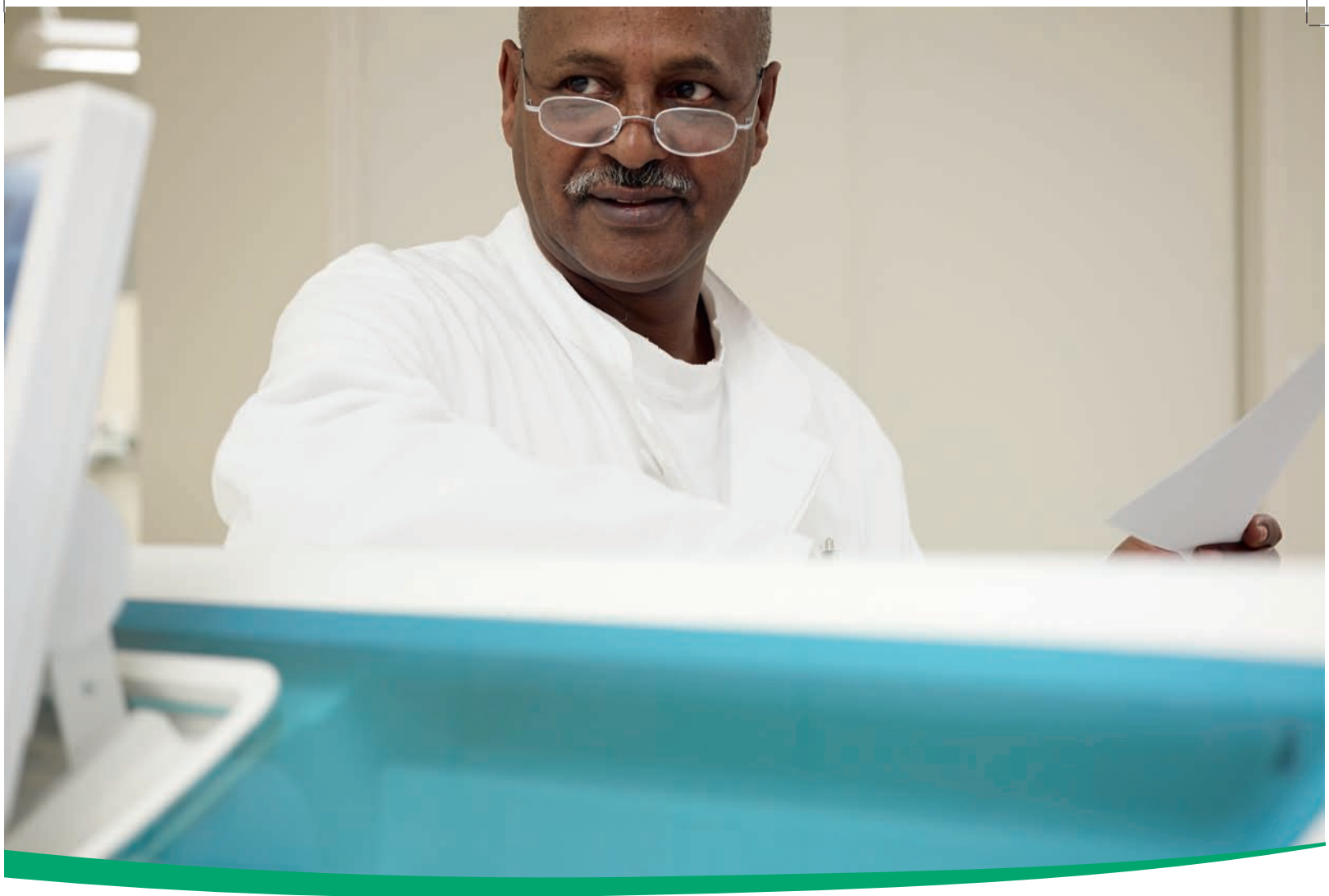




cobas[®] 4000 analyzer series
cobas e 411 analyzer



cobas[®]
Life needs answers



cobas[®] brand

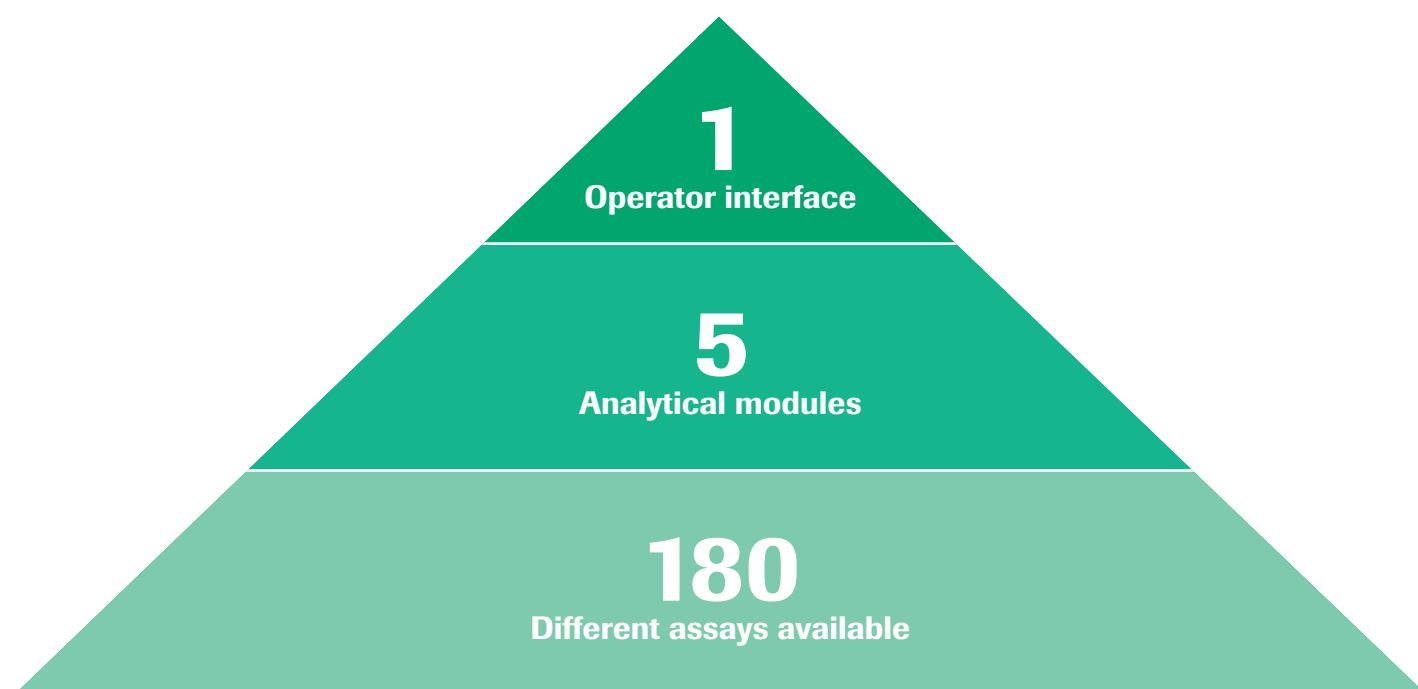
Roche Diagnostics introduces the **cobas[®]** brand as the umbrella for products used to complete or expand the screening, diagnostic and monitoring applications of the professional laboratory.

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 86 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 hs with $\leq 10\%$ CV at 99th population percentile
- HCG+B and TSH requires 10 and 50 μL sample volume, respectively

Nine minutes STAT applications

deliver unmatched turnaround time for emergency samples

hCG+ β , Troponin T hs, 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.

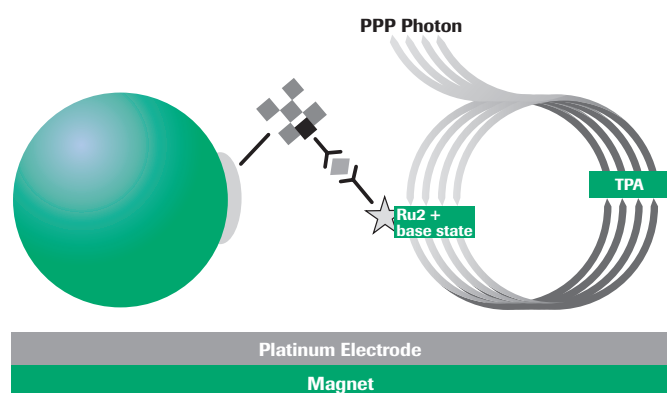
The population of China according to the World Factbook¹ is 1.306.313.812 people¹. Imagine that you need to find one person immersed within the entire population of China.

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 billion², 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. It is available as both, a disk system and a rack system.	
System components	Analytical module including Window XP embedded operated touch screen PC Sample handling module: rack or disk operated	
Test throughput	Up to 86 tests/hr	
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
	Rack	RD standard 5 position rack
	Rack types	Routine, STAT, Control, Calibrator
	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
	Sample cup	2,5 ml
	Micro cup	not allowed
	Cups on tube	Cup on top of a 16 x 75/100 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)
	Sample cup:	200 µl (standard Cup on Tube) 150 µl with special setting
Sample barcode types	Code 128 Codabar (NW 7) Interleaved 2 of 5 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 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 2-point calibration per lot or per cobas e-pack
QC methods	Individual QC + cumulative QC Preventive QC after calibration
Electrical requirements	Power requirements: 100 – 120 VAC 50/60 Hz single phase or 200 – 240 VAC 50/60 Hz single phase Power consumption 800 VA
Water/waste requirements	Water container 3 Liters Water requirements 10 µS/cm or 0.1 mega Ohm, bacteria-free Water consumption approx. 3 L for 250 tests 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) Ambient humidity: 20% to 80% Noise Output: 60 dbA (stand-by mode) 63 dbA (avg. during operation)
Physical dimensions	Width: 1200 to 1700 mm (disk/rack) Depth: 730 to 950 mm (disk/rack) 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

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

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

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

Anemia
Ferritin
Vitamin B ₁₂
Folate
RBC Folate

Critical Care
IL6
PCT
S- 100

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

*Assay is under development

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

cobas e 411 analyzer

Notes

[illegible]

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