Products and Solutions 2015
Roche Diagnostics
THE POWER OF KNOWING
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 committed 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

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.

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 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
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.

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.

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.

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.

Professional Diagnostics Business Area
- Serum work area
- Point-of-care testing
- Specialty testing
- IT- and workflow
- Custom Biotech

Molecular Diagnostics Business Area
- Virology
- Blood screening
- Genomics / oncology
- Microbiology
- Biochemical reagents

Tissue Diagnostics Business Area
- Primary staining
- Advanced staining
- Workflow management
- Digital pathology

Diabetes Care Business Unit
- Blood glucose monitoring
- Insulin delivery
- Diabetes workflow management

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

Total solution provider
Personalized solutions for different throughput needs
Comprehensive and differentiated testing menu
Pioneer in Personalized Healthcare
Commitment and innovation for diagnostics

Global and local experts in >130 countries
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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
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.

**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

**Unique reagent concept for maximum handling convenience and minimal logistic efforts**
- No mixing
- No preparation
- Easy logistics
- Minimal storage space

**No mixing**
**Ready to use**
**Easy logistics**
**Minimal storage space**

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

### 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

<table>
<thead>
<tr>
<th>Theoretical throughput (tests/hour, with ISE)</th>
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</thead>
<tbody>
<tr>
<td>Reagent channels</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>200</td>
</tr>
<tr>
<td>300</td>
</tr>
</tbody>
</table>

![cobas 8000 modular analyzer series](image)
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

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 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

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

*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.
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

Tests per hour

<table>
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<th>Channels</th>
<th>0</th>
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cobas® 6000 analyzer series
The success story continues

www.cobas.com
cobas® 6000 analyzer series
The success story continues

True workflow consolidation

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

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

3 cobas c 501 module
- ISE measurements (K, Na, Cl)
- More than 120 assays and applications on the clinical chemistry platform including proteins, enzymes, DAlTs, 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.

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

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 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.

**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)

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

**Unique reagent concept**
- Convenient and error-free handling of cobas c 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 4000 analyzer series solution**

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

**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

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**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

**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 e packs
- Economic usage with high stabilities and convenient kit sizes

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

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**cobas p 312 pre-analytical system**

- Disposable tips and cups for carryover-free sample pipetting

**cobas IT solutions**

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

**cobas e 411 immunochemistry analyzer (rack system)**
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.

### 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 performance¹

**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

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

**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
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.

**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
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.

**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
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.

**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.

Customized solutions for every lab
cobas® IT solutions
Centralized, decentralized and beyond

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

- Central laboratory
- Satellite laboratory
- Emergency room/ward
- Health clinic

One system
Common user interface

cobas® IT solutions
www.cobas.com
**cobas® middleware solutions**

*Intelligent workflow management for your laboratory*

**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

**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

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**Intelligent workflow management for your laboratory**

<table>
<thead>
<tr>
<th>Pre-analytical</th>
<th>Analytical</th>
<th>Post-analytical</th>
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<tr>
<td>Sample ID and tracking</td>
<td>Result generation</td>
<td>Add-on test management</td>
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<tr>
<td>Sample preparation</td>
<td>Quality control</td>
<td>Archiving and retrieval</td>
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</tbody>
</table>

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Please check with your local Roche representative for availability of the IT solution in your country.
cobas® infinity IT solutions
More powerful than you can imagine

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.

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

**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

**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**
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.

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**cobas p 512 and cobas p 612 pre-analytical systems**  
*Professional management of laboratory processes*

**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 an 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

- **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

- 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

---

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

**www.cobas.com**
**cobas p 501 and cobas p 701**

**post-analytical units**

*The automated archive*

---

**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

---

**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® 8100 automated workflow series
3-D intelligence in lab automation

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

Input station
6. Sample check module
7. Destopper
8. Barcode labeler/tube feeder

Aliquot station
9. Aliquot module
**cobas® connection modules (CCM)**

*Everything designed to work together as one*

---

**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

**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.

---

**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

Please note that not all versions are distributed in all countries. For further details contact your local affiliate.
## Overview of Serum Work Area tests

| Anemia | Ferritin | Cot | | Folate | Cot | | Folate RBC | Cot | | Iron | Cot | | Iron binding capacity – Unsaturated | Cot | | Soluble transferrin receptor | Cot | | Transferrin | Cot | | Vitamin B12 | Cot | | Lactate Dehydrogenase | Cot |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | Calcium | Cot | | N-MID Osteocalcin | Cot | | P1NP | Cot | | Phosphorus | Cot | | PTH | Cot | | PTH (1-84) | Cot | | β-CrossLaps | Cot | | Vitamin D total | Cot |
| Cardiac | Apolipoprotein A1 | Cot | | Apolipoprotein B | Cot | | Cholesterol | Cot | | CK | Cot | | CK-MB | Cot |
| Drugs of Abuse Testing | Amphetamines (Ecstasy) | Cot | | Barbiturates | Cot |

### Tests

- **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**
- **Troponin I**
- **Troponin I STAT**
- **Troponin T**
- **Troponin T hs STAT**
- **Troponin T hs STAT**
- **AT III**
- **D-Dimer**
- **Amphetamines (Ecstasy)**
- **Barbiturates**

### Other Tests

- **Barbiturates (Serum)**
- **Benzodiazepines**
- **Cannabinoids**
- **Cocaine**
- **Ethanol**
- **Fentanyl**
- **LSD**
- **Methadone**
- **Methadone metabolites (EDDP)**
- **Methaqualone**
- **Opiates**
- **Oxycodone**
- **Phencyclidine**
- **Propoxyphene**
- **Amylase – pancreatic**
- **Amylase – total**
- **ACTH**
- **Anti-Tg**
- **Anti-TPO**
- **Anti-TSH-R**
- **Calcitonin**
- **Corisol**
- **C-Peptide**
- **FT3**
- **FT4**
- **hGH**
- **Hydroxybutyrate Dehydrogenase**
- **IGF-1**
- **Insulin**
- **Lipase**
- **PTH STAT**
- **T3**
- **T4**
- **Thyroglobulin (TG II)**
- **Thyroglobulin confirmatory**
- **TSH**
- **T-uptake**
- **Anti-Mullerian Hormone**
- **DHEA-S**
- **Estradiol**
- **FSH**
- **hCG**
- **hCG plus beta**
- **LH**
- **Progesterone**
- **Prolactin**
- **SHBG**

### Notes

1. not on cobas c 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.

