



Real-time PCR
Virology
Women's health
Genomics/Oncology
Full automation
Blood screening
Microbiology
Companion Diagnostics

Molecular Diagnostics

Headquartered in Pleasanton, California, Roche Molecular Diagnostics is a business area of Roche that develops and manufactures innovative tests based on our Nobel Prize winning polymerase chain reaction (PCR) technology. PCR is the technology that underlies a new generation of medical diagnostic tests. The testing menu includes the indication areas of Hepatitis C, Hepatitis B, HIV, Transplantation (CMV, HSV 1&2, VZV, EBV), as well as Women's Health (HPV, CT/NG), Oncology/Genomics (BRAF, EGFR, KRAS), and Microbiology (MRSA, VRE, C.diff and MTB). These are designed to provide information that allows healthcare providers to select and monitor patient response to therapy or identify molecular characteristics of a disease.

RMD's products also help to ensure the safety of blood and blood products by using its approved systems to screen donations.

With a broad product portfolio, RMD supplies a wide array of innovative medical diagnostic products, services, and technologies to hospitals and laboratories worldwide.

Solutions from Roche for Molecular Diagnostics

Innovative, reliable and efficient







To meet the requirements for safe, high-quality PCR diagnostics, Roche has developed the concept of flexible, combinable system modules. Depending on test requirements and sample volumes, these modules can provide a customized, efficient solution for every laboratory. The broad range of IVD CE-marked test kits can analyze different parameters from manually or automatically prepared samples.

Your benefit









Customized solutions for the PCR laboratory:

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

Workflow solutions from Roche Molecular Diagnostics

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

Workflow solutions from Roche Molecular Diagnostics

Laboratory needs	Sample purification	PCR system
Infectious diseases/virology		
• Low throughput	Manual	COBAS® TaqMan® 48 analyzer
		
• Medium throughput	Manual or COBAS® AmpliPrep instrument	COBAS® TaqMan® 48 analyzer
		
• High throughput • Backup system • Flexibility	COBAS® AmpliPrep instrument	3 x COBAS® TaqMan® 48 analyzer
		
• High throughput • Full automation	cobas p 630 instrument, COBAS® AmpliPrep/COBAS® TaqMan® system	
		
	cobas s 201 system (Blood screening)	
		

low <2,000 tests/year; medium >2,000 tests/year; high >6,000 tests/year.

Parameter menu



cobas s 201 system			
LightCycler® 2.0 analyzer			
cobas 4800/cobas z 480 instrument			
COBAS® Amplicor/Amplicor analyzer			
COBAS® TaqMan® analyzer			
Parameter	Test kit	Detection	
Viruses			
Cytomegalo	COBAS AmpliPrep/COBAS TaqMan CMV test	quantitative	•
	LightCycler CMV quant test		•
Epstein Barr	LightCycler EBV quant test		•
Hepatitis A	LightCycler Hepatitis A Virus quantification kit		•
Hepatitis B	COBAS AmpliPrep/COBAS TaqMan HBV test, v2.0		•
	COBAS TaqMan HBV test for use with High Pure system		•
Hepatitis C	COBAS AmpliPrep/COBAS TaqMan HCV qualitative test, v2.0	qualitative	•
	COBAS AmpliPrep/COBAS TaqMan HCV quantitative test, v2.0	quantitative	•
	COBAS TaqMan HCV test for use with High Pure system, v2.0		•
	LINEAR ARRAY HCV genotyping test	genotyping	•
Herpes	LightCycler HSV 1&2 qual test	qualitative & differentiation	•*
Human Immundeficiency	COBAS AmpliPrep/COBAS TaqMan HIV test, v2.0	quantitative	•
	COBAS TaqMan HIV test for use with High Pure system, v2.0		•
	COBAS AmpliPrep/COBAS TaqMan HLA-B*5701 screening test	qualitative	•
	COBAS AmpliPrep/COBAS TaqMan HIV qualitative (for research only)		•
Human Papilloma	cobas HPV test	qualitative/genotyping	•
	LINEAR ARRAY HPV genotyping test	genotyping	•
	AMPLICOR Human Papillomavirus test	qualitative/genotyping	•
Parvo B 19	LightCycler Parvo B19 quantification kit (for research only)	quantitative	•
Varicella-Zoster	LightCycler VZV qual test	qualitative	
Other pathogens			
Chlamydia trachomatis/Neisseria gonorrhoeae	cobas 4800 CT/NG test	qualitative	•
	COBAS AMPLICOR CT/NG		•

