing of PCR products and sequence capture technologies
- Quickly perform haplotyping, genotyping, rare variant detection, structural variant detection, and heterozygote calling
- Analyze disease-associated regions in oncology and immunogenetics, or viral quasispecies present within infected populations in infectiology

An integrated solution – from sample prep to data analysis

GS Junior Titanium Reagents and accessoires

Benchtop instrument and computer

Data processing and analysis software

NimbleGen sequence capture

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 variant detection sensitivity, sample capacity and speed to results. Compared to other hybridization-based enrichment technologies on the market, Roche NimbleGen products provide the highest capture efficiency and coverage uniformity available[1,2], as a result of its superior design algorithms and proprietary probe synthesis technology.

Roche NimbleGen 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.

Your benefit

Most relevant content

- Uniform coverage of your target region, from the leader in custom designs, building highest confidence in variant detection and data reporting

Proven performance

- Best-in-class 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

For life science research only.
Not for use in diagnostic procedures.

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** is a free online tool that enables you to quickly and easily design SeqCap EZ Choice and SeqCap RNA Choice Systems.

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: 10.7171/jbt.13-2402-002.

Digital Services

Easy

Simple

Engaging

Transparent

Relevant information

Collaboration

Roche DiaLog

The consolidation and growth of medical laboratories is leading to ever-more complex processes and diagnostics systems are evolving constantly to keep pace.

This brings challenges for the people who use them. To make life easier, Roche has developed a one-stop solution that makes every aspect of laboratory management easier and more efficient.

Roche DiaLog
The changing world of diagnostics

Introducing Roche DiaLog
A single platform designed to give you faster and more convenient online access to all the information and services you need.

Your benefit
- Simplicity: one gateway to Roche
- Increased transparency of your processes
- Receive personalized support
- Stay up-to-date

Product characteristics
Roche DiaLog: One point of entry to all Roche Diagnostics digital services. Access to Roche with just one login and password from any device (pc, tablet, mobile). Facilitates engaging interaction for a new form of direct two-way communication that's simple, always open, personalized and up-to-date.

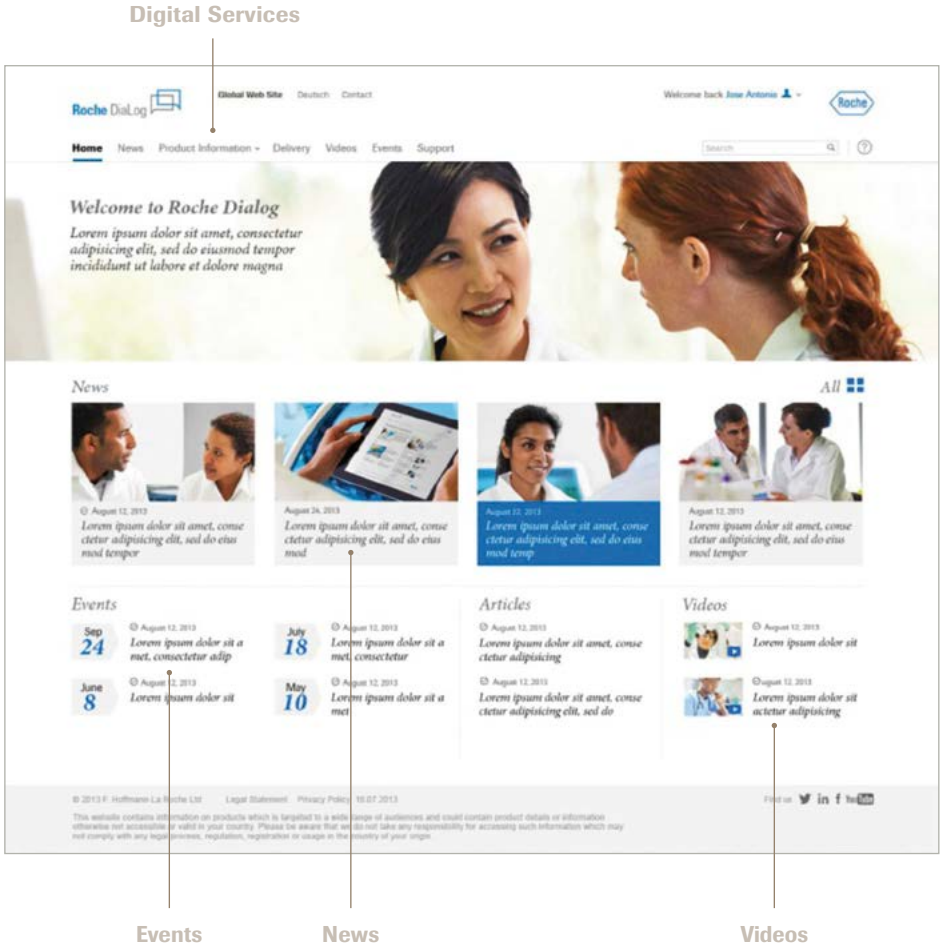
Digital Services are applications to support your core business.