[www.cobas.com](http://www.cobas.com)
<table>
<thead>
<tr>
<th>Testosterone</th>
<th>Cobas c 111</th>
<th>Cobas c 501</th>
<th>Cobas c INTegra® 411</th>
<th>400 plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline phosphatase (IFCC)</td>
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<td>Alkaline phosphatase (opt.)</td>
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<td>Ammonia</td>
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<td>Bilirubin – direct</td>
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<td>Bilirubin – total</td>
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<td>Cholinesterase Acetyl</td>
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<td>Cholinesterase Butyryl</td>
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<td>Gamma Glutamyl Transferase</td>
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<tr>
<td>TPLA (Syphilis)</td>
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**Hepatology**

<table>
<thead>
<tr>
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<td>Ceruloplasmin</td>
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<td>α1-Antitrypsin</td>
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**Inflammation**

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<tbody>
<tr>
<td>Bicarbonate (CO2)</td>
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<td>Calcium</td>
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<td>HbA1c (hemolysate)</td>
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**Hepatology**

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<tr>
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<td>hCG</td>
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<td>Uric acid</td>
<td>hCG plus beta</td>
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Please check with your local Roche representative on availability of the assays and tests in your country.
ECL – unique immunoassay technology
Still light years ahead

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

ECL 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.
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

<table>
<thead>
<tr>
<th>CRP concentration (mg/L)</th>
<th>Δ Absorbance</th>
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<tr>
<td>0 20 40 60 80 100 120 140 160</td>
<td>DuREL technology  Radius I  Radius II</td>
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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 relapers 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

**EASL HBV management guidelines update 2012**

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

---

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

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

**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)
- 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)

**Comparison of the time required until acute infection can be detected using different HIV antigen/antibody combination immunoassays**


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 Reticulation

Elecsys® Syphilis immunoassay
Confidence in all stages of treponemal infection

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<sub>3</sub> EDTA, K<sub>2</sub> 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)

Roche offers an automated panel of 3 assays for efficient and reliable assessment of syphilis infections.

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• Clinical specificity: 99.88% (n = 8079)
  – Blood donors: 99.93% (n = 4579)
  – Routine samples: 99.80% (n = 3500)
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.

**Elecsys® TORCH panel**

**Reliable screening for early diagnosis**

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.

**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

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.
Elecsys® Troponin T high sensitive (TnT hs)
Improved performance – better clinical decisions

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 not be 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

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

* 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

* Elecsys® Troponin T high sensitive package insert.
Elecsys® NT-proBNP
A leap forward in the diagnosis and stratification of cardiovascular disease

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 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

**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
- 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

### Suspicion of acute heart failure because of symptoms and signs

<table>
<thead>
<tr>
<th>Patient age (Years)</th>
<th>NT-proBNP values (pg/mL)</th>
<th>Interpretation</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 50</td>
<td>&lt; 300</td>
<td>Acute HF unlikely</td>
<td>NPV = 98 %</td>
</tr>
<tr>
<td>50–75</td>
<td>300–450</td>
<td>Acute HF less likely, alternative causes must be considered</td>
<td></td>
</tr>
<tr>
<td>&gt;75</td>
<td>300–900</td>
<td>Acute HF likely, consider confounding factors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;900</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;1800</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NPV = 98 %**

**PPV = 92 %**
Lp(a), hsCRP and Homocysteine
Improving cardiovascular risk assessment – allowing better treatment decisions

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 values1 (figure 1)

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

• 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 disease5 (figure 2)

Figure 2: 90% of cases can be identified

Consolidation
• Accurate and reliable measurement on a fully consolidated platform

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

Product characteristics

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

Elecsys® IL-6, PCT and Tina-quant® CRP
For early and effective sepsis management – because time matters

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

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

<table>
<thead>
<tr>
<th>Assay</th>
<th>Elecsys BRAHMS PCT</th>
<th>Elecsys IL-6</th>
<th>CRP on cobas c analyzers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample material</td>
<td>Serum, Li-heparin and K3-EDTA plasma</td>
<td>Serum, Li-heparin and K+- and K3-EDTA plasma</td>
<td>Serum, Li-heparin and K+- and K3-EDTA plasma</td>
</tr>
<tr>
<td>Sample volume</td>
<td>30 μL</td>
<td>30 μL</td>
<td>2 μL</td>
</tr>
<tr>
<td>Assay time</td>
<td>18 min.</td>
<td>18 min.</td>
<td>10 min.</td>
</tr>
<tr>
<td>Measuring range</td>
<td>0.02 – 100 ng/mL</td>
<td>1.5 – 5,000 pg/mL</td>
<td>0.3 – 350 mg/L</td>
</tr>
<tr>
<td>Analytical sensitivity</td>
<td>&lt;0.02 ng/mL</td>
<td>1.5 pg/mL</td>
<td>0.3 mg/L</td>
</tr>
<tr>
<td>Functional sensitivity</td>
<td>&lt;0.06 ng/mL</td>
<td>5 pg/mL</td>
<td>0.6 mg/L</td>
</tr>
<tr>
<td>Traceability</td>
<td>Standardized against BRAHMS PCT LIA</td>
<td>WHO Standard NIBSC 1st IS 89/548</td>
<td>IRMM reference preparation CRM470 (RPPHS)</td>
</tr>
</tbody>
</table>

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

Reliable results
• Robustness against interference (e.g. HAMA) by blocking proteins, fragmented catcher or tracer antibodies or chimeric antibodies1
• 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, HEA, 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

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

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

Elecsys® HE4
An oncological biomarker improving ovarian cancer care

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. 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.