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

cobas s 201 system			
LightCycler® 2.0 analyzer			
cobas 4800/cobas z 480 instrument			
COBAS® Amplicor/Amplicor analyzer			
COBAS® TaqMan® analyzer			
Parameter	Test kit	Detection	
Chlamydia trachomatis	COBAS TaqMan CT test	qualitative	•
Chlostridium difficile	cobas 4800 C.diff test		•
Methylicin resistant staphylococcus aureus	LightCycler MRSA advanced		•*
Mycobacteria Tuberculosis	COBAS TaqMan MTB test		•
Vancomycin resistant enterococcus	LightCycler VRE		
Sepsis pathogens			
Bacteria /Fungi	LightCycler SeptiFast test MGRADE	qualitative & differentiation	•
	LightCycler SeptiFast mecA test MGRADE	qualitative & identification	•
Blood screening			
HIV-1**, HIV-2, HCV, HBV	cobas TaqScreen MPX test, v2.0	qualitative/differentiation	•
Parvo B 19/HAV	cobas TaqScreen DPX test		•
Westnile virus	cobas TaqScreen WNV test	qualitative	•
Oncology			
BRAF	cobas 4800 BRAF V600 mutation test	qualitative (mutation detection)	•
KRAS	cobas KRAS mutation test		•
EGFR	cobas EGFR mutation test		•
Translocation t 9;22***	LightCycler t(9;22) quantification kit (for research only)	relative quantification	•
Genetics			
Factor V Leiden	Factor V Leiden kit	qualitative/Mutation detection	•
Factor II	Factor II (Prothrombin) G20210A kit		•
HLA-B*5701	COBAS AmpliPrep/COBAS TaqMan HLA-B*5701 screening test	qualitative	•

*Will be launched in 2013 ** Groups M and O *** BCR-ABL fusion transcripts

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 samples and controls into sample input tubes of the COBAS AmpliPrep system.

The **cobas p 630** system can be combined with up to 3 COBAS AmpliPrep instruments and the new AmpliLink software v3.3 to ensure full traceability of workflow.



Your benefit

Efficiency

- Automated handling of primary tubes

Flexibility

- Compatible with a variety of primary tubes
- Modular design

Full traceability

- Barcode tracking from primary tube to result

Process surveillance

- Monitors liquid handling

Product features

- Uncapping and recapping of the sample tube
- Pipetting Roche controls from control tubes to sample tubes
- Pipetting samples from primary 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 μ L samples
- 149 tubes per hour for 1.0 mL samples



COBAS® AmpliPrep instrument

Nucleic acid purification made simple



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

Your benefit

Safety and reliability

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

Efficiency

- Handles up to 4 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 features

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

Unit dimensions

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

Capacity

- 72 samples; up to 144 purifications per day

Throughput

- approx. 15 – 24 samples/hr



COBAS® TaqMan® analyzer and COBAS® TaqMan® 48 analyzer

Innovation for routine PCR



The COBAS TaqMan 48 analyzer is a compact benchtop instrument that minimizes manual steps and shortens analysis times due to 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 manually or 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 instrument combined with the COBAS AmpliPrep instrument and docking station is the solution for high throughput PCR.

Your benefit

Efficiency and reliability for routine PCR

- Reliable results within 2–3 hours
- Sensitive, highly linear tests can handle both low titer and high titer samples in the same run
- Greater safety due to AmpErase enzyme contamination prevention and internal controls for detecting possible PCR inhibitors



COBAS® TaqMan® 48 instrument



COBAS® TaqMan® analyzer

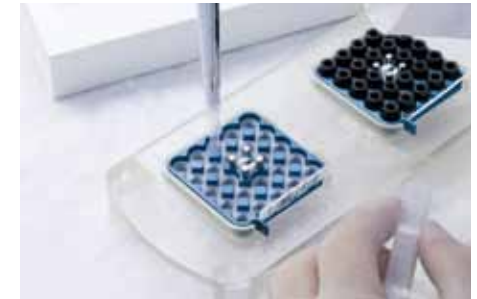
Product features

COBAS TaqMan 48 instrument

- Compact desktop model
- 2 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
- 4 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*

* Research use only, not 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 strategy with improved sensitivity for the new era of direct acting antiviral agents (DAAs).

