Unsure, unclear, uncertain, words no one ever wants to hear when faced with a life-changing decision. That’s why clarity is important. It gives strength to those undergoing a treatment they know will work. It’s the feeling of relief when cancer is found just in time, or the rush of freedom when preventing heart disease.

We can’t change the past or prevent the inevitable, but we can build a better future. And the secret? Diagnostics – the reason we can overcome health challenges ahead, knowing the actions we take today translate into a healthier tomorrow.

We give you...
As the world leader in diagnostics, Roche’s vision is simple: We believe in the Power of Knowing – that you have the correct diagnosis, the right treatment, and the ability to prevent disease or predict the care you need.

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

The new cobas 8100 fully automated workflow series
The cobas 8100 automated workflow series is a new solution for use in diagnostic laboratories. The integrated diagnostics platform fully automates routine laboratory tasks while maximising test reliability and patient safety. Using intelligent robotics, the new system automatically prepares blood samples for immediate testing and post-analytical processing.

The image shows a complete laboratory solution, consisting of the cobas 8100 workflow system, connected to two cobas 8000 analysers and a cobas p 701 post-analytical system.
At Roche Diagnostics, we generate the Power of Knowing, ensuring that everything we do matters to the lives we touch.

We give The Power of Knowing to:

Laboratories, so they can be the most reliable partners for healthcare professionals, providing them with fast and accurate results for optimal patient care.

Healthcare professionals, so they can better make the right decisions for their patients at the right time.

Payers and policymakers, so they can better invest in the right solutions for the future of healthcare.

Patients and the public, so they can benefit from improved control over their health and wellbeing.

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

We give you

The Power of Knowing

THE POWER OF KNOWING
Our areas of expertise
Covering all in vitro diagnostic segments
in all major disease areas

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

We are active in all major diagnostic segments:

- Clinical chemistry & immunoassays
- Hematology & hemostasis
- Urinanalysis

We focus on all endemic disease areas:

- Oncology
- Cardiology & metabolism
- Infectious diseases

- Molecular diagnostics
- Tissue diagnostics
- Point-of-care diagnostics

- Inflammatory & autoimmune
- Women’s health
- Critical 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 have the power to move beyond diagnosis and reach a new phase of sustainable healthcare in disease prevention and management.

The more questions we answer, the more lives we save.
Comprehensive cervical cancer screening and diagnosis portfolio

Cervical cancer is the third most common cancer in women. Globally, almost half a million women are diagnosed with cervical cancer each year, and half of them die from the disease. Diagnosis in the pre-cancer stage is critical as the cure rate can be as high as 98%. However once cancer has developed and spread to other organs, less than 20% of women survive past five years of diagnosis.

It has long been known that the conventional pap smear misses cases of pre-cancer, and the sensitivity of the single smear test is only 50-70%.

Roche’s cobas HPV test is a cervical cancer screening test that detects high-risk human papillomavirus (HPV) infection, the underlying cause of cervical cancer. By specifically detecting HPV 16 and 18, the test identifies women with the greatest risk of developing cervical pre-cancer to allow timely and appropriate preventative measures to be taken.

Clinically validated by the landmark ATHENA trial, the Roche cobas HPV test received FDA approval in April 2014 for first-line primary screening for cervical cancer.

In addition, Roche’s CINtec PLUS* test has been demonstrated to provide greater accuracy in pinpointing early-stage cervical disease, lowering rates of false positive results for women, irrespective of age.

*The fully automated CINtec PLUS cytology test is available in Europe, Asia, Latin America and Canada. It may not be approved for all uses discussed in this document.

“We have the tools to not only prevent cervical cancer, but to also detect it early on.

But women need to be educated about these tools – because with them, we can put an end to cervical cancer.”

Tamika F. is a 12-year survivor of cervical cancer. Since she finished her treatment in 2001, she has been part of the cervical cancer advocacy community, as well as the cervical cancer survivor community.
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 prioritise 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 handle expanding testing and data volumes. We further drive laboratory efficiency by providing our customers with modular solutions and comprehensive test menus.
INR monitoring has never been so easy
Tools for networking, organising and analysing data are increasingly in demand across many healthcare settings, from laboratories and hospitals to patient self-testing. The challenge of translating raw data into actionable healthcare information is one of the major tasks being addressed by Roche Diagnostics.

There has been an extraordinary increase in the use of vitamin K antagonists (VKAs), driven mainly by an ageing population. Millions of people worldwide are now taking VKAs for a variety of conditions. To ensure VKAs are performed as they should, a regular blood test measuring an individual’s international normalised ratio (INR) is required. This test can be performed at home using a small drop of blood from the fingertip.