Elecsys® ProGRP
Crucial information for differential diagnosis in lung cancer

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 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.

*in development


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 assays¹

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: 30 μL
- Limit of detection (LoD): 3 pg/mL
- Measuring range (lower end defined by LoD): 3 – 5,000 pg/mL

Lung cancer differential diagnosis

ProGRP serum/plasma level

SCLC > 85.7 pg/mL

NSCLC < 85.7 pg/mL

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

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.

www.cobas.com
**Elecsys® Calcitonin**

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

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**

<table>
<thead>
<tr>
<th>MODULAR ANALYTICS</th>
<th>EVO &lt; E 170</th>
<th>cobas e 601/602 module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immulite® 1000/2000/2500</td>
<td>max. CV at 4.4 pg/mL</td>
<td>11.4%</td>
</tr>
<tr>
<td>Liaison® CT II-Gen</td>
<td>max. CV at 22.0 pg/mL</td>
<td>13%</td>
</tr>
</tbody>
</table>

**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

**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

**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**

<table>
<thead>
<tr>
<th>Cut-off</th>
<th>Grey zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000,000</td>
<td></td>
</tr>
<tr>
<td>100,000</td>
<td></td>
</tr>
<tr>
<td>10,000</td>
<td></td>
</tr>
<tr>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

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

Figure 1: Calcitonin is a highly specific marker for MTC, allowing early and specific diagnosis and reliable monitoring. Source: Performance Evaluation Study 2013, data available upon request.
Elecsys® Tg II
The power to offer more for differentiated thyroid cancer (DTC) management

The main application for Thyroglobulin (Tg) testing is the post-operative follow-up of patients with differentiated thyroid carcinoma (DTC). Detectable levels of serum Tg after total thyroidec-tomy 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

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, K2-EDTA plasma, K3-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 %

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

* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation with a total allowable error of ≤ 20 %
Elecsys® Anti-TSHR
Complex testing simplified and automated

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

**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**

- **Area under curve (AUC):** 0.98 (95% CI: 0.97–0.99)


**Figure 1:** Clinical accuracy of Elecsys Anti-TSHR

**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.

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.
Elecsys® Vitamin D total
Allowing better patient care with results you can trust

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.

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

Elecsys® Anti-Mullerian Hormone (AMH) PROVIDING CLINICAL CONFIDENCE IN THE ASSESSMENT OF OVARIAN RESERVE

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
Elecsys® sFlt-1 / PIGF
Short term prediction and diagnosis of preeclampsia

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

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

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

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

Product characteristics

Technical assay features on Elecsys® sFlt-1 and PIGF

<table>
<thead>
<tr>
<th></th>
<th>sFlt-1</th>
<th>PIGF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay time</td>
<td>18 min.</td>
<td></td>
</tr>
<tr>
<td>Sample material</td>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>Sample volume</td>
<td>20 μL</td>
<td>50 μL</td>
</tr>
<tr>
<td>Measuring range</td>
<td>10–85,000 pg/mL</td>
<td>3–10,000 pg/mL</td>
</tr>
</tbody>
</table>

The Elecsys sFlt-1 / PIGF 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.

<table>
<thead>
<tr>
<th>Early onset preeclampsia – gestational week 20 – 34</th>
<th>Late onset preeclampsia – gestational week 34 to end of pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>sFlt-1 / PIGF ≥ 85</td>
<td>Diagnosis</td>
</tr>
<tr>
<td>Prediction rule-in in the next 4 weeks</td>
<td>99.4 % specificity the patient has preeclampsia</td>
</tr>
<tr>
<td>Sensitivity: 88.0%</td>
<td>the patient will not develop preeclampsia in the next 1 week</td>
</tr>
<tr>
<td>sFlt-1 / PIGF &lt; 85</td>
<td>Prediction rule-in in the next 4 weeks</td>
</tr>
<tr>
<td>≥ 38</td>
<td>38.6 % PPV the patient is at high risk to develop preeclampsia within the next 4 weeks</td>
</tr>
<tr>
<td>Prediction rule-out for the next 1 week</td>
<td>99.1 % NPV the patient will not develop preeclampsia in the next 1 week</td>
</tr>
<tr>
<td>sFlt-1 / PIGF &lt; 38</td>
<td>Prediction rule-out for the next 1 week</td>
</tr>
<tr>
<td>≥ 38</td>
<td>99.1 % NPV the patient will not develop preeclampsia in the next 1 week</td>
</tr>
</tbody>
</table>

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

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.
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

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

<table>
<thead>
<tr>
<th>Cystatin C</th>
<th>Creatinine</th>
</tr>
</thead>
<tbody>
<tr>
<td>GFR mL/min/1.73m²</td>
<td>Creatinine-blind area</td>
</tr>
<tr>
<td>&gt;89</td>
<td>60 – 89</td>
</tr>
<tr>
<td>30 – 59</td>
<td>15 – 29</td>
</tr>
<tr>
<td>&lt;15</td>
<td></td>
</tr>
</tbody>
</table>

Stages of chronic kidney disease according to NKF KDOQI:¹²
- 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)

Immunosuppressive Drug Monitoring
Trusted and consistent results for organ transplant patients

