# cobas e 411 analyzer

Roche

cobas®

*Life needs answers*

# cobas® brand

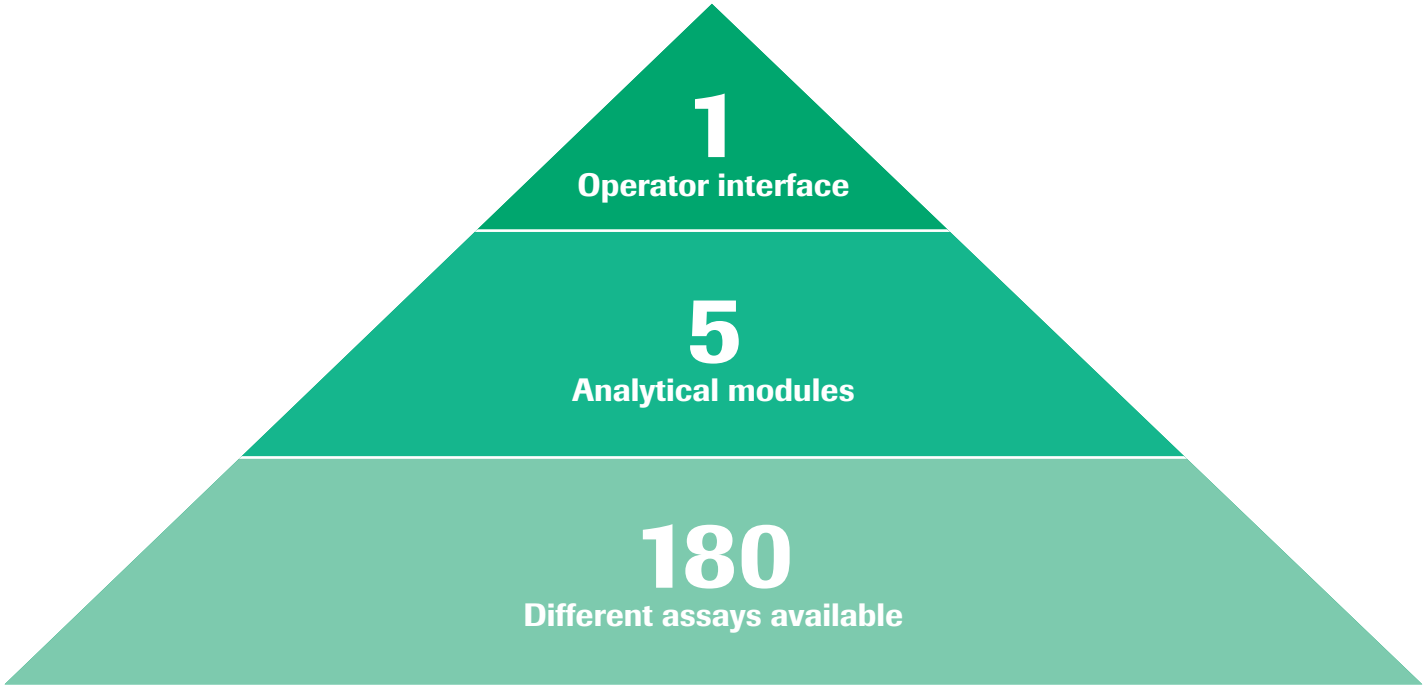
Roche Diagnostics introduces the **cobas** brand as the umbrella for products used to complete or expand the screening, diagnostic and monitoring applications of the professional laboratory.

**cobas** brand includes:

- serum work area with clinical chemistry and immunochemistry
- data management and preanalytical solutions
- products for coagulation analysis and urinalysis
- instruments for rapid blood and cardiovascular testing
- Polymerase Chain Reaction-based applications for virology and women's health testing

# cobas® modular platform

*Flexibility you can build on*




Today's laboratories are challenged with delivering high standards of laboratory services with fewer resources. They face constant pressure to lower operating costs while aspiring to grow their business in new areas. Their concern for patient care is paramount, and they demand only the best in diagnostic testing and services.