For over 20 years, CoaguChek systems from Roche have set the standard in point-of-care INR testing for patients on oral anticoagulant therapy. More than 2 million patients on VKAs around the world are now testing with the CoaguChek system. It’s convenient, portable, easy to use and, above all, it delivers anticoagulation results that doctors, nurses and patients can trust.

Christian S. has an artificial heart valve and needs to take long-term anticoagulation therapy. The self-monitoring device allows him to check his coagulation levels himself, giving him back a great deal of freedom and independence.

“Technological progress has been a huge help to those of us who have to take anticoagulants. It’s made us free and independent.”
Our competitive advantages
Offering total solutions with a strong commercial presence

Increased value of Diagnostics
In vitro diagnostics 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.

Roche offers the most comprehensive diagnostic solutions:
- Breadth of technologies
- Comprehensive test menu
- IT and workflow connectivity

Roche builds on a strong commercial presence:
- Active in all in vitro diagnostic segments
- Large installed base worldwide
- Present in over 130 countries

Roche is the leader in Personalised Healthcare
With our leading Pharmaceuticals and Diagnostics businesses under one roof, we are better positioned to deliver Personalised 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.

Roche Pharma and Diagnostics Divisions collaborate from discovery to market, constantly advancing Personalised Healthcare.

IVD accounts for
~2% of worldwide healthcare spending

IVD influences
>60% of clinical decision-making

Roche
Diagnostics
16.1% Others 23.6%

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Roche
Diagnostics
16.1% Others 23.6%
Precise testing for life or death decisions with high-sensitive cardiac tests
Approximately 10% of all emergency room consultations are for patients with heart attack symptoms. In the US alone, more than 5.5 million patients are seen in emergency departments every year for chest pain. Rapid, accurate diagnosis and early risk assessment are critical when a patient arrives.

However, diagnosing heart attack patients is one of the most challenging problems facing doctors in hospital emergency departments. A heart attack requires immediate and often serious intervention like heart catheterisation or coronary bypass surgery. A blood test that can accurately determine whether a patient is having a heart attack can mean the difference between life and death.

Twenty years ago, physicians had to rely on symptoms and electrocardiograms (ECG), which could miss over 50% of all heart attacks. Roche has developed a high-sensitive test which detects the presence of troponin T, a protein that is released into the bloodstream during a heart attack. The Troponin T test has since become a reliable indicator of heart attack and the gold standard worldwide in cardiac critical care, literally saving millions of lives.

 Prof. Christian Müller, Cardiologist and Head of Outcome Research at the University Hospital Basel, Switzerland, has been examining the use of troponin T to rule-in or rule-out heart attacks in the emergency setting for years.

“The high-sensitivity cardiac troponin has become an indispensable test in the early diagnosis of a heart attack, also enabling us to detect small heart attacks that we could have missed with the use of conventional tests, and to focus the right resources for patients from the outset.”
“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

Access to Diagnostics
Improving breast cancer diagnosis in Asia

The Roche SPHERE programme
Breast and gastric cancer are among the most common cancers in Asia. The incidence rates are increasing faster than in Western countries due to changes in lifestyle and diet. HER2-positive cancer, a particularly aggressive form that affects about one in five people with breast or gastric cancer, can be treated with Herceptin (trastuzumab).

As Herceptin is a targeted treatment that only works in people with HER2-positive cancer, samples of a patient’s tumour must be tested for HER2 before treatment. The accuracy of the test is critical, requiring proficiency in tissue collection and processing, as well as laboratory procedures.

In 2010 Roche launched the SPHERE programme (Scientific Partnership for HER2 Testing Excellence) in Asia-Pacific. The aim is to help integrate HER2 testing of breast and gastric cancer patients at the point of disease diagnosis. We are also seeking to increase the reliability and reproducibility of HER2 testing by:

- training surgeons in taking and handling tissue biopsies
- establishing training and quality control procedures for lab technicians
- assisting pathologists in scoring and interpreting results
- educating oncologists in the need for reliable HER2 testing and the link to treatment decisions.

In addition, the programme aims to educate, share best practices and facilitate communication relating to HER2 testing between pathologists and technicians across the Asia-Pacific region. The ultimate goal is for people to receive accurate, timely diagnosis of the disease and appropriate treatment options.

SPHERE now operates in 12 Asia-Pacific markets: Bangladesh, China, Hong Kong, India, Indonesia, Korea, Malaysia, Myanmar, the Philippines, Taiwan, Thailand and Vietnam.