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

**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.

*N = 1029 samples, Weighted Deming Regression
y = 1.07 x - 0.269, r = 0.97

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

**Product characteristics**

<table>
<thead>
<tr>
<th>Assay time</th>
<th>Tacrolimus</th>
<th>Cyclosporine</th>
<th>Sirolimus*</th>
<th>Everolimus*</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 min.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample material</th>
<th>EDTA whole blood</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sample volume</th>
<th>300 μL</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sample pretreatment</th>
<th>Identical sample pretreatment</th>
</tr>
</thead>
</table>

| 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 |

<table>
<thead>
<tr>
<th>Measuring range</th>
<th>0.5 – 40 ng/mL</th>
<th>30 – 2,000 ng/mL</th>
<th>0.5 – 30 ng/mL</th>
<th>0.5 – 30 ng/mL</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total imprecision</th>
<th>cobas e 411 analyzer</th>
<th>cobas e 601/e 602 modules</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.1 – 14.2 %</td>
<td>4.2 – 9.2 %</td>
</tr>
<tr>
<td></td>
<td>2.4 – 10.4 %</td>
<td>3.1 – 6.4 %</td>
</tr>
</tbody>
</table>

*Sirolimus and Everolimus in development

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

**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

---

*cobas t 411 coagulation analyzer*
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 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 following percutaneous coronary interventions. Multiplate delivers best-in-class predictivity and evidence is available demonstrating that Multiplate guided anti-platelet therapy has the potential to improve patient outcome.

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.

Your benefit

Cost-effective therapies
• in cardiac surgery
• in coronary interventions

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

Best predictivity

Comprehensive reagent menu of CE marked tests and controls

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

8 Aradi et al. (2013). *J Am Coll Cardiol*. 61(10); E1922.
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
### Urinalysis from Roche

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

**Urine diagnostics portfolio**

<table>
<thead>
<tr>
<th>Automation grade</th>
<th>Combur-Test®</th>
<th>Urisys 1100®</th>
<th>cobas u 411 urine analyzer</th>
<th>cobas 6500 urine analyzer series</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workloads</td>
<td>manual</td>
<td>10 – 50 samples per day</td>
<td>30 – 100 samples per day</td>
<td>100 – 1,000 samples per day</td>
</tr>
<tr>
<td>Test strips</td>
<td>Combur®2,3,4,5,6,7,9,10 Test</td>
<td>Combur® Test UX</td>
<td>Combur® Test M</td>
<td>cobas u pack</td>
</tr>
<tr>
<td>Consumables</td>
<td>cobas u cuvette</td>
<td>cobas u pack</td>
<td>cobas u pack</td>
<td>cobas u pack</td>
</tr>
</tbody>
</table>

**Urine diagnostics** 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® 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.

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**Easy strip handling**
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- 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.*
Urisys 1100® analyzer
Connected, compact and intuitive solution for urinalysis

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® Test® UX
- Memory capacity: 100 results
- Printer: Thermal printer
- Connectivity to the cobas POC IT solution

Urisys 1100® analyzer
Connected, compact and intuitive solution for urinalysis

Urine test strips

<table>
<thead>
<tr>
<th>Parameters</th>
<th>SG</th>
<th>pH</th>
<th>LEU</th>
<th>NIT</th>
<th>PRO</th>
<th>GLU</th>
<th>KET</th>
<th>UBG</th>
<th>BIL</th>
<th>BL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combur® Test UX</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Calibration | Control-Test M calibration strip

* Combur® Test®, Combur® Test® are not available in all countries.
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

**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.**

1. Sample ID input
   Work list via LIS, barcode scanner or manual input

2. Result download
   Display of sample ID + test strip

3. One workplace
   Microscopic examination and input via keypad

4. Consolidated results
   Upload to LIS/Host or print out in one single record

5. Upload of microscopic results
   Upload to LIS/Host or print out in one single record
cobas® 6500 urine analyzer series

Fully automated urine work area on a modular platform

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

Product characteristics

**cobas u 601 urine analyzer**
- Fully automated urine strip new generation
- 12 on-board parameters
- Throughput: 240 samples/hour
- cobas® 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® cuvette)
- Parameters:
  - Erythrocytes
  - Leukocytes
  - Bacteria
  - Non-squamous epithelial cells
  - Epithelial cells
  - Hyaline cells
  - Pathological casts
  - Crystals
  - Yeasts
  - Mucus
  - Sperm
  - Leukocytes

www.cobas.com

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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
<table>
<thead>
<tr>
<th>Test Category</th>
<th>Combur (visual strips)</th>
<th>TRF (visual strip)</th>
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<th>cobas b 123*</th>
<th>Accu-Chek® Inform II</th>
<th>CoaguChek® XS Plus</th>
<th>Urisys 1100®</th>
<th>cobas b 101*</th>
<th>Relecon® Plus and Relecon® sprint</th>
<th>cobas b 123*</th>
<th>cobas b 121*</th>
<th>cobas b 221*</th>
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* in addition several calculated parameters are available
### **cobas® POC IT solution**

*Bringing it all together*

---

**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

---

<table>
<thead>
<tr>
<th>Hepatology</th>
<th>Combur (visual strips)</th>
<th>POC/P (visual strip)</th>
<th>Accu-Chek Inform II</th>
<th>CoaguChek XS, XS Plus and XS Pro</th>
<th>Accutrend® Plus</th>
<th>Unips 1100®</th>
<th>cobas b 101®</th>
<th>Radiotest® Plus and Radiotest® sprint</th>
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</table>

* in addition several calculated parameters are available
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® bge link software
Central control of your Roche blood gas and electrolyte analyzers

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

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• Extensive data management possible through integration into cobas® POC IT solution
**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, PO₂, PCO₂
- Total hemoglobin tHb
- Oxygen saturation SO₂
- Hematocrit Hct

**Extended emergency profile**
Parameters:
- Blood gases pH, PO₂, PCO₂
- Electrolytes Na⁺, K⁺, Ca²⁺, Cl⁻
- Total hemoglobin tHb
- Oxygen saturation SO₂
- Hematocrit Hct

---

**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**
*Quick and efficient testing in critical care*

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.
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

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

### Product characteristics

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Versions</th>
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<tbody>
<tr>
<td>pH/blood gas (PO₂, PCO₂, pH)/CO-oximetry</td>
<td>2 4 6</td>
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<tr>
<td>Electrolytes (Na⁺, K⁺, Ca²⁺, Cl⁻)/hematocrit</td>
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<tr>
<td>Metabolites Glu/Lac</td>
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<td>Metabolites Glu/Lac/Urea (BUN)</td>
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<tr>
<td>Bilirubin</td>
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</tbody>
</table>
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.