Just as every patient requires individualized care, every laboratory is unique. Striking the balance between high standards and efficient operation requires tailor-made solutions. With **cobas** modular platform, Roche has developed a platform concept that delivers individualized solutions based on a common architecture for various workloads and testing requirements.

**cobas**® 4000 is the second member of the new cobas modular platform. It offers small workload laboratories a complete solution for clinical chemistry and immunochemistry testing.

## Common universal reagent carriers

- Simplifies logistics
- Efficient use of reagents

## Common applications and analytical technologies

- Comparable patient results
- Combines routine and innovative testing

## Common operator interface

- Requires less training
- Promotes staff flexibility

The **cobas** modular platform is designed to reduce the complexity of laboratory operation and provides efficient and compatible solutions for network cooperation.


# The immunoassay analyzer cobas e 411

*2nd generation platform of ECL technology*

**cobas® 4000 analyzer series** **2nd generation**

Elecsys 1010®/2010® 1st generation


# **cobas e** 411 **analyzer**
# *Features*

*Bench top analyzer for heterogeneous immunoassays.*

**cobas e** 411 offers rapid STAT and turnaround time, an on-board capacity of 18 tests and throughput of up to 88 tests per hour. Sample carrier options include disc or Roche/Hitachi five-position rack.

For immunological analysis of serum or plasma.