In 2013 close to 13,500 pathologists, surgeons and technicians participated in the training programme.
Access to Diagnostics
Working together to treat newborns at risk of HIV

Innovative testing technology expands access to care in remote areas

Roche’s AMPLICARE programme
Early HIV diagnosis means infants can get the right treatment and stay healthy. To this end, Roche has supported the introduction of a new way of testing blood samples that are dried on a card, but still be able to effectively and reliably test for HIV. Under the state-of-the-art results process, doctors are notified of the test findings immediately. This collection card has expanded access to HIV diagnosis throughout the remotest areas of southern Africa, and Roche is continuing to work with a number of other organisations in public-private partnerships to ensure subsequent medical care for infants with HIV.

The AmpliCare programme was set up by Roche a little over 10 years ago to help combat HIV/AIDS in developing countries. Today, it operates in sub-Saharan Africa, parts of Asia and Latin America in partnership with the Clinton Health Access Initiative, UNICEF, UNITAID, local governments and other multilateral organisations.

Since 2002, over 1,350,000 infants have been tested for HIV within the programme, more than 2,100,000 patients on HIV/AIDS therapy have had their viral levels monitored, some 600 healthcare professionals have been trained in diagnostic testing, and 30 testing centres have been set up in different countries in Africa and Asia.
Access to diagnostics

Helping to reduce cancer mortality in Turkey

Investment in early diagnosis and screening centres, and promotion of awareness programmes to support the fight against cancer

Supporting KETEMs in Turkey

Awareness of the importance of prevention and early diagnosis in increasing the chances of survival is paramount in fighting cancer. Improving knowledge of health and building healthcare capacity is a priority for the Turkish Ministry of Health. To create new models in cancer control and reduce cancer mortality rates, the Ministry built Cancer Early Diagnosis Screening and Training Centres (KETEMs) throughout the country.

The KETEMs are equipped with the latest diagnostic equipment and conduct screening programmes for breast, cervical and colorectal cancer. The centres also serve to drive awareness of the importance of prevention and early diagnosis in cancer.

In 2009 Roche supported the construction of a KETEM in Ankara, the capital city of Turkey. Today this centre is one of about 120 KETEMs integrated at government hospitals throughout the country, each rendering services for populations of 250,000.
Our organisational setup

Built for sustainable success

Our Business Areas/Units

The Roche Diagnostics Business Areas and Units are set up according to the fields of activities of our customers and are responsible for research and development, product portfolio management, global strategic direction and marketing, along with business development in their area of expertise.

Professional Diagnostics

Serum work area/immunoassays and clinical chemistry
Point-of-care testing
Speciality testing (hemostasis, hematology, urinalysis)
Lab IT and workflow management
Custom Biotech (applications for industrial diagnostics and pharmabiotech manufacturing)

Molecular Diagnostics

Virology
Blood screening
Genomics/oncology
Microbiology
Women’s health
Biochemical reagents
Nucleic acid purification and realtime PCR

Tissue Diagnostics

Primary staining
Advanced staining
Workflow management
Digital pathology

Sequencing Unit

Offering sequencing solutions for both clinical and life science segments

Diabetes Care

Blood glucose monitoring
Insulin delivery
Diabetes workflow management
Our areas of expertise
Covering all in vitro diagnostic segments in all major disease areas

We are active in all major diagnostic segments:

Clinical chemistry & immunoassays
Modular instruments with a wide range of immunoassays and clinical chemistry tests for emergency rooms, health clinics, large hospitals and laboratory networks.

Hematology & hemostasis
Blood testing, providing fast, accurate results, helping healthcare providers identify and monitor infections, leukemia, chemotherapy, coagulation and anemic conditions.

Urinanalysis
Offering a range of urine testing products, from single-use strips to semi- and fully-automated systems, including digital urinary microscopy.

Molecular diagnostics
Providing advanced solutions in virology, women’s health, oncology, microbiology and genomics for labs, and screening products for blood banks.

Tissue diagnostics
Improving the lives of all patients afflicted with cancer by providing innovations in tissue-based cancer diagnostics that increase testing efficiency and improve medical value.

Point-of-care diagnostics
Portable or bed-side instruments and IT solutions delivering quick, accurate and reliable results for critical and primary care clinicians and for patient self-testing.

We focus on all endemic disease areas:

Oncology
Offering a broad portfolio of tumour markers, molecular and tissue diagnostic tests for cancer screening, diagnosis and monitoring, enabling personalized medicines.

Cardiology & metabolism
Tackling the globally increasing prevalence for conditions such as diabetes, diabetic retinopathy, atherosclerosis and cardiac disease.

