



cobas[®] 6000 analyzer series
The success story continues



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Life needs answers



cobas[®] 6000 analyzer series

The success story continues

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 tailored 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.

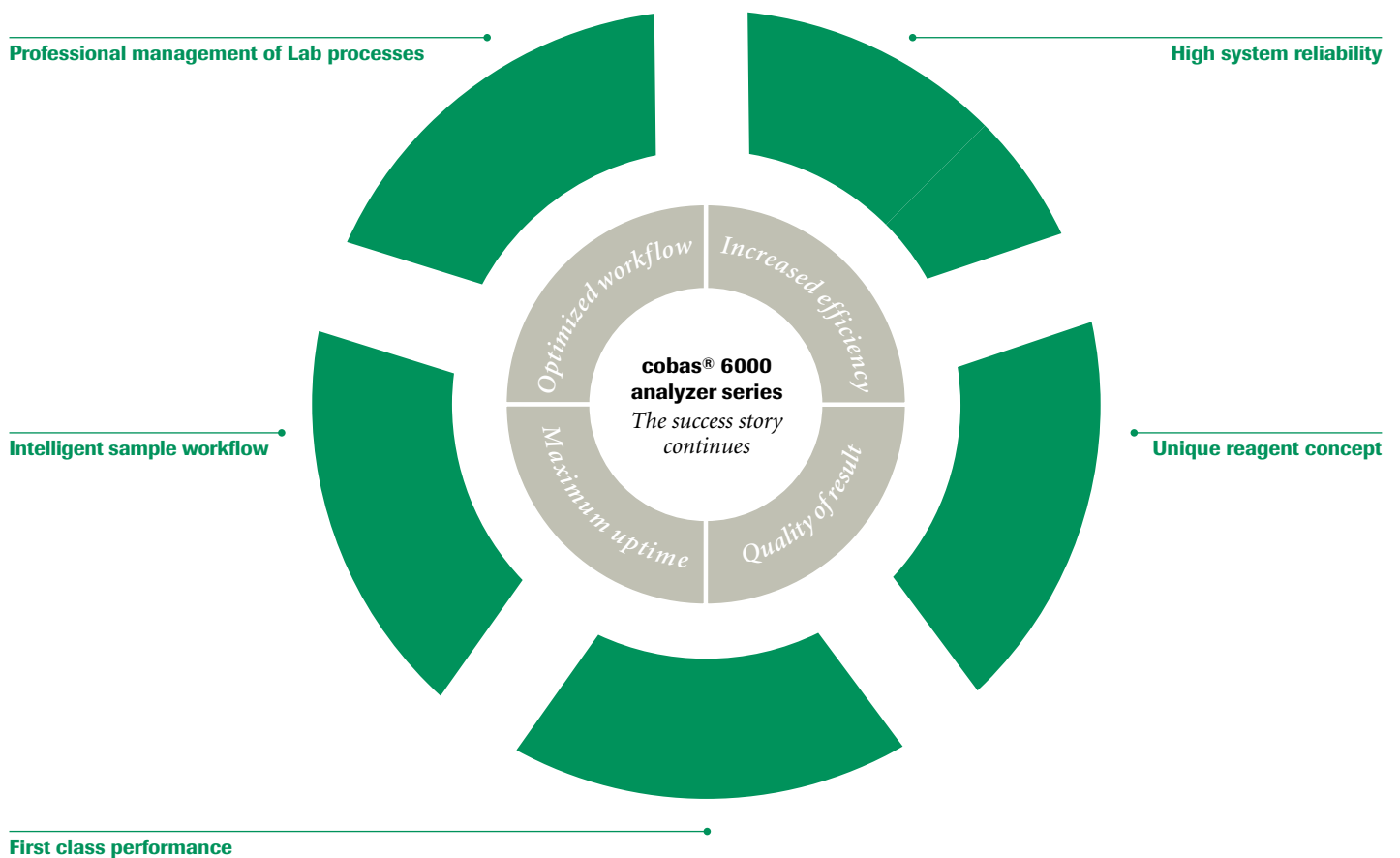
The **cobas** 6000 analyzer series is a member of the **cobas** modular platform. It offers medium workload laboratories tailored solutions for clinical chemistry and immunochemistry testing.

The more than 8,000 active systems only six years after launch are the best testimonial for the successful concept that perfectly fits customer needs.

cobas[®] 6000 analyzer series

Built to meet your needs

There are 5 good reasons why the cobas 6000 analyzer series offers new dimensions in increased efficiency, quality of result, maximum uptime and optimized workflow:



“Our experience has shown the Roche analyzers to be very robust and require low maintenance”