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 features

- 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

- **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

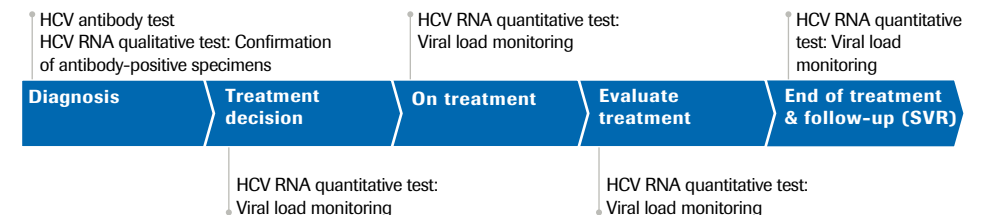
Product features

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

Workflow

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

Roche offers the cobas system family to run the key tests for the diagnosis and management of HCV



Key steps in the diagnosis and management of HCV

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 features

- 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 analysis system that allows variable batch sizes – between 1 and 48 tests per run
- Internal controls included in the same reaction batch
- Specificity: 99%
- Sensitivity: 0.46 CFU/PCR, corresponding to a calculated concentration of 18 CFU/mL sputum



COBAS TaqMan 48 instrument and MTB kits

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 features

Scalable, modular system

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

Pooling and data management server

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

Test menu

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

cobas TaqScreen MPX test, v2.0

- 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 B19 DNA and qualitative detection of HAV
- B19 target values are traceable to the WHO B19 International standard
- Meets current regulatory requirements for plasma intended for further manufacture

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
- Can be used to screen individual plasma specimens from organ and tissue donors when obtained while the donor's heart is still beating
- Capable of detecting other members of JEV serogroup



Pooling and data management server



Hamilton MICROLAB STAR
Pipettor instrument for automated pooling



COBAS AmpliPrep instrument and
COBAS TaqMan instrument combined
with a docking station



cobas[®] 4800 system

Engineered for peace of mind



The **cobas** 4800 system offers state-of-the-art, fully automated sample preparation, real-time PCR amplification/detection and easy-to-use software for the detection of *C. trachomatis* (CT), *N. gonorrhoeae* (NG) and HPV (human papillomavirus) analysis.

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

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

Your benefit

Reliable results

- By sophisticated concept of sample preparation and multivariable software algorithm for result generation

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

Future proved

- Constantly expanding menu

Test menu

cobas 4800 HPV test

- Only FDA approved hr HPV assay which simultaneously detects 14 high-risk HPV genotypes and identifies HPV type 16 & 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

Parameters in development**

- **cobas 4800 MRSA/SA test:** Intended to be used for the direct, qualitative detection of MRSA & *S. aureus* in nasal swabs
- **cobas 4800 C.diff test:** Intended to be used for the direct, qualitative detection of *C. difficile* toxin B gene in liquid or soft stool specimens of patients suspected of having *C. difficile*-associated disease
- **cobas 4800 HSV 1/2 test:** Intended to be used for the direct, qualitative detection of HSV 1 and 2 from anogenital lesions

Product features

- 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 188)
- 6 detection channels
- 96 well plate format
- Dimensions: 57 cm width, 59 cm depth, 50 cm high

* Please see details on page 154.

** Planned for launch in 2013; for local launch check with your Roche representative.

*** Currently available for software v1.1.



cobas x 480 instrument



cobas z 480 analyzer

The cobas HPV test

Know the risk



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

The **cobas** 4800 HPV test is the only clinically validated CE-marked, and FDA-approved assay, that simultaneously provides results on 14 known „high-risk“ genotypes, including individual results on the highest-risk genotypes, HPV 16 and HPV 18, giving three results in just one test. HPV genotypes 16 and 18 are known to be responsible for more than 70 percent of all cervical cancer cases.