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

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

www.cobas.com

* Intensive care unit, emergency room, neonatal intensive care unit, operating room.
**Accu-Chek® Inform II system**  
*Professional glucose testing for the wireless age*

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.

---

**Your benefit**

**Implements 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

---
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.

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):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Time to result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myoglobin</td>
<td>8 min.</td>
</tr>
<tr>
<td>D-dimer</td>
<td></td>
</tr>
<tr>
<td>Troponin T</td>
<td>12 min.</td>
</tr>
<tr>
<td>NT-proBNP</td>
<td></td>
</tr>
<tr>
<td>CK-MB</td>
<td></td>
</tr>
</tbody>
</table>

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* Cardiac care unit.
Roche CARDIAC® Trop T Sensitive test
Visual test for the rapid diagnosis of myocardial infarction

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 myocardial 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

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

**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

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

**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

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

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

**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

Accutrend® Plus system
Screening for cardiovascular risk factors

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.

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

<table>
<thead>
<tr>
<th>Test</th>
<th>Measuring ranges</th>
<th>Measuring time</th>
<th>Sample material</th>
<th>Sample volumes</th>
<th>Operating conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>20 – 600 mg/dL</td>
<td>12 sec</td>
<td>Fresh capillary blood</td>
<td>15 – 50 μL</td>
<td>18° – 35°C</td>
</tr>
<tr>
<td></td>
<td>1.1 – 33.3 mmol/L</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>150 – 300 mg/dL</td>
<td>180 sec</td>
<td>Fresh capillary blood</td>
<td>15 – 40 μL</td>
<td>18° – 35°C</td>
</tr>
<tr>
<td></td>
<td>3.88 – 7.76 mmol/L</td>
<td></td>
<td>Use of heparin-coated pipettes possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td>70 – 600 mg/dL</td>
<td>max. 174 sec</td>
<td>Fresh capillary blood</td>
<td>10 – 40 μL</td>
<td>18° – 30°C</td>
</tr>
<tr>
<td></td>
<td>0.80 – 6.86 mmol/L</td>
<td></td>
<td>Use of heparin-coated pipettes possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactate</td>
<td>0.8 – 22 mmol/L</td>
<td>60 sec</td>
<td>Fresh capillary blood</td>
<td>15 – 50 μL</td>
<td>5° – 35° or 15° – 35°C depending on concentration of analyte</td>
</tr>
</tbody>
</table>

Accutrend Plus system
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.

**Product characteristics**

- 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

**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

**Covering a wide range of daily routine and emergency testing**

- Muscle diseases
- Anemia
- Lipid metabolism disorders
- Bone diseases
- Liver diseases
- Renal diseases
- Gout
- Diabetes / Pancreatitis

**Reflotron® Plus system and Reflotron® Sprint systems**

*Flexible testing to support your clinical decisions*

The Reflotron Plus system is a single-test clinical chemistry system which allows the measurement of 17 parameters from whole blood, plasma or serum – including liver and pancreas enzymes, metabolites, blood lipids, hemoglobin and potassium.

Immediate and reliable test results ensure quick performance and verification of the diagnosis without delay.

The system is suitable for primary care settings, as a back-up system in hospitals and private labs, at screening sites and for health check-ups.
cubas b 101 system
Managing diabetes and dyslipidemia at the point of “need”

The cubas 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.

Your benefit
Test precision and guideline compliant
• cubas 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

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 cubas 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

Parameters and measuring range in the therapeutically important range
• HbA1c disc:
  – IFCC: 20 – 130 mmol / mol
  – NGSP: 4 – 14 %
  – eAG*
• Lipid disc:
  – CHOL: 50 – 500 mg/dL
  – TG: 45 – 650 mg/dL
  – HDL: 15 – 100 mg/dL
  – LDL, Non-HDL and TC/HDL*

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

* Plasma for lipid panel only.

IFCC: International Federation of Clinical Chemistry
DCCT: Diabetes Control and Complications Trial
NCEP: National Cholesterol Education Program
NGSP: National Glycohemoglobin Standardization Program

* calculated
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
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**

<table>
<thead>
<tr>
<th>Laboratory needs</th>
<th>Sample purification</th>
<th>PCR system</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women's health and genetic/oncology parameters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Low to high throughput</td>
<td>cobas® 4800 System</td>
<td>cobas x 480 Instrument, cobas z 480 analyzer</td>
</tr>
<tr>
<td>• Pre-analytic sample processing</td>
<td>cobas p 480 Instrument</td>
<td></td>
</tr>
</tbody>
</table>

| Microbiology and special virology assays and customizable assay protocols | | |
| • Low and medium throughput | High Pure or MagNA Pure LC 2.0 System, LightCycler® 2.0 System | |
| • Single sample testing | cobas Liat System | |
## Test overview