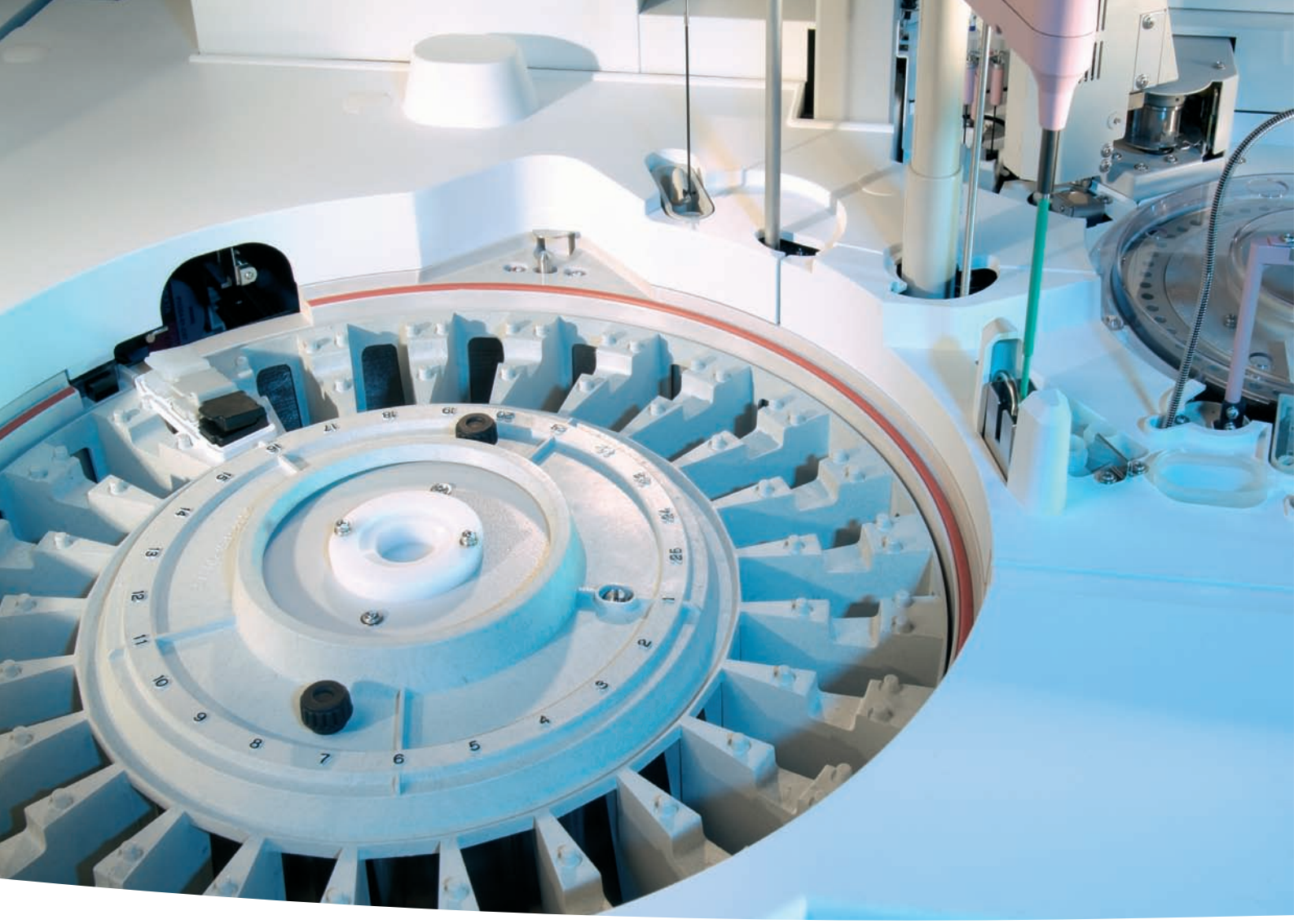
## Benefits

**Easy to operate**
The customized keyboard and easy-to-learn software make training and operation simple and keep user involvement to a minimum.

**Unique programming-by-loading concept**
Barcode-based data entry is carried out automatically by loading reagents, controls and calibrators onto the system – a rapid, robust and safe procedure.

**STAT facilities for urgent samples**
**cobas e** 411 disk system features two STAT sample positions that can be accessed at any time, delivering results rapidly in response to clinicians‘ requests . The **cobas e** 411 rack system features a STAT port for immediate access emergency testing.

**Innovative technology**
Novel Electrochemiluminescence (ECL) technology provides superior analytical performance. Increased sensitivity means that extremely low levels of antigen, as well as subtle changes in levels, can be detected. The very wide measuring range facilitates cost and time efficient testing by reducing the need to dilute and repeat samples.



# Reagents

*One grip handling of reagents*

### Three ways to unmatched performance

As the heart of the **cobas e** 411 analyzer, ECL technology delivers the unique combination of nine minute STAT applications, high analytical sensitivity and wide measuring ranges for unparalleled performance in immunochemistry.

**Wide measuring ranges**
reduces the amount of tests rerun due to out of range results

examples:
- Estradiol range of 5 – 4,300 pg/mL
- Progesterone range of 0 – 60 ng/mL
- total-PSA range of 0 – 100 ng/mL

**High analytical sensitivity**
enables the use of innovative tests and requires less sample volume examples:

- Troponin T 4$^{th}$ gen. with <10% CV at 95$^{th}$ population percentile
- hCG+, and TSH requires 10 and 50 µL sample volume, respectively

**Nine minutes STAT applications**
deliver unmatched turnaround time for emergency samples

hCG+ß, Troponin T 4$^{th}$ Gen., CK-MB, Myoglobin, PTH*

# Features
## *ECL technology*

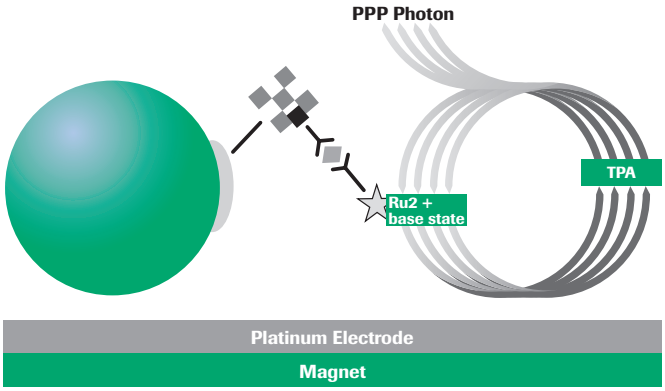
*ECL does what no other detection method can do:*

*ECL keeps the light on longer for accurate results the first time.*

*The population of China according to the World Factbook[1] is 1.306.313.812 people[1]. Imagine that you need to find one person immersed within the entire population of China.*

**How hard do you think it would be?**
**Now do it in 18 minutes.**
That's the magnitude of ECL's job: detection of one part in 1.3 billion[2], in 18 minutes or less.