They include:
- Technical documents provides instant access to all documentation to operate instruments and reagents. It contains a powerful search-engine and the ability to get notified when new documents become available.
- Track & Trace provides a comprehensive overview of all order-related information, including past orders, delivery notes and invoices and track the connections among them.
- Inventory Management allows to maintain stock levels always under control for both Roche and non-Roche products. It tracks the goods usage and suggests replenishment actions bringing the Inventory to the next step in terms of control and optimization.
- Live chat is an additional support channel, providing direct access to Roche support agents whenever needed. Live chat also enables exchanging pictures or documents to help better explain challenges and resolutions.

And this is just the beginning. Roche DiaLog is always evolving, continuously introducing improvements and new services.

Current offering*:

**Not all services are available in all countries*



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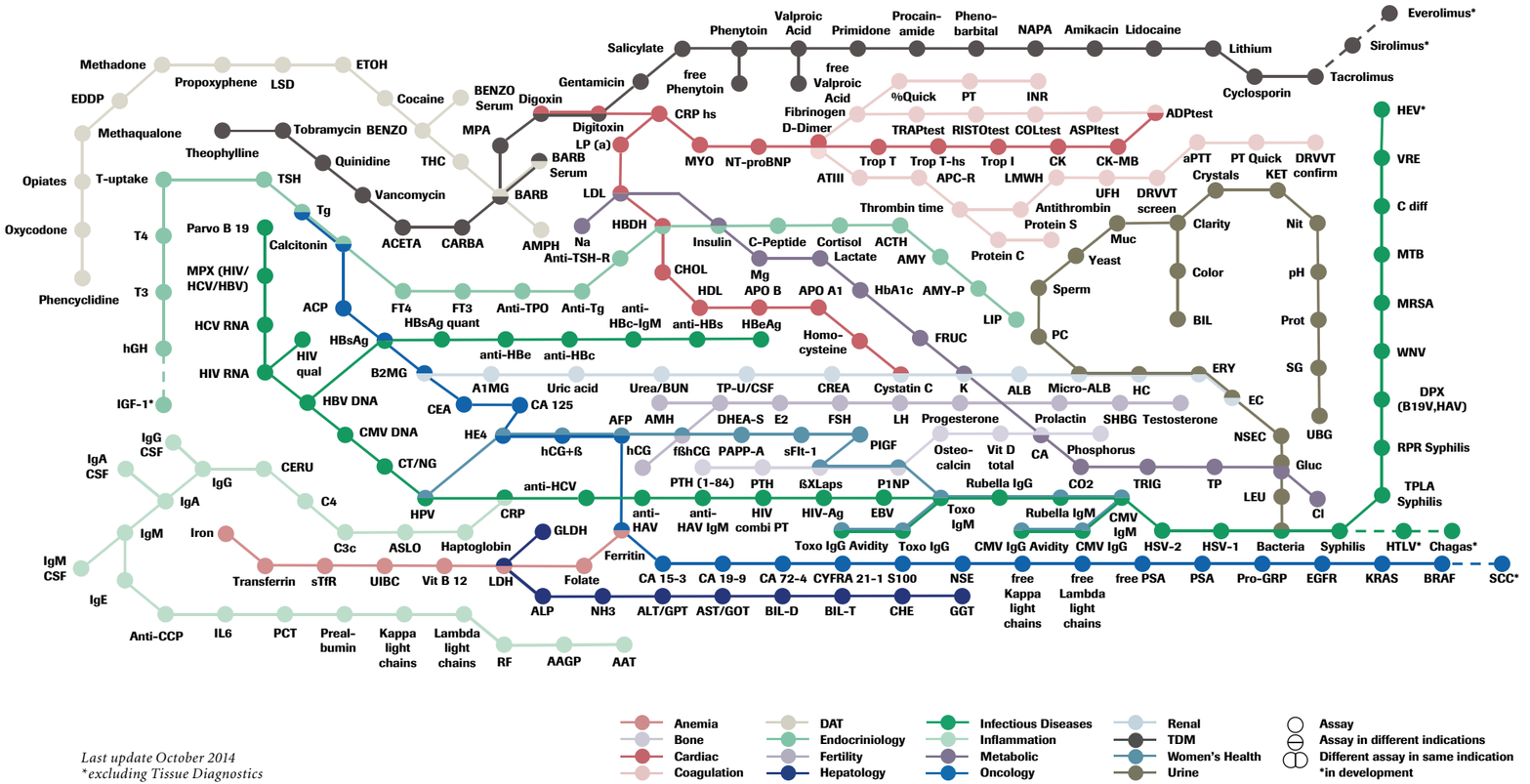
Notes

Roche Diagnostics test portfolio*



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**excluding Tissue Diagnostics*

Not for distribution in the US.

For additional information please contact
your local Roche representative.

Roche Diagnostics International Ltd
CH-6346 Rotkreuz
Switzerland
www.roche.com

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