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test kit</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytomegalovirus</td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® CMV Test</td>
<td>quant.</td>
</tr>
<tr>
<td></td>
<td>LightCycler® CMV quant Test</td>
<td></td>
</tr>
<tr>
<td>Epstein Barr</td>
<td>LightCycler® EBV quant Test</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>LightCycler® Hepatitis A Virus quantification Kit</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>COBAS® TaqMan® HBV test for use with High Pure System</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HCV qualitative Test, v2.0</td>
<td>qual.</td>
</tr>
<tr>
<td></td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HCV quantitative Test, v2.0</td>
<td>quant.</td>
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<tr>
<td></td>
<td>COBAS® TaqMan® HCV Test for use with High Pure System, v2.0</td>
<td></td>
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<tr>
<td></td>
<td>LINEAR ARRAY HCV genotyping Test</td>
<td>genot.</td>
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<tr>
<td><strong>Herpes</strong></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>LightCycler® HSV 1 and 2 quant Test</td>
<td>qual. and diff.</td>
</tr>
<tr>
<td></td>
<td>COBAS® HSV 1 and 2 Test</td>
<td></td>
</tr>
<tr>
<td><strong>Human immunodeficiency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HIV Test, v2.0</td>
<td>qual.</td>
</tr>
<tr>
<td></td>
<td>COBAS® TaqMan® HIV Test for use with High Pure System, v2.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HLA-B*5701 screening Test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HIV qualitative (for research only)</td>
<td></td>
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<tr>
<td><strong>Human Papillomavirus</strong></td>
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<tr>
<td></td>
<td>COBAS® HPV Test</td>
<td>qual./genot.</td>
</tr>
<tr>
<td></td>
<td>LINEAR ARRAY HPV genotyping Test</td>
<td>genot.</td>
</tr>
<tr>
<td></td>
<td>AMPLICOR® Human Papillomavirus Test</td>
<td>qual./genot.</td>
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<tr>
<td><strong>Parvo B 19</strong></td>
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<tr>
<td></td>
<td>LightCycler® Parvo B19 quantification Kit (for research only)</td>
<td>quant.</td>
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<tr>
<td><strong>Varicella-Zoster</strong></td>
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<td></td>
<td>LightCycler® VZV qual Test</td>
<td>qual.</td>
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<tr>
<td><strong>Other pathogens</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlamydia trachomatis/Neisseria gonorrhoeae</td>
<td>COBAS® 4800 CT/NG Test</td>
<td>qual.</td>
</tr>
<tr>
<td></td>
<td>COBAS® AMPLICOR CT/NG</td>
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<tr>
<td>Chlamydia trachomatis</td>
<td>COBAS® TaqMan® CT Test</td>
<td>qual.</td>
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<tr>
<td>Chlostridium difficile</td>
<td>COBAS® Cdiff Test</td>
<td></td>
</tr>
<tr>
<td>Methyllicin resistant staphylococcus aureus</td>
<td>LightCycler® MRSA advanced Test</td>
<td>qual. and diff.</td>
</tr>
<tr>
<td></td>
<td>COBAS® MRSA/GA Test</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria Tuberculosis</td>
<td>COBAS® TaqMan® MTB Test</td>
<td>qual.</td>
</tr>
<tr>
<td><strong>Sepsis pathogens</strong></td>
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<td></td>
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<tr>
<td>Bacteria/Fungi</td>
<td>LightCycler® SeptiFast Test MGRADE</td>
<td>qual. and diff.</td>
</tr>
<tr>
<td></td>
<td>LightCycler® SeptiFast mecA Test MGRADE</td>
<td>qual. and ident.</td>
</tr>
<tr>
<td><strong>Blood screening</strong></td>
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<tr>
<td>HIV-1, HIV-2, HCV, HBV</td>
<td>COBAS® MPX</td>
<td>qual./diff.</td>
</tr>
<tr>
<td></td>
<td>COBAS® TaqScreen MPX Tests</td>
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<tr>
<td>B19V/HAV</td>
<td>COBAS® DPX</td>
<td></td>
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<tr>
<td></td>
<td>COBAS® TaqScreen DPX Test</td>
<td></td>
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<tr>
<td>West Nile virus</td>
<td>COBAS® WNV</td>
<td>qual.</td>
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<td></td>
<td>COBAS® TaqScreen WNV Test</td>
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<tr>
<td>HEV</td>
<td>COBAS® WNV</td>
<td>qual.</td>
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<tr>
<td><strong>Influenza A/B</strong></td>
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<tr>
<td>Influenza A/B</td>
<td>COBAS® Influenza A/B</td>
<td>qual.</td>
</tr>
<tr>
<td>Influenza A/B-RSV</td>
<td>COBAS® Influenza A/B-RSV</td>
<td>qual.</td>
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<tr>
<td><strong>Bacteria</strong></td>
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<td></td>
</tr>
<tr>
<td>Strep A</td>
<td>COBAS® Strep A</td>
<td>qual.</td>
</tr>
<tr>
<td><strong>Oncology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRAF</td>
<td>COBAS® 4800 BRAF V600 Mutation Test</td>
<td>qual. (mutation detection)</td>
</tr>
<tr>
<td>KRAS</td>
<td>COBAS® KRAS Mutation Test</td>
<td></td>
</tr>
<tr>
<td>EGFR</td>
<td>COBAS® EGFR Mutation Test</td>
<td></td>
</tr>
<tr>
<td>PIK3CA</td>
<td>COBAS® PIK3CA Mutation Test (research use only)</td>
<td>qual. and ident.</td>
</tr>
<tr>
<td>BCR-ABL</td>
<td>LightCycler® t(9;22) quantification Kit (for research only)</td>
<td>rel. quant.</td>
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<td><strong>Genetics</strong></td>
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<tr>
<td>Factor V Leiden</td>
<td>Factor V Leiden Kit</td>
<td>qual. (mutation detection)</td>
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<tr>
<td>Factor II</td>
<td>Factor II (Prothrombin) G20210A Kit</td>
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<tr>
<td>HLA-B*5701</td>
<td>COBAS® AmpliPrep/COBAS® TaqMan® HLA-B*5701 screening Test</td>
<td>qual.</td>
</tr>
</tbody>
</table>

* 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.
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

**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.
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](http://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.

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<td>* Dual-target for HIV-1 and dual-probe for HCV</td>
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<td>†† Dual-probe</td>
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<tr>
<td>†† Dual-probe</td>
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</tbody>
</table>

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

Flexibility
• Compatible with a variety of sample tubes
• Modular design

Full traceability
• Barcode tracking from patient tube to result

Process surveillance
• Monitors liquid handling

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
• 148 tubes per hour for 1.0 mL samples
• 157 tubes per hour for 500 uL samples
The **cobas p 480 Instrument** reduces laboratory hands-on-time, and offers a fast, reliable way to uncap and recap PreserCyt® 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 vortexing
- Minimizes the risk of sample mix-up or user error

**Improve sample reproducibility and process reliability**
- 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

**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
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 analyzer**.