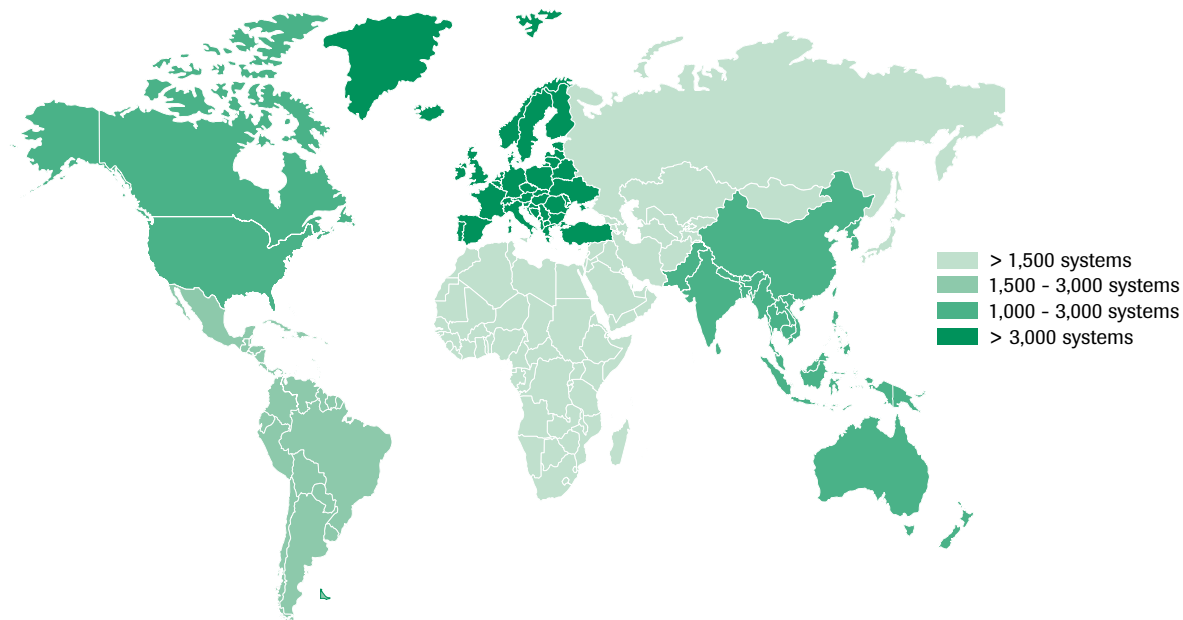
Dr Jos Pouwels, The Netherlands

High system reliability *Maximum system uptime*

High performing labs operate 24/7 and expect high reliability from their systems. The **cobas** 6000 analyzer series delivers by providing a maximum system uptime.

- Partnership with Hitachi: 35 years as a total solution provider
- More than 8,000 systems with over 6,500 **cobas c** 501 and 6,600 **cobas e** 601 modules installed worldwide
- Proactive automated maintenance for reliable operation
- Over 96% uptime including maintenance on a 24/7 base*

* Source: *Internal Roche service reports*



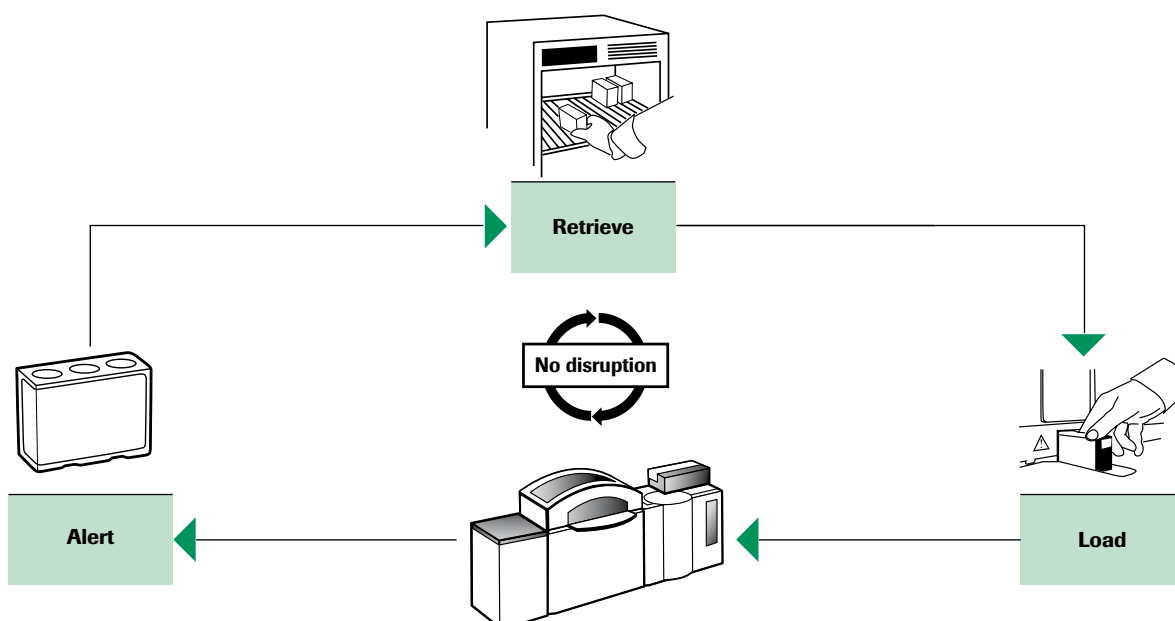
*“The lab has already seen a 20% savings in reagent costs in the first 4 months of operation...
The size of cobas reagent packs is very small so we don’t need as much storage space as we did previously”*

Mary Sorensen MT (ASCP) MBA, USA

Unique reagent concept *Convenient handling, cost-effective operation*

From routine assays to innovative biomarkers, high performing labs need easy-to-use and cost-effective reagents. The **cobas** 6000 analyzer series delivers by offering liquid ready-to-use reagents based on a unique reagent concept.