Infectious diseases
Infectious diseases caused by virus or bacteria are a major cause of death and morbidity worldwide and constitute an ever-growing medical need.

Women’s health
Focusing on fertility and pregnancy care as well as conditions and diseases such as breast cancer, cervical cancer, arthritis and osteoporosis.

Critical care
Systems and assays for testing and monitoring time-sensitive parameters for use in hospital laboratories and near the site of patient care.

Facts & Figures
Roche Diagnostics

2013
Employees 28,961
Sales 10,476 m
Growth: 4% (CER*)

* CER = Constant exchange rates

Share of IVD sales 2013

2013 sales by Business Area/Unit

2013 sales by Region

Main Roche Diagnostics Sites

Regional hub
T&D / Manufacturing
Facts & Figures

Roche Professional Diagnostics

2013
Employees 1,183 (permanent FTEs)
Sales CHF 5,746 million (56% of divisional sales)
Growth 8% (local currency)

Market position (status 2012)
Professional diagnostics market*
Roche Diagnostics 16.1%
Abbott 11.3%
Danaher 10.2%
Johnson & Johnson 5.2%
bioMerieux 4.4%
Alere 4.3%
Sysmex 4.0%
Becton Dickinson 3.2%
Bio-Rad 3.1%
Siemens 14.6%
Roche Diagnostics 16.1%
Others 23.6%

* Source: Industry analyst report, Roche analysis, company reports

Main sites
Rotkreuz (Switzerland (HQ)), Indianapolis (USA), Mannheim (Germany), Perugia (Germany)

Disease Areas
Variety of indication fields, including oncology, virology, cardiovascular, inflammatory and infectious diseases

Customers
Hospital and commercial labs, lab networks, point-of-care, ICUs, patient bedside, doctor's practice, pharmacies and homes, blood banks

Best-sellers 2013
Immunoassays CHF 2,571 million (+14%)
Clinical Chemistry CHF 1,572 million (+5%)
Coagulation self-monitoring CHF 370 million (+7%)
Haematology CHF 172 million (+9%)

Key product launches 2013
- cobas 8100 Next-generation modular preanalytics
- cobas infinity IT solution Managing data & sample workflow (all sizes)
- cobas u 601 Fully automated urine test strip analyser
- Cyclosporine/Tacrolimus Immunoassay for monitoring of immuno-suppressive drug therapy
- Calcitomin Immunoassay for medullary thyroid cancer diagnosis and monitoring
- proGRP Immunoassay for the diagnosis of small cell lung cancer

RDP portfolio
- ~100 immunoassays
- ~120 clinical chemistry tests
- 30 instruments with ~100 combinations

RDP is the largest Business Area. It is a leading supplier of solutions, instruments, tests, software and services for small- to mid-size and large-size commercial and hospital labs and laboratory networks.

The Business Area is complementing its solution offering by constantly strengthening its portfolio in point-of-care testing.

By combining analytics and pre-/post-analyses with sample and data flow concepts, Roche Professional Diagnostics is enabling total lab solution offerings.

Segments and products

Serum work area (SWA): immunoassays and clinical chemistry*
Modular instruments and solutions for small to mid-size and large-size laboratories with a wide range of immunoassays and clinical chemistry assays.
- cobas 4000 analyser series (low-volume labs)
- cobas 6000 analyser series (mid-volume labs)
- cobas 8000 modular analyser series (large-volume labs)

Point-of-care (POC) testing*
POC instruments and IT solutions delivering quick, accurate and reliable results for critical- and primary-care clinicians and for patient self-monitoring.
- cobas c104 coagulation monitoring system
- cobas c103 POC system (blood gases)
- cobas c102 POC system (blood glucose)
- cobas c101 system (HbA1c and lipid testing)
- cobas c102 system (point-of-care cardiac testing)
- cobas IT 1000

Speciality testing*
Urine analysis products ranging from single-use strips to semi- and fully-automatic systems.
Haemostasis systems and tests combining innovation with proven medical and diagnostic expertise, setting new standards in platelet function testing.
- cobas u 411 uridine analyser
- cobas u 610 uridine analyser
- cobas u 601 uridine analyser
- cobas v 701 microscopy analyser
- Combur-Test strip
- Multiplette analyser

Lab IT and workflow management*
Innovative pre- and post-analytical systems and solutions to support workflow optimisation, improving testing efficiency and services to clinicians and ultimately patients.
- cobas p 312 pre-analytical system
- cobas p 512 post-analytical system
- cobas p 812 pre-analytical system
- cobas 8100 automated workflow series
- cobas infinity IT solutions

Custom Biotech
Supplies raw materials, reagents, instruments and services. Custom Biotech customises its offering to the quality and regulatory needs of biopharmaceutical and diagnostic manufacturers.