The **cobas z 480 analyzer** is also available as a 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

### 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 acquired 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
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 42,000 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.
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 PI3CA (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 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® 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 toxinotypes and 20 ribotypes

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

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

---

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**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**

![Image of mixed batch testing](image)

- MRSA/SA samples
- C. difficile samples
- HSV 1 and 2 samples

Automated sample preparation with cobas x 4800 Instrument

Amplification and detection with cobas z 4800 analyzer

**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)
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.

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
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.

**COBAS® AmpliPrep Instrument**

*Nucleic acid purification made simple*

---

**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

**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
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

**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 preparation**
- 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® 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: 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)

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

1. **HCV antibody test**
   - HCV RNA qualitative test: Confirmation of antibody-positive specimens

2. **Treatment decision**
   - On treatment
   - Evaluate treatment
   - End of treatment and follow-up (SVR)
   - HCV RNA quantitative test: Viral load monitoring

**Key steps in the diagnosis and management of HCV**
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® 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

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Date FDA Approved</th>
</tr>
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<tbody>
<tr>
<td>Interferon alfa-2b</td>
<td>INTRON® A</td>
<td>1991</td>
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<td>Lamivudine</td>
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<td>TYZEKA™</td>
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</tr>
<tr>
<td>Tenofovir</td>
<td>VIREAD (HIV)</td>
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</tbody>
</table>
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 antiviral 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.

- A test that is clinically validated – Used in key clinical studies, demonstrating clinical utility of CMV viral load monitoring.

- 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. The first standarized CMV viral load test with CE and FDA approval.

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CMV viral load test standardization enables improvement in CMV infection management

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

5 COBAS® AmpliPrep/COBAS® TaqMan® CMV Test package insert data
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

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

COBAS TaqMan® MTB Test
Rapid MTB detection
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

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

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

**LightCycler® Systems**

*Excellence in real-time PCR*

**Your benefit**

**High precision**
- Reproducible results independent of the sample position

**High flexibility**
- Suitable for all common assay formats and dyes

**High sensitivity**
- Even single copies can be detected

**High operator convenience**
- Data analysis according to your needs

**Versatility**
- Absolute or relative quantification, melting curve analysis or genotyping – the software offers all options

**Available reagents**
- Generic kits for 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)

**Product characteristics**

<table>
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<tr>
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<th>LightCycler® 2.0 Instrument</th>
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<th>LightCycler® 96 System</th>
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<td>Throughput</td>
<td>1–32 reactions</td>
<td>1–96 or 1–384 reactions</td>
<td>1–96 reactions</td>
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<tr>
<td>Hardware</td>
<td>6 detection channels</td>
<td>5 excitation and detection filters</td>
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<tr>
<td>Disposable</td>
<td>Capillaries</td>
<td>96 or 384 multiwell plates</td>
<td>96 multiwell plates or tube strips</td>
</tr>
<tr>
<td>System features</td>
<td>• Excellent temperature homogeneity in all wells/vessels</td>
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<td>• Freely programmable protocols, data import and export, creation of macros and templates.</td>
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<td>• 40 cycles are possible in 40 minutes</td>
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<tr>
<td>Assay formats</td>
<td>SYBR Green I, hydrolysis and hybridization probes</td>
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<tr>
<td>Reagents</td>
<td>• Generic kits for PCR and RT-PCR</td>
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<td></td>
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*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.*

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

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
• SeptiFast identification of bacteria and fungi
• SeptiFast mec A resistance screening
• Factor V mutation detection
• Factor II mutation detection

For medical research

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

Data display for a qualitative detection analysis

Genotyping analysis
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

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 SeptiFast 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 the LightCycler SeptiFast Test

<table>
<thead>
<tr>
<th>Gram (-) bacteria</th>
<th>Gram (+) bacteria</th>
<th>Fungi</th>
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<tr>
<td>Escherichia coli</td>
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<td>Klebsiella (pneumoniae/oxytoca)</td>
<td>CoNS (Coagulase negative Staphylococci)</td>
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<tr>
<td>Serratia marcescens</td>
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<td>Enterobacter (cloacae/aerogenes)</td>
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<tr>
<td>Proteus mirabilis</td>
<td>Enterococcus faecium</td>
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<tr>
<td>Pseudomonas aeruginosa</td>
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<tr>
<td>Acinetobacter baumannii</td>
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<tr>
<td>Stenotrophomonas maltophilia</td>
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</table>

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

**Product characteristics**

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

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

* For general lab use.
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
# Tissue diagnostics

## Leading future innovation

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<td>SYMPHONY</td>
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<td>VANTAGE workflow management software</td>
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<td>iScan scanners and Virtuoso software</td>
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### 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

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

### 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

### BenchMark IHC / ISH automated staining series
- Fully automated IHC* and ISH* systems, driven by easy-to-use barcoded slides and reagents

### Digital pathology
- Systems with different capacity available to fit small to large laboratories
- Open systems for antibodies
- VIRTUALSO 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

### 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.
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.

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, de-paraffinisation, staining and coverslipping
- Reagents: solutions are sealed, pre-packaged, 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
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

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
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 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

**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

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

BenchMark IHC / ISH platform

Automated slide staining systems

![BenchMark GX system](image1)

![BenchMark XT system](image2)

![BenchMark ULTRA system](image3)
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.
### 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)
- **ultraView Universal DAB Detection Kit**
- **ultraView 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**
- **ultraView SISH Detection Kit**
- **ultraView SISH DNP Detection Kit**
- **ultraView Red ISH Detection Kit**

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<tr>
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<td>Cytokeratin 5/6 (D5/16B4)</td>
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<td>EZH2 (SP129)</td>
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<td>p63 (4A4), Ventana</td>
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<td>p63 (4A4), Ventana</td>
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<td>PSA, CONFIRM</td>
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<tr>
<td>PSAP (PASE/ALJ)</td>
<td>CONFIRM</td>
<td>PSAP (PASE/ALJ)</td>
</tr>
</tbody>
</table>

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.
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.