- No preparation and no mixing required
- Reloading of chemistry reagents during operation
- Same reagents for all **cobas** serum work area systems
- Economic usage with high stabilities and convenient kit sizes



“We looked at the competition but we felt that Roche has the best system. We performed studies for precision and accuracy on Roche tests. We also discussed with colleagues in other labs and found the quality to be very high”

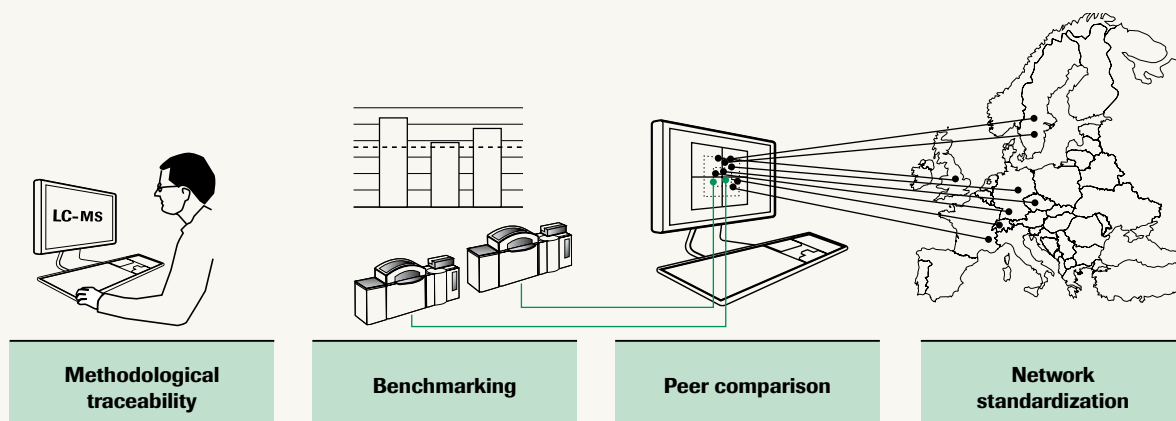
Dr Pier Mario Gerthoux, Italy

First class performance *Right the first time*

High performing labs stake their reputation on quality. The trust of their clinicians is paramount. The **cobas** 6000 analyzer series delivers high quality results based on experience, innovation and advanced technologies.

- State-of-the-art immunoassay testing using ECL technology

- Reference-traceable results with minimal lot-to-lot variance
- High quality results by ensuring sample and result integrity (e.g. test-specific serum indices, disposable immunoassay tips and cups, and clot detection)
- Innovative tests on a standardized, automated platform
- Results standardized to other **cobas** serum work area systems



“With the cobas 6000, routine and STAT tests have been combined in a single analyzer. We can offer a broader menu and reduce the number of instruments”

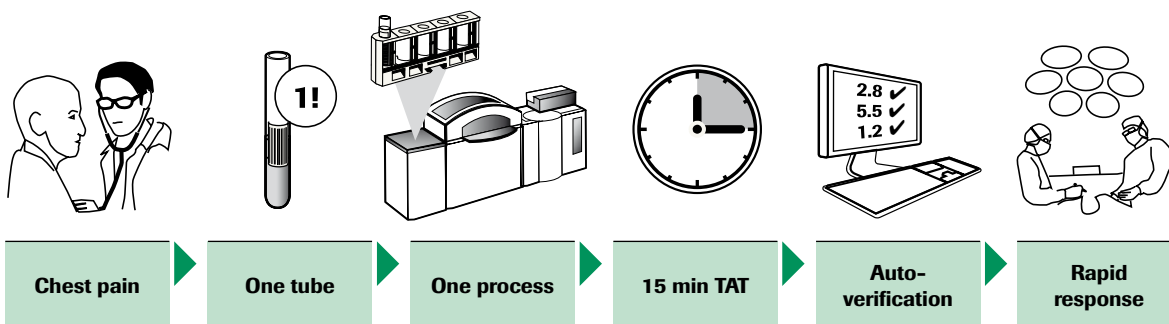
Dr Pier Mario Gerthoux, Italy

Intelligent sample workflow

Efficient testing of clinical and immunochemistry from a single tube

High performing labs need an efficient mix of broad test menu and fast result turnaround time - even as workloads grow. The **cobas** 6000 analyzer series delivers by optimizing workflows through flexible consolidation and automation.

- Consolidates more than 200 tests on one system
- Combines STAT with routine testing without disruption
- Sample Rotor Buffer for optimal sample routing and fast TAT
- Can expand existing system configurations onsite



“Increased laboratory automation and simplified workflow is helping the hospital move towards its goal of becoming the largest specialist center in the region”

Dr Jos Pouwels and Dierk Wermeulen

Professional management of lab processes *The next level of efficiency*

Professional management of laboratory processes in terms of workflow optimization is recognized as a major contributor for further improvement of laboratory cost and quality position in the market. Roche provides innovative pre- and postanalytical systems to support workflow optimization, which results in a beneficial improvement of testing efficiency, service to clinicians and provided patient care.

- Wide range of complete pre and postanalytical solutions from small Task Target Automated to Total Lab Automation

cobas p 312 system is the ideal companion for the cobas[®] 6000 analyzer series

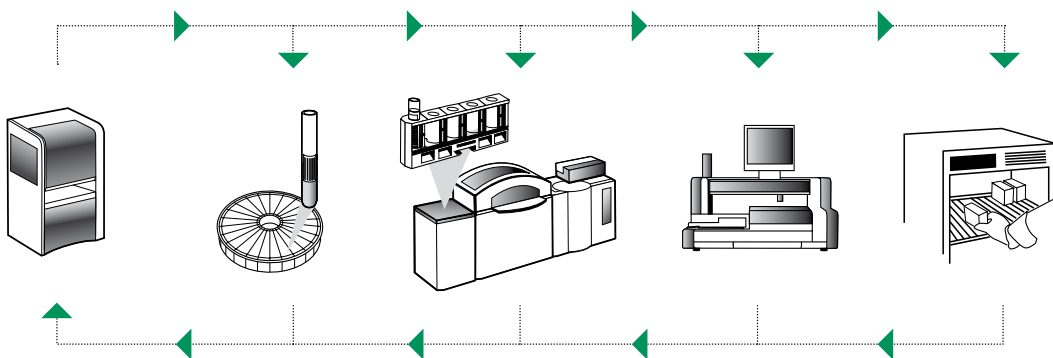
Organizing your laboratory using a single square meter footprint

The **cobas p 312** is Roche's answer to fulfill automation needs of many small to mid sized laboratories. It includes the necessary functionality to significantly improve laboratory's organization and increase workflow efficiency. This on a single square meter.