* Product list is non-exhaustive

Key tests

<table>
<thead>
<tr>
<th>Disease area</th>
<th>Test on the market*</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>HER2 (human epidermal protein 4)</td>
<td>Ovarian cancer</td>
</tr>
<tr>
<td></td>
<td>PSA (prostate specific antigen)</td>
<td>Prostate cancer</td>
</tr>
<tr>
<td></td>
<td>proGRP</td>
<td>Small cell lung cancer</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>Troponin T-hs</td>
<td>Acute coronary syndrome</td>
</tr>
<tr>
<td></td>
<td>NT-proBNP</td>
<td>Heart failure</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>HIV combi PT</td>
<td>HIV</td>
</tr>
<tr>
<td></td>
<td>Anti-HIV</td>
<td>Hepatitis C</td>
</tr>
<tr>
<td></td>
<td>TORCH panel</td>
<td>Toxoplasmosis, rubella, cytomegalovirus, herpes simplex, others</td>
</tr>
<tr>
<td></td>
<td>Syphilis</td>
<td>Syphilis (Treponema pallidum)</td>
</tr>
<tr>
<td></td>
<td>E-R, PCT and Tip-quart CRP</td>
<td>Septicemia management</td>
</tr>
<tr>
<td>Metabolic diseases</td>
<td>HbA1c</td>
<td>Diabetes management</td>
</tr>
<tr>
<td></td>
<td>Vitamin D total</td>
<td>Determination of vitamin D level</td>
</tr>
<tr>
<td></td>
<td>zIF1/2</td>
<td>Preeclampsia</td>
</tr>
<tr>
<td></td>
<td>AMH</td>
<td>Ovarian reserve</td>
</tr>
</tbody>
</table>

* Not available in all markets
Facts & Figures

Roche Molecular Diagnostics (RMD) develops and markets advanced diagnostics and blood screening platforms and tests based on Roche’s proprietary real-time Polymerase Chain Reaction (PCR) technology. PCR’s unique ability to exponentially amplify small amounts of target DNA has resulted in numerous diagnostic techniques which would otherwise be too time-consuming or impossible to perform. Today, numerous diagnostic techniques are based on PCR’s unique ability to exponentially amplify small amounts of target DNA.

RMD portfolio
> 10 instruments
> 25 assays

Main sites
Pleasanton (USA (HQ)), Branchburg (USA), Rotkreuz (Switzerland)

Disease Areas
Virology, oncology, blood screening, women’s health, microbiology

Customers
Hospital and commercial labs, blood banks, life sciences, academia

 Technologies
Polymerase chain reaction (PCR)

Best-Sellers 2013
Virology (HBV, HCV, HIV) CHF 514 million (+1%)
Blood screening CHF 317 million (+2%)

Key product launches 2013
CAP/CTM HCV v2.0 Quant Test (US) Detection and monitoring of HCV
cobas 4800 EGFR Test (US) Lung cancer, CDx with Tarceva

Segments and products

Virology*
Early detection and viral load identification (the quantity of virus in the blood) for the right treatment decision, i.e. selection of the medicine, the therapeutic dose and duration of treatment. Viral load monitoring during treatment is also crucial for determining treatment efficacy.
Tests: HIV, HCV, HBV, HAV, CMV
- cobas AmpliPrep/cobas TaqMan analyser
- cobas AmpliPrep/cobas TaqMan 48 analyser
- cobas p 830 analyser
- cobas 6800/8800 systems (launch in Q4 2014)

Blood screening*
Provides blood banks with highly sensitive and automated real-time PCR tests to detect HIV, Hepatitis, Parvovirus and West Nile Virus, helping to ensure the highest level of safety for blood supplies.
Tests: Multiplex HIV/HCV/HBV, Duplex B19V/HAV, West Nile Virus
- cobas a 201 system
- cobas a 451 system
- cobas 6800/8800 systems

Genomics and oncology*
Gene-based tests helping doctors to select the right therapy, thus enabling personalised healthcare.
Tests: BRAF, KRAS, EGFR and PIK3CA mutation tests
- cobas 4800 system

Microbiology*
Quick detection and identification of bloodstream infections typically caused by bacteria and fungi to assist doctors in making appropriate decisions about antibiotics or antifungal therapies.
Tests: MRSA/S, Tuberculosis, Sepsis, Herpes, C. difficile
- LightCycler analyser
- cobas TaqMan
- cobas 4800 system