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

Your benefit

Evidence based

- Clinically validated in Roche's landmark ATHENA trial, the largest U.S.-based registration study for cervical cancer screening, including more than 47,000 women
- One in 10 women in the landmark ATHENA study who tested positive for either HPV genotype 16 or 18 had evidence of cervical pre-cancer, even though their pap was normal

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 features

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 (Cytoc Corp.) and SurePath[®] preservative fluid (not approved in the US) (BD Diagnostics-TriPath)
- Sample volume of 1 mL is sufficient

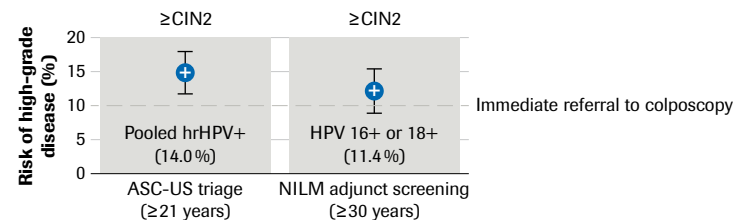
Test principle:

- 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 \geq CIN2 by screening strategies assessed in ATHENA at baseline



1 in 10 women \geq 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

*7–10 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. The **cobas** oncology menu will be expanded during the next years.

Your benefit

Reliable results

- Complete and controlled IVD system consisting of **cobas** DNA sample preparation kit, **cobas** BRAF, KRAS, and EGFR 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

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

cobas EGFR mutation test

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



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

cobas DNA sample preparation kit

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

Assay specific analysis packages

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

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 features

- 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

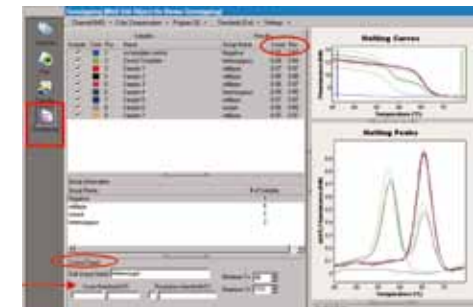
- CMV quantification
- EBV quantification
- HSV 1/2 detection and differentiation
- VZV detection
- MRSA Advanced detection
- SeptiFast identification of bacteria and fungi
- SeptiFast mec A resistance screening
- Factor V mutation detection
- Factor II mutation detection

For medical research

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

Samples				Cells		
Include	Color	Pos	Name	Combined	Target	Control
	Blue	1	no template control	Success	Negative	Success
	Green	2	Negative Control	Success	Negative	Success
	Red	3	Positive Control	Success	Positive	Success
	Black	4	Sample 1	Failure	Positive	Success
	Pink	5	Sample 2	Failure	Positive	Success
	Green	6	Sample 3	Negative	Negative	Success
	Blue	7	Sample 4	Failure	Positive	Success
	Green	8	Sample 5	Failure	Positive	Success

Data display for a qualitative detection analysis



Genotyping analysis

LightCycler® SeptiFast test

Rapid identification of sepsis pathogens

Sepsis is a leading, infectious complication for critically ill patients. It represents about 15% of all nosocomial infections. Despite improvements in medical care, sepsis is still a challenge for internal medicine. Any delay in the management of infection is deleterious, especially in patients whose illness is severe. Shortening this delay is of paramount importance. In the LightCycler 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 dem LightCycler® SeptiFast test

Gram (-) bacteria	Gram (+) bacteria	Fungi
<ul style="list-style-type: none"> • Escherichia coli • Klebsiella (pneumoniae/oxytoca) • Serratia marcescens • Enterobacter (cloacae/aerogenes) • Proteus mirabilis • Pseudomonas aeruginosa • Acinetobacter baumannii • Stenotrophomonas maltophilia 	<ul style="list-style-type: none"> • Staphylococcus aureus* • CoNS (Coagulase negative Staphylococci) • Streptococcus pneumoniae • Streptococcus spp • Enterococcus faecium • Enterococcus faecalis 	<ul style="list-style-type: none"> • Candida albicans • Candida tropicalis • Candida krusei • Candida glabrata • Candida parapsilosis • Aspergillus fumigatus

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

LightCycler® MRSA Advanced test

Enabling improved infection control



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

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

Your benefit

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

Ensure fast and simple operation