The simplicity of this solution and the small space requirements allow its easy implementation in almost any laboratory.

This automation solution with the **cobas p 312** will take over following key tasks:

- Sample registration at a single entry point
- Sorting and distribution of samples
- Recursive workflow
- Archiving



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True workload consolidation



1 Core unit

- Loading capacity of 150 samples in two trays of 75
- Load 5-position racks via dedicated STAT port with rerun buffer or by tray
- Simple operation with continuous loading and unloading

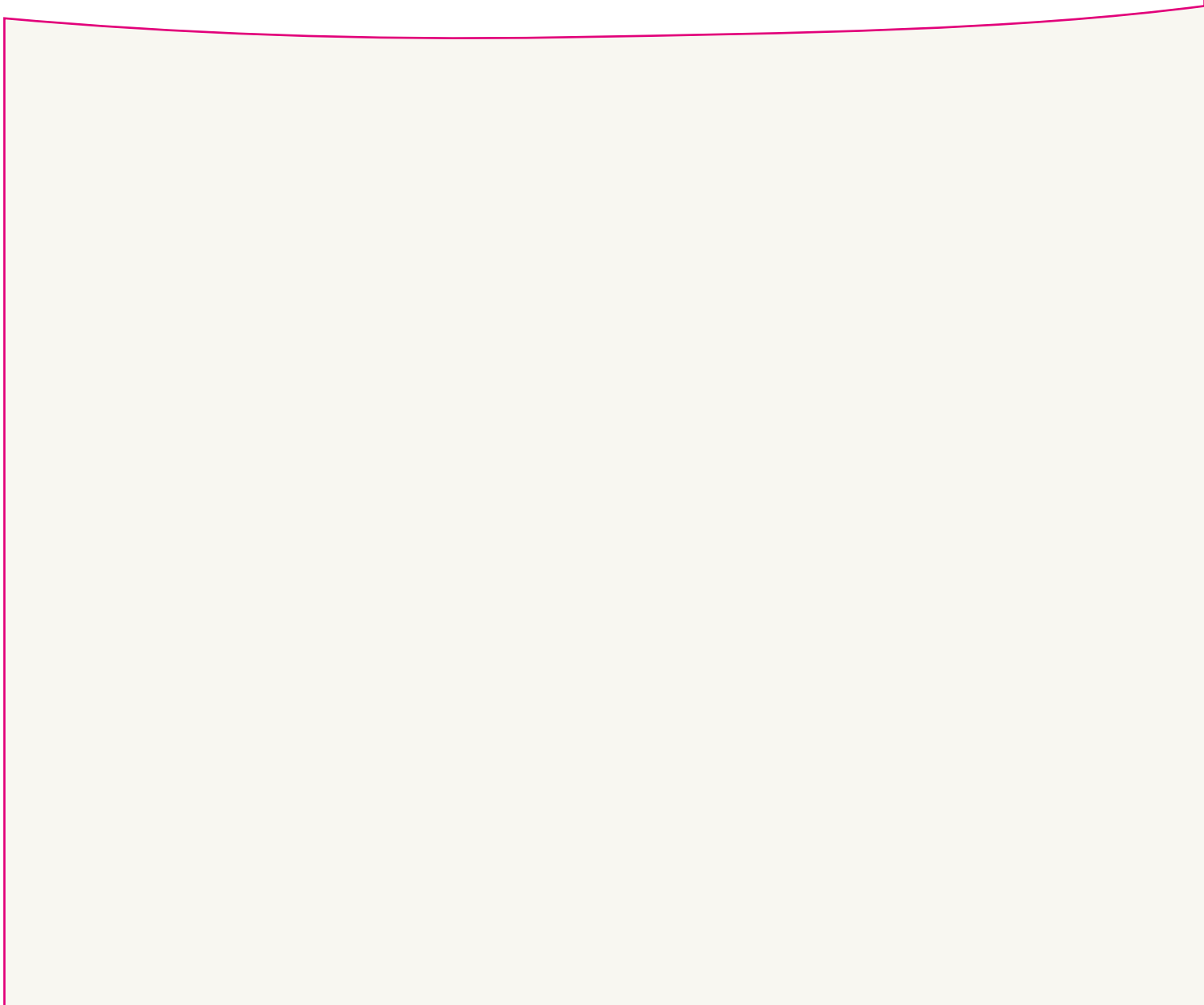
2 cobas c 501 module

- Clinical chemistry, ISE (K, Na, Cl), over 100 homogeneous immunoassays, HbA1c (whole blood measurement)
- Throughput of up to 1,000 tests/hour
- 60 direct-access assays
- Automatic reagent loading during operation
- Specimen integrity via serum indices, clot and liquid level detection
- Contact-free ultrasonic mixing