Women’s health*
Screening tests for human papillomavirus (HPV), the commonest cause of cervical cancer, as well as C. trachomatis / N. gonorrhoeae (CT/NG), which may cause pelvic inflammatory disease.
Tests: HPV, CT/NG
- cobas 4800 system

Nucleic acid purification and gene expression*
To isolate nucleic acids from many types of sample material and evaluate how a gene is used in the synthesis of a functional gene product.
- Magna Pure Compact
- Magna Pure LC
- LightCycler 2.0
- LightCycler 480
- LightCycler 96

* Not available in all markets   ** For research use only

Key tests

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<tr>
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<tbody>
<tr>
<td>Cancer</td>
<td>cobas 4800 BRAF V600 Mutation</td>
<td>Melanoma</td>
</tr>
<tr>
<td></td>
<td>cobas 4800 KRAS Mutation</td>
<td>Colorectal cancer</td>
</tr>
<tr>
<td></td>
<td>cobas 4800 EGFR Mutation</td>
<td>Non-small cell lung cancer</td>
</tr>
<tr>
<td></td>
<td>cobas PIK3CA Mutation (BID)**</td>
<td>Breast, colorectal and other solid tumours</td>
</tr>
<tr>
<td></td>
<td>cobas HPV</td>
<td>Cervical cancer</td>
</tr>
<tr>
<td>Infectious</td>
<td>cobas AmpliPrep/cobas TaqMan Dual Target HIV-1, v 2.0</td>
<td>HIV</td>
</tr>
<tr>
<td>diseases</td>
<td>cobas MRSA/MSRA</td>
<td>Multidrug-resistant Staphylococci aureus</td>
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<tr>
<td></td>
<td>cobas TeqScreen DPX</td>
<td>Parvovirus B19 / Hepatitis A</td>
</tr>
<tr>
<td></td>
<td>cobas TeqScreen MPX, v 2.0</td>
<td>HIV-1 (groups M&amp;O), HIV-2, HCV, HBV</td>
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<tr>
<td></td>
<td>cobas TeqScreen West Nile Virus</td>
<td>West Nile virus</td>
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<tr>
<td></td>
<td>cobas AmpliPrep/cobas TaqMan HBV, v 2.0</td>
<td>Hepatitis B</td>
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<tr>
<td></td>
<td>cobas AmpliPrep/cobas TaqMan HCV, v 2.0</td>
<td>Hepatitis C</td>
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<td></td>
<td>cobas HSV</td>
<td>Herpes</td>
</tr>
<tr>
<td></td>
<td>cobas 4800 CT/NG</td>
<td>C. trachomatis and N. gonorrhoeae infection</td>
</tr>
</tbody>
</table>

* Source: Industry analyst report, Roche analysis, company reports
Roche Tissue Diagnostics (RTD, Ventana Medical Systems, Inc. in North America) is a world-leading supplier of automated, tissue-based cancer diagnostic solutions. It develops and manufactures medical diagnostic instruments, reagents, digital pathology solutions, and image management and workflow software that provide innovative automation technology for use in slide-based tissue diagnostics to aid in diagnosis of cancer and infectious disease.

RTD develops cornerstone and novel tests for breast, lung, cervical, lymphoma, colorectal and prostate cancers to help physicians provide timely, accurate answers.

In addition, the company offers premier workflow solutions designed to improve laboratory workflow efficiency, providing automated safeguards to enhance the quality of patient healthcare. Its instruments and reagent systems are used in histology, cytology and drug discovery laboratories worldwide.

Working with Roche's Pharmaceutical Division as well as external pharma partners, RTD enables the development of patient-selection biomarkers faster and more efficient.

RTD delivers an end-to-end offering, with expertise at every stage from discovery to marketing; helps reduce biotech companies’ development and marketing risks; provides global access through a global commercial network and installed base; and offers a differentiated, broad instrument and reagent portfolio.

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RTD delivers an end-to-end offering, with expertise at every stage from discovery to marketing; reduces patient and technician risk and reduces exposure to harmful chemicals.

### Key product launches 2013

| HER2 (4B5) antibody for IHC (CE/IVD) | Companion diagnostic (Perjeta and Kadcyla) for breast cancer |
| BRAF V600E (VE1) antibody for IHC (US Class I, CE/IVD) | Detects BRAF V600E mutation in a variety of tumors |
| CINtec® PLUS antibody for IHC (CE/IVD) | Early screening of cervical precancer |
| GRAM Stain (US Class I, CE/IVD) | Fully automated, for detecting Gram-positive and Gram-negative bacteria for classifying infection |

### Specimen workflow

Delivers specimen chain of custody, lean integrated processes and full visibility into lab operations anytime, from anywhere. VANTAGE workflow solution is a comprehensive solution for histology labs — an exclusive end-to-end product that automates, streamlines and integrates lab workflow and information flow to provide increased productivity and improved patient safety gains.