Breast cancer diagnostics
Empowering clinical confidence

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.

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

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

HER2 (4B5) Rabbit Monoclonal Antibody
• Clinical confidence with a world-class HER2 rabbit monoclonal antibody

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

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

Cyclin D1 (SP4) on mantle cell lymphoma with OptiView DAB IHC Detection Kit.
The Roche and Ventana Medical Systems, Inc. (Ventana) cervical cancer portfolio 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 p16INK4a (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 recommendations1 as well as a major Pan-European clinical study2 indicate 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

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* 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.
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

<table>
<thead>
<tr>
<th>MMR mutations</th>
<th>IHC result MLH1</th>
<th>IHC result PMS2</th>
<th>IHC result MSH2</th>
<th>IHC result MSH6</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLH1 mutation</td>
<td>Loss</td>
<td>Loss</td>
<td>Preserved</td>
<td>Preserved</td>
</tr>
<tr>
<td>MSH2 mutation</td>
<td>Preserved</td>
<td>Preserved</td>
<td>Loss</td>
<td>Loss</td>
</tr>
<tr>
<td>MSH6 mutation</td>
<td>Preserved</td>
<td>Preserved</td>
<td>Preserved</td>
<td>Loss</td>
</tr>
<tr>
<td>PMS2 mutation</td>
<td>Preserved</td>
<td>Loss</td>
<td>Preserved</td>
<td>Preserved</td>
</tr>
</tbody>
</table>

Powered by the OptiView DAB IHC detection system.
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. 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.

1 Source: Roche Personalized Healthcare brochure, 2011.
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 hemato-pathology 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 hemopathology assays are optimized for use on the fully automated Ventana BenchMark IHC/ISH series of instruments to maximize quality and laboratory efficiency.

Ventana hemopathology 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

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.

**Comprehensive menu to aid in diagnosis and subtyping**

**CD30: cornerstone biomarker that helps inform clinical decisions**

**Hematopathology diagnostics**
*A comprehensive solution helping you detect and subtype*
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.”

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

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

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.

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.

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 Koeppen, H., Januario, T., Filvaroff, E. (2012). Mod. Pathol. 25; 480A.
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.

**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

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.
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:

- Eliminate redundancies, reduce errors
- Lean workflow
- Establish your chain of custody

Your benefit

**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

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.

- 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

- The VANTAGE workflow management system brings all of our automated platforms together, creating a chain of custody that encompasses your entire lab

- 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
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

**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.*
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

1. Scoping
Scope the project, define objectives and deliverables

2. Fact-finding
Value stream mapping of sample journey from requesting to results delivery Measure process performance within the value stream maps to identify bottlenecks

3. Analysis
Gap analysis to reveal difference between current state and target objectives

4. Devised solution
Specifically tailored to your service Pilot and measure recommended improvement plan Derive improvement plan

5. Implementation
Empower staff to continually look for process improvements

6. Continuous improvement
Assess on-going performance against KPIs and through benchmarking
Roche 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 and benchtop 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.
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.

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### 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

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### 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

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### Product characteristics

<table>
<thead>
<tr>
<th>Throughput</th>
<th>700 Mb per 23 hours run</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read length</td>
<td>Up to 1,000 bp</td>
</tr>
<tr>
<td>Consensus accuracy</td>
<td>99.997%</td>
</tr>
<tr>
<td>Data processing and bioinformatics</td>
<td>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</td>
</tr>
<tr>
<td>Applications</td>
<td>De novo sequencing, Re-sequencing, Sequence capture/targeted resequencing, Transcriptome analysis, Gene regulation studies, Epigenetic changes, Metagenomes and microbial diversity, Ancient DNA</td>
</tr>
</tbody>
</table>
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

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

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

- 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

An integrated solution – from sample prep to data analysis

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

**Product characteristics**

SeqCap Target Enrichment Systems is a solution-based capture method that enables enrichment of the whole exome or custom 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.

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For life science research only.
Not for use in diagnostic procedures.
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
Trademarks
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ACCU-CHEK  COBAS H
ACCU-CHEK INFORM  COBAS INFINITY
ACCU-CHEK PERFORMA  COBAS INTEGRA
ACCUTREND  COBAS P
AMPERASE  COBAS S
AMPLICHIP  COBAS U
AMPLICOR  COBAS X
AMPLILINK  COBAS Z
AUTOQC  COMBUR 10 TEST
AMPLIPREP  COMBUR 7 TEST
BENCHMARK  COMBUR 5 TEST
CASY  COMBUR-TEST
CEDEX  CONFIRM
CELLAVISTA  DISCOVERY
COAGUCHEK  ELECSYS
COASYS COBAS  454
COBAS  GENOME SEQUENCER
COBAS B  GS JUNIOR
COBAS BGE LINK  GS FLX
COBAS C  HERCEPTIN
COBAS E  INFORM

INNOVATIS  iScan Coreo Au
IVIEW  LIFE NEEDS ANSWERS
LIGHTCYCLER  LINEAR ARRAY
MAGNA PURE  MGRADE
MODULAR  MODULAR ANALYTICS EVO
MODULAR PRE-ANALYTICS  EVO
MRSA ADVANCED  NIMBLEGEN
OPTIVIEW  PATHWAY
PEGASYS  PRECINORM
REALTIME READY  REFLOTRON
ROCHE CARDIAC  ROCHE MICROSampler
SAFE-T-PRO  SEPTIFAST
SOFTCLIX  SYMPHONY
TAQMAN  TARCEVA
TINA-QUANT  TROPT
ultraVIEW  URISYS
URISYS 1100  URISYS 2400
VANTAGE  VENTANA
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