3 cobas e 601 module

- Heterogeneous immunoassays, including cardiac markers and over 80 assays for anemia, bone and tumor markers, hormones, and infectious diseases
- Throughput of up to 170 tests/hour
- 25 direct-access assays
- Carry-over free disposable tips
- Clot and liquid level detection
- 9 minute STAT applications for NT-proBNP, Troponin T high sensitive (5th gen.), Troponin I, CK-MB, Myoglobin, hCG, and PTH





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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

cobas[®] 6000 analyzer series

Technical specifications

System	2nd Generation SWA: modular, analytical system platform, consolidated work area for Clinical Chemistry and Immunology, expandable and re-configurable on site	
System components	Control Unit:	PC, monitor, keyboard, printer, etc. on an ergonomic stand
	Core Unit:	Sample input/output, sample transport by Intelligent Process Management
	Analytical modules:	2 analytical modules
Type of modules	cobas c 501 module:	Photometric measuring unit (incl. ISE)
	cobas e 601 module:	ECL technology measuring unit
Number of module combinations	7 module combinations Up to 3 modules in one core unit cobas c 501 modules: 1 to 2 modules cobas e 601 modules: 1 to 2 modules cobas c 501 e 601 modules: 2 to 3 modules (only 2 units of one module type for SWA combinations possible)	
Sample throughput	Up to 120 racks/hr or 600 samples/hr	
Test throughput (theoretical max)	170 up to 2,170 tests/hr	- overall
	1,000 up to 2,000 tests/hr	- with cobas c 501 modules
	170 up to 340 tests/hr	- with cobas e 601 modules
	1,170 up to 2,170 tests/hr	- with cobas c 501 and cobas e 601 modules
Number of channels (reagent slots)	Up to 151 channels, in total 63 channels (including ISE, automatic setting) on cobas c 501 module 25 channels on cobas e 601 module	
Programmable parameters	191 parameters with photometric and HetIA modules 117 photometric tests, 3 ISE tests, 8 formulas, 3 serum indices with photometric modules 60 heterogeneous tests with cobas e 601 modules	
Sample material	Serum, Plasma, Urine, CSF	
Core unit analytics	Rack:	5 position rack, RD standard rack
	Rack types:	Routine, STAT, Control, Calibrator, Rerun (manual), Wash
	Tray:	Tray with 15 racks/75 samples, RD standard tray
	STAT port:	STAT samples are processed with priority
Sample container types	Primary tubes:	5 to 10 mL; 16 x 100, 16 x 75, 13 x 100, 13 x 75 mm
	Sample cup:	2.5 mL
	Micro cup:	1.5 mL, (exception: cobas e 601 module)
	Cups on tube:	Cup on top of a 16 x 75/100 mm tube; Cup on top of one non standard tube
	False bottom tube (FBT):	one type is definable
Sample volume	1 - 35 µL	
Sample dilution	3 - 121 times, diluent > 100 µL	
Sample clot detection	Available for cobas c 501 and cobas e 601 module	
Minimum sample volume	Primary tubes:	700 µL
	Sample cup:	100 µL
	Micro cup (FBT):	50 µL
Sample barcode types	Code 128; Codabar (NW 7); Interleaved 2 of 5; Code 39	



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Common specifications

Control unit	PC: Windows XP, Pentium IV processor, DVD-RAM Monitor: 17" TFT touch screen colour monitor Keyboard 101 – key enhanced, country-specific Printer: optional PC stand: optional, ergonomic (UL, CE, GS, TÜV) cobas[®] link data station
System interfaces	RS 232 serial interface, bi-directional Interface to cobas link data station for cobas teleservice functionalities and automatic download
Sample data base	10.000 routine/STAT samples
Test methods	For photometric modules: 1 point, 1 point + prozone check, 2 point, 2 point kinetic, 2 point + prozone check, 3 point, 1 point + kinetics Rate A, Rate A + serum index, Rate A with blank, Rate B
Calibrator/QC input	Via specified racks through the input buffer or STAT port
Calibration methods	Start-up, Re-calibration For photometric modules: Linear, non-linear multi-points, 2 point calibration, K-factor up to 100 different calibrators pre programmable Storage of up to 180 curves Preventive calibration of the stand-by cobas c and cobas e packs on cobas c 501: Two k-factor can be defined for different sample types
QC methods	For e- and photometric modules: Real-time QC, individual QC, cumulative QC Up to 100 controls pre programmable Preventive QC after calibration of the stand-by cassettes/rack packs Auto QC: QC without operator intervention (timer triggered)
Rerun/reflex function	Automatic rerun and manual rerun Automatic reflex is supported by the system, reflex request to be provided by PSM or LIS
Electrical requirements	Power requirements: 230 Volts AC; 110 Volts AC 2.4 kVA (for cobas c 501 e 601) Frequency: 50 Hz or 60 Hz +/- 0.5 %
Water/waste requirements	Water: Bacteria free, deionised water supply: resistance of < 1,0 µS/cm Water consumption: Under routine conditions in average 15 L/hr, max. 30 L/hr (per module) Water pressure: 0.5 – 3.5 kg/cm ² , (49 – 343 Kpa) Biohazards waste: Separate container behind the system L. concentrated Central drain port, diameter: ≥ 50 mm / 2 inches Wall drain < waste: 100 mm above the floor / 4 inches
Regulatory requirements	GS, CE, UL, C-UL
Operating conditions	Ambient temperature: 15 to 32 °C / 59 to 90 °F Ambient humidity: 45 to 85 % (RH, without condensation) Heat Output: 1.5 kW (5400 kJ/hr for cobas c 501, 4320 kJ/hr for cobas e 601) Noise Output: < 68 dB
Physical dimensions	Width: 188 to 498 cm / 74 to 196 inches Core Unit: 69 cm / 27.2 inches cobas c or cobas e module: 120 cm / 47.2 inches Depth: cobas c or cobas e module: 98 cm / 38.6 inches Core unit: 104 cm / 41 inches Height: 130 cm / 51 inches Control unit: Width: 80 cm / 31.5 inches, depth: 80 cm / 31.5 inches
Weight	510 to 1230 kg / 1124 to 2711 lb cobas c 501 module: 330 kg / 730 lb cobas e 601 module: 360 kg / 795 lb Core unit (sample loader, control unit, rack rotor): 180 kg / 400 lb