- **VANTAGE workflow solution**

### Primary staining

Based on the application of haematoxylin and eosin (H&E) dye to examine tissue structure, the SYMPHONY platform fully automates slide preparation and improves visualization, providing exceptional discrimination of microanatomic detail. The platform also helps prevent cross-contamination between patient samples through individual slide staining.

- **SYMPLYONY system**

### Special stains platform

Delivers complete looking-through staining automation for special stains to enhance stain quality and turnaround time. Provides automated deparaffinisation and independent slide heating, helps reduce patient and technician risk and reduces exposure to harmful chemicals.

- **BenchMark Special Stains system**

### Advanced staining platforms

Immunochemistry (IHC) and in situ hybridisation (ISH) allow visualization of molecular targets on tissues, thus revealing the presence and properties of abnormal cells, DNA and RNA sequences.

- **BenchMark ULTRA instrument**
- **BenchMark GX instrument**
- **BenchMark XT instrument**
- **DISCOVERY ULTRA instrument**
- **DISCOVERY XT system**

### Digital pathology

Integrated digital pathology solutions including image acquisition, image management, advanced image analysis algorithms and comprehensive patient reporting. Full integration of digital pathology tools provides even greater efficiency, productivity and diagnostic intelligence.

- **iScan Corvo slide scanner**
- **VENTANA iScan HT slide scanner (RUO)**
- **Virtual image and workflow management software**
- **Companion algorithm image analysis software**
- **VENTANA Vector education & collaboration software**

### Key tests

Advanced staining assays, digital pathology and companion diagnostics

A selection of the broad portfolio of 250+ assays, digital pathology algorithms and companion diagnostic tests:

### Test on the market

<table>
<thead>
<tr>
<th>Test on the market</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY KIT</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>INFORM HER2 Dual UHR DNA Probe Cocktail</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>INFORM HER2 DNA Probe**</td>
<td>Breast/Estrogenic cancer</td>
</tr>
<tr>
<td>anti-ER (EPR6269) Rabbit Monoclonal Primary Antibody</td>
<td>Prostate cancer</td>
</tr>
<tr>
<td>anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody</td>
<td>Multiple cancers</td>
</tr>
<tr>
<td>VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody</td>
<td>Non-small cell lung cancer**</td>
</tr>
<tr>
<td>CINtec PLUS Cytology Kit</td>
<td>Cervical cancer</td>
</tr>
<tr>
<td>CONFIRM ANTI-PR (EII) 35 BM PAB</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>CONFIRM ANTI-ki-67 (3S-3) RABBIT MONOCLONAL PRIMARY ANTIBODY</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>CONFIRM ANTI-PS (D3-2) PRIMARY ANTIBODY</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>CONFIRM ANTI-ER (SP1) 44 BM PAB</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>VENTANA anti-HER2/neu (N8B) Rabbit Monoclonal Primary Antibody</td>
<td>Breast cancer</td>
</tr>
</tbody>
</table>

* Source: Industry analyst report, Roche analysis, company reports

** Ex-US only
Facts & Figures
Roche Diabetes Care

2013
Employees 5,500
Sales CHF 2,459 million (23.5% of divisional sales)
Growth: -3% (local currency)

Market position*
Blood glucose monitoring market
Roche 29.1%
Lifescan 26.5%
Animas 11%
Insulet 9%
Smith 0.5%
Bayer 14.6%
Others 15.2%
Abbott 14.6%

Insulin delivery system market
Roche 13%
Medtronic 67%
Roche 29.1%
Lifescan 26.5%
Bayer 14.6%

Sites
Basel (Switzerland (HQ)), Mannheim (Germany), Indianapolis (USA), Ponce (Puerto Rico)

Disease Areas
Metabolic diseases/diabetes

Customers
People with diabetes, hospitals, healthcare professionals, diabetes nurse educators, reimbursement authorities

Best-sellers 2013
Blood glucose monitoring CHF 2,235 million (-3%)
Insulin delivery systems CHF 224 million (+1%)

Key product launches 2013
Accu-Chek Combo (US) Interactive insulin delivery system combining bG monitoring and a durable insulin pump
Accu-Chek Active New and maltose-independent version of the Accu-Chek Active meter
Accu-Chek Aviva and Accu-Chek Performa Next generation of the proven and trusted Accu-Chek Aviva and Accu-Chek Performa blood glucose meters featuring no-code technology and a range of easy-to-use diabetes management functionalities as pre- and post-meal markers or reminders.

RDC portfolio
12 bG monitoring systems
5 lancing devices
3 insulin delivery systems
6 infusion sets for insulin delivery systems
6 information management solutions

Blood glucose monitoring
Blood glucose meters are designed for self-monitoring of blood glucose, helping people with diabetes to keep their blood glucose levels in (near-) normal range by adjusting their medication – especially their insulin doses – to suit their individual needs.

Meters:
- Accu-Chek Active
- Accu-Chek Aviva
- Accu-Chek Aviva Expert
- Accu-Chek Aviva Connect
- Accu-Chek Aviva Nano
- Accu-Chek Compact Plus
- Accu-Chek Mobile
- Accu-Chek Performa
- Accu-Chek Performa Connect
- Accu-Chek Performa Nano

Lancing systems:
- Accu-Chek FastClix
- Accu-Chek Multiclix
- Accu-Chek SoftClix
- Accu-Chek Safe-T-Pro
- Accu-Chek Safe-T-Pro Uno

Insulin delivery
Connected to the body via an infusion set, insulin pumps deliver the exact amount of insulin required to cover physiological needs. The newest portfolio additions combine the insulin pump with bG testing, a pump remote control and extensive data management features.

Insulin pump systems:
- Accu-Chek Combo
- Accu-Chek Insight
- Accu-Chek TenderLink Plus
- Accu-Chek Rapid Link Plus
- Accu-Chek Insight Flex
- Accu-Chek Insight Tender
- Accu-Chek Insight Rapid
- Accu-Chek LinkAssist Plus

Infusion sets:
- Accu-Chek FlexLink Plus
- Accu-Chek Insight Flex

Diabetes management systems
Facilitate the visualisation and assessment of individual blood glucose patterns by making the most of the data held within the blood glucose meter and insulin pump to support the user’s decision-making.

Platforms:
- Accu-Chek 360° software
- Accu-Chek Smart Pix
- Accu-Chek Connect

* Product list is non-exhaustive

* Source: Industry analyst report, Roche analysis, company reports
Roche Sequencing is developing an integrated portfolio, providing customers with a complete DNA sequencing solution by investing in potential breakthrough technologies and seeking the most innovative technologies.

This is evidenced by Roche’s recent partnership with Pacific Biosciences to develop an NGS platform utilizing their SMRT technology for the clinical sequencing, and the acquisition of Genia Technologies’s based on single molecule semiconductor-based, DNA sequencing platform using nanopore technology. Both will potentially provide us with the most advanced and differentiated next generation sequencing portfolio, for all customer segments. We continue to invest in additional opportunities in the sequencing market, as we are fully committed to expanding the applications of sequencing for a future in diagnostics.

We are continuing to innovate in the target enrichment space. Our SeqCap Target Enrichment System is a highly differentiated target enrichment product with a strong future, and we plan further product launches to expand this portfolio. This target enrichment technology currently includes reagents for targeting genomic DNA, epigenomics and has recently added RNA sequencing methods to the portfolio.

**Facts & Figures**

**Roche Sequencing**

### DNA testing market*: 10-year estimates

Next-generation sequencing (NGS) will be the fastest-growing segment

<table>
<thead>
<tr>
<th>Year</th>
<th>DNA Testing Market ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>2,000</td>
</tr>
<tr>
<td>2018</td>
<td>8,000</td>
</tr>
<tr>
<td>2023</td>
<td>12,000</td>
</tr>
</tbody>
</table>

**Sites**

- Pleasanton (CA, USA (HQ)), Mountain View (CA, USA), Madison (WI, USA), Branford (CT, USA)

**Customers**

- Basic research: Academia; Biomarker discovery: Pharma, CROs;
- Genomic studies: Genome centres; Translational: Hospital laboratories;
- Agriculture: Government, Biotech

**Applications**

- Genome Sequencing: De Novo, targeted (re-)sequencing, mutation detection, exome sequencing; Bisulfite treated DNA sequencing, RNA Sequencing;
- Translational: Oncology, human genetics, pre-natal, newborn; infectious disease

**Best-sellers 2013**

- GS FLX Titanium Kits, GS Junior Titanium Kits, SeqCap EZ Exome Library, SeqCap EZ Choice Library

**Key product launches 2013**

- GS Junior Long Reads version 3.0: Enables GS Junior users to sequence DNA (both amplicon and shotgun) libraries with read lengths of 700-800 bases and beyond
- NimbleGen SeqCap EZ Reagents: Expanded target enrichment kits and accessories for a complete workflow

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* Includes LDT estimates