## Reaction Phase – Measuring Cell




**"Electro" refers to electrical stimulation.**
**+**
**"Chem" indicates a chemical reaction.**
**+**
**"Luminescence"means "produces light."**
**=**
**Electrochemiluminescence (ECL)**

### Exclusive technology

Electrochemiluminescence (ECL) technology, found exclusively on the Roche ELECSYS® 2010 and MODULAR® ANALYTICS E-170 systems, cobas 6000 analyzer series and the **cobas e** 411 analyzer is so sensitive it can parallel the sensitivity of PCR3. This is the equivalent of reliably finding one red M&M® in an Olympic-sized pool of blue ones – in just 18 minutes.

ECL is a unique and highly sensitive luminescence (light) detection system that amplifies the signal you want and reduces any signals you don't want to deliver unmatched low-end sensitivity and broad dynamic measuring ranges.

### Virtually eliminates repeats and reruns

The measuring cell uses an amplified signal to detect ultra-low concentrations of analyte. By precisely controlling electrically-initiated reactions, ECL technology virtually eliminates unnecessary repeats and reruns, providing accurate results the first time.

References
1. The World FactBook: http"//www.cia.gov/cia/publications/factbook/geos/ch.html
2. Calculation on file at Roche Diagnostics
3. Roche Diagnostics Elecsys HBsAg Package Insert.

# **cobas e** 411 **analyzer**
*Specifications*

| | |
|---|---|
| **System** | Fully automated, random access system for immunoassay analysis.<br>It is available as both, a disk system and a rack system. |
| **System components** | Analytical module including Window XP embedded operated touch screen PC<br>Sample handling module: rack or disk operated |
| **Sample throughput** | Up to 88 samples/hr (theoretical max) |
| **Test throughput** | Up to 88 tests/hr (theoretical max) |
| **Number of channels** | 18 channels/reagent slots for up to 18 different assays |
| **Programmable parameters** | Max 60 assays definable via 2D-barcode (programming by loading) |
| **Sample types** | Serum, Plasma, Urine |
| **Sample input/output** | Load/unload capacity: 30 samples (disk); 75 samples on 15 racks<br>Rack: RD standard 5 position rack<br>Rack types: Routine, STAT, Control, Calibrator<br>STAT handling: Any unoccupied position on the sample disk, dedicated STAT port on rack feeder |
| **Sample container types** | Primary tubes: 5–10 ml; 16x100, 16x75, 13x100, 13x75mm<br>Sample cup: 2,5 ml<br>Micro cup: not allowed<br>Cups on tube: Cup on top of a 16x75/100 mm tube |
| **Sample volume** | 10 to 50 µl per test, depending on assay protocol |
| **Minimum sample volume** | Primary tubes : 600 µl (13mm tube), 1,000 µl (16mm tube)<br>Sample cup: 200 µl (standard Cup on Tube), 150 µl with special setting |
| **Sample barcode types** | Code 128<br>Codabar (NW 7)<br>Interleaved 2 of 5<br>Code 39 |
| **On board control unit** | PC with Pentium III processor with coloured 15” SVGA touch screen monitor |
| **System interfaces** | RS 232 serial interface, bi-directional<br>Standard PC ports (USB, Ethernet, Serial etc) for other communication devices |

# **cobas e** 411 **analyzer**
*Specifications*

| | |
|---|---|
| **Sample data base** | 2.000 tests for routine, STAT and control results |
| **Test methods** | Pre-defined assay protocols (sandwich, competitive, titration) |
| **Calibrator/QC Input** | Via rack or sample disk |
| **Calibration methods** | “Upon QC failure” triggered<br>2-point calibration per lot or per cobas e-pack |
| **QC methods** | Individual QC + cumulative QC<br>Preventive QC after calibration |
| **Electrical requirements** | Power requirements: 100 –120 VAC 50/60 Hz single phase or<br>200 – 240 VAC 50/60 Hz single phase<br>Power consumption 800 VA |
| **Water/waste requirements** | Water container 3 Liters<br>Water requirements 10 µS/cm or 0.1 mega Ohm, bacteria-free<br>Water consumption approx. 3 L for 250 tests<br>approx. 12 mL/cycle |
| **Regulatory requirements** | GS, CE, UL, C-UL, CB-report and certificate |
| **Operating conditions** | Ambient temperature: 18 to 32 °C (64.4 °F to 89.6 °F)<br>Ambient humidity: 20% to 80%<br>Noise Output: 60 dbA (stand-by mode)<br>63 dbA (avg. during operation) |
| **Physical dimensions** | Width: 1200 to 1700 mm (disk/rack)<br>Depth: 730 to 950 mm (disk/rack)<br>Height: 560 mm (w/o PC unit) |
| **Weight** | Approx. 170 kg (disk) and 210 kg (rack) |

# **cobas e** 411 **analyzer**

## *Assay menu*

| Thyroid Function |
|---|
| Anti-Tg |
| Anti-TPO |
| Anti TSH-receptor |
| $FT_3$ |
| $FT_4$ |
| $T_3$ |
| $T_4$ |
| T-Uptake |
| Tg |
| TSH |

| Cardiac |
|---|
| CK-MB (mass) |
| CK-MB (mass) STAT |
| Digoxin |
| Digitoxin |
| Myoglobin |
| Myoglobin STAT |
| NT-proBNP |
| Troponin T |
| Troponin T STAT |
| Troponin I* |
| Troponin T HS* |

| Fertility / Hormones |
|---|
| ACTH |
| C-peptide |
| Cortisol |
| DHEA-S |
| Estradiol |
| free β-HCG |
| FSH |
| HCG+β |
| HCG STAT |
| Insulin |
| LH |
| PAPP-A |
| Progesterone |
| Prolactin |
| SHBG |
| Testosterone |

| Maternal Care |
|---|
| AFP |
| free β HCG |
| hCG+ β |
| PAPP-A |
| PLGF |
| sFLt |

| Anemia |
|---|
| Ferritin |
| Vitamin $B_{12}$ |
| Folate |
| RBC Folate |

| Tumor Markers |
|---|
| AFP |
| CA 125 II |
| CA 15-3 |
| CA 19-9 |
| CA 72-4 |
| CEA |
| CYFRA 21-1 |
| free PSA |
| NSE |
| S-100 |
| total PSA |

| Critical Care |
|---|
| IL6 |
| PCT |
| S- 100 |

*Assay is under development

STAT assays are currently available on **cobas e** 411

| Infectious Disease |
| --- |
| Anti-HAV |
| Anti-HAV IgM |
| Anti-HBc |
| Anti-HBc IgM |
| Anti-Hbe |
| Anti-HBs |
| Anti-HCV |
| HBsAg confirmatory |
| CMV IgG |
| CMV IgM |
| HBeAg |
| HBsAg |
| HIV Antigen |
| HIV Antigen confirmatory |
| HIV combi |
| Rubella IgG |
| Rubella IgM |
| Toxo IgG |
| Toxo IgM |

| Bone Markers |
| --- |
| β-CrossLaps |
| 25-$(OH)_2$ Vitamin $D_3$ |
| Intact PTH |
| N-MID Osteocalcin |
| PTH STAT |
| Total-$P_1$NP |

| Others |
| --- |
| IgE |
| S-100 (brain damage) |
| anti-CCP |

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