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

cobas[®] 6000 analyzer series: STAT consolidation

A multi-center evaluation of the 9 minute STAT applications

Introduction

Results for critical tests often require a dedicated workstation to achieve fast turnaround time (TAT). While this approach reduces TAT for STAT samples, it requires more staff and increases costs. In response Roche has developed 9 minute STAT applications that can be performed in conjunction with routine testing on the cobas 6000 analyzer series. These applications include the most time-critical immunoassays:

- Troponin T high sensitive (Gen. 5)
- Myoglobin
- NT-proBNP
- Intra-operative PTH
- Troponin I
- CK-MB
- hCG

A multi-centre evaluation study was conducted to assess the impact on turnaround time and workflow of introducing the 9 minute applications on systems with existing routine workloads. Prepared by a Roche site investigator, with active participation of clients, findings are presented from Henri Mondor Hospital (France, referred to as “Henri Mondor”), Massachusetts General Hospital (USA, “MGH”), and University of Regensburg Clinic (Germany, “Regensburg”).

Flexible consolidation

The clients conducted workflow assessments typical of their workload in off-peak, peak and night shift scenarios. They evaluated the TAT of STAT samples and monitored the impact on TAT for the routine workload.

STAT consolidation

Off-peak workload: MGH conducted a run typical of an afternoon shift: 124 samples were processed in four hours with a total of 1,174 requests, of which 46 were STAT. Test mix was 64% clinical chemistry (CC) only, 19% mixed and 16% immunochemistry (IC) only.

Results: TAT of STAT samples were achieved in less than 12 minutes (11 minutes average), with no adverse effect on rou-

tine TAT of 16 minutes (12 minutes average). The observed time to result was 5 to 7 minutes faster (Fig. 1).

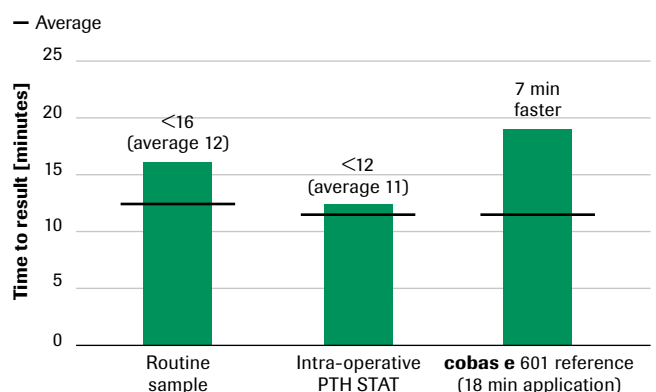


Fig. 1: Night shift scenario, MGH



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Peak workload: Regensburg conducted a run typical of its peak workload: 207 samples were processed in four hours with a total of 1,699 requests, of which 15 were STAT. Test mix was 72% CC only, 25% mixed and 3% IC only.

Results: TAT of STAT samples was achieved in less than 17 minutes (15 minutes average), with no adverse impact on routine TAT. The observed TAT was 7 minutes faster than the reference run with 18 minutes applications (Fig. 2).

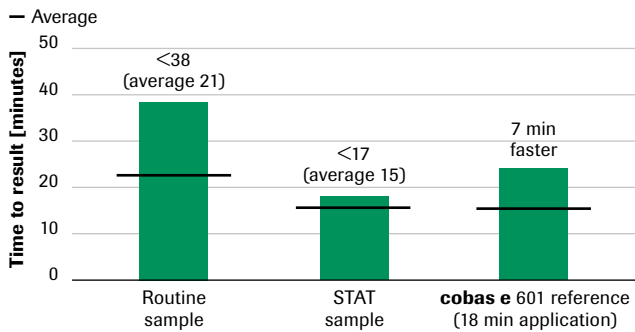


Fig. 2: Peak workload scenario, Regensburg

Night shift workload: Henri Mondor conducted a run typical of its night shift: 40 samples were processed per hour with a total of 432 requests. Of these samples, 10 were STAT with each sample having 12 requests ("Chest Pain" Panel: Basic Metabolic Panel¹ + CK + LDH + troponin T + myoglobin. Test mix was 60% CC only, 30% mixed and 10% IC only.

Results: TAT of STAT Chest Pain Panel samples was achieved in less than 19 minutes (16 minutes average) with no adverse effect on routine TAT of 19 minutes (15 minutes average). The observed TAT was 6 minutes faster than the reference run with 18 minute applications (Fig. 3).

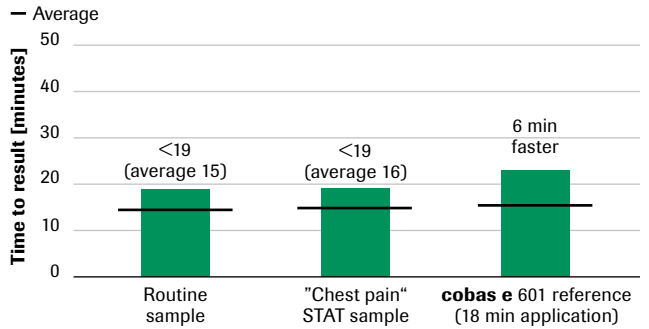


Fig. 3: Night shift scenario, Henri Mondor

With the **cobas 6000** analyzer series, each client was able to eliminate a dedicated STAT analyzer by consolidating STAT and routine onto a single platform. And by using the 9 minute STAT applications, they were able to improve the TAT of their STAT samples without impacting the routine, even during peak hours.

Superior analytical performance

The **cobas 6000** analyzer series also demonstrated high analytical performance in terms of comparability, time to result, and precision.

High comparability

Method comparisons demonstrated good comparability between the 18 minute and 9 minute applications, as well as between the **cobas e 411** 9 minute applications and the **cobas 6000** 9 minute applications. Total precision was comparable between the 18 minute and 9 minute applications. In fact, assay precision exceeded expectations and performed consistently better than required according to Roche product specification documents (Fig. 4). Limit of quantification was consistently better than the predefined performance limit.

“Lab-specific workflow analysis simulating Regensburg University’s central laboratory morning shift of typical routine and STAT parameters on cobas® 6000 revealed a significant reduction of mean sample times...”

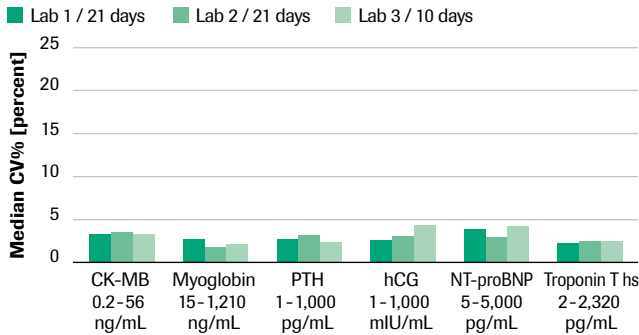


Fig. 4: Total precision according to CLSI for 9 min STAT applications on the cobas e 601 module

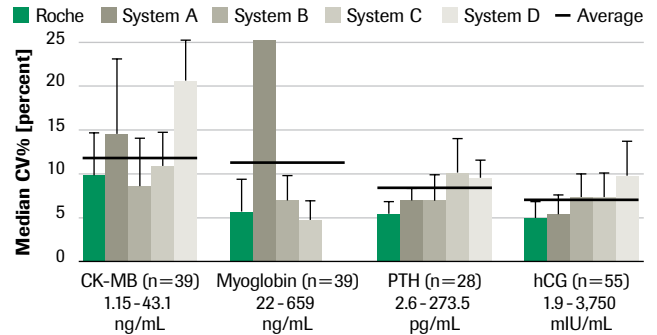


Fig. 6: Median CV% calculated using consolidated data from an external quality survey (2008 until January 2009)

Fast time to result

In comparison with representative assays in the market - the 9 minute STAT applications have the fastest time to result.

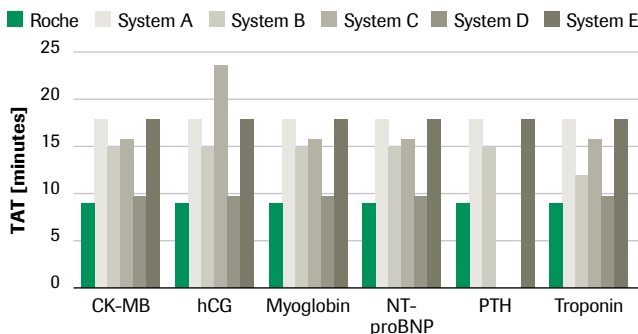


Fig. 5: Analytical time to result comparison of available STAT tests

Low imprecision

In comparison with representative assays in the market - the 9 minute STAT applications also had the lowest average imprecision in terms of inter-laboratory Coefficient of Variation (CV%) (Fig. 6).

Troponin T: 10% CV at the 99th percentile

The Troponin T high sensitive (Gen. 5) assay meets the precision recommendations established in recent guidelines² by achieving less than 10% CV at the 99th percentile upper reference limit of 14 pg/mL. This assay was designed to support cardiologists and emergency physicians with a higher sensitivity for myocardial necrosis (Fig. 7). In addition, the 9 minute application delivers cardiac results that help to meet the NACB recommendations³ for turnaround time.

	C Tn T	C Tn I
Aid in the differential diagnosis of acute coronary syndrome (ACS) to identify acute myocardial infarction (AMI)	•	•
Risk stratification of patients presenting with ACS	•	•*
Cardiac risk stratification in patients with chronic renal failure (CRF)	•	
Helpful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac Tn	•	

Fig. 7: Intended use of cardiac Troponin T and Troponin I assays according to Roche package inserts

“TnT-hs assays... are well adapted for clinical use where in some instances of pathological issues (renal insufficiency) clinical biochemistry has to be very precise to give the best reliable patient follow-up.”

“I recommend release of these STAT assays to the market, unconditionally. I would use the evaluated [cobas[®] 6000] unit to replace my lab’s current STAT instrumentation without hesitation.”

Dr. James Flood, MGH

Seamless implementation

Roche is committed to ensuring the seamless implementation of the **cobas 6000** analyzer. To this end the **cobas 6000** simulation tool has been developed to assist Roche representatives in designing the optimum system configuration for each laboratory. It assesses the suitability of the 9 minute STAT applications for different workloads (Fig. 8).

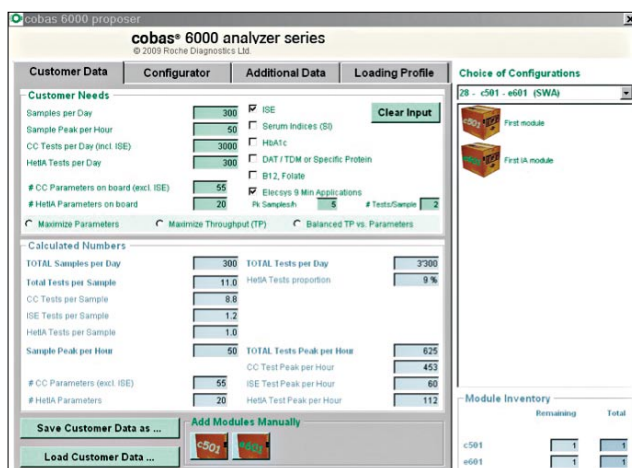


Fig. 8: cobas[®] 6000 simulation tool

Conclusion

A multi-center evaluation of the 9 minute STAT applications demonstrated the ability of the cobas 6000 analyzer series to consolidate STAT samples without disrupting the routine workload. STAT sample turnaround time was significantly improved, and analytical performance maintained excellent comparability and precision.

References

- 1 Basic Metabolic Panel: Sodium, Potassium, Chloride, CO₂, Calcium, Glucose, Urea, Creatinine (8 tests).
- 2 Thygesen, K., Alpert, J.S., White, H.D. (2007). Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. *Circulation*; 106: 2634-53.
- 3 National Academy of Clinical Biochemistry and IFCC Committee for Standardization of Markers of Cardiac Damage Laboratory Medicine Practice Guidelines: Analytical issues for biochemical markers of acute coronary syndromes. Apple FS et al. *Clinical Chemistry* 2007, 53:4.; 547-541.

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

cobas[®] 6000 analyzer series: Proven efficiency gains and cost savings

An independent site evaluation at Fairview Cleveland Clinic, Cleveland, Ohio, USA

Introduction

Migrating to the cobas[®] 6000 analyzer series can deliver quantifiable efficiency gains and cost savings. Through a structured client assessment protocol, Roche documented the efficiencies gained by using the analyzer series within a client-approved case study report. Prepared by a third party research firm, with active participation of the client, findings from Fairview Hospital, Cleveland Clinic in Cleveland, Ohio, USA are presented.

Flexible consolidation

Fairview Cleveland Clinic has an annual workload of 3.1 million reportable tests for clinical chemistry and immunoassays.

The instruments utilized in the before scenario included two Siemens Dimension[®] RxL analyzers, one Tosoh HPLC analyzer for dedicated HbA1c testing, one Siemens ADVIA Centaur[®] analyzer, and a dedicated analyzer for lithium testing (Figure 1).

The after scenario utilized the cobas[®] 6000 <cce> configuration for routine workload use, cobas[®] 6000 <ce> for backup and esoteric testing use, and the ADVIA Centaur[®] analyzer for other immunoassays (Figure 2).

The client noted that further consolidation of testing from the ADVIA Centaur[®] analyzer and the manual serology workstation to the cobas[®] 6000 analyzer series is planned after the evaluation.

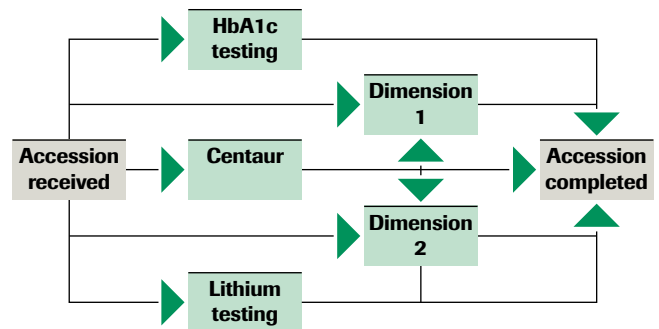


Fig. 1: Before scenario workflow

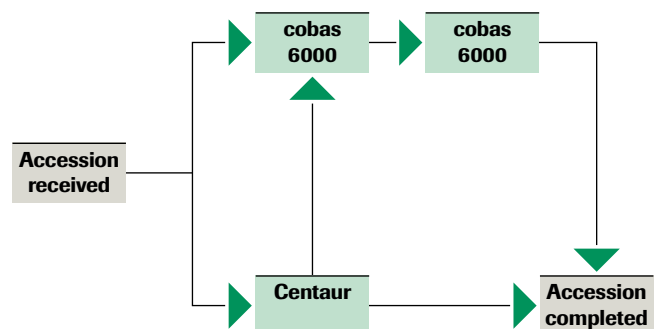


Fig. 2: After scenario workflow



“The client realized a significant reduction of over 30% in operating costs.”

Single point of entry

The consolidation of workstations has eliminated aliquots and sharing of samples between workstations by creating a single point of sample entry.

Before: Dimension® RxL accepted most tube types but required a certain minimum amount of sample volume. During an observation period of 4 times 15 minutes, 23 out of a total of 95 samples or 24% required testing in special low sample volume tubes (micro-cups).

After: The **cobas**® 6000 analyzer series accepted many tube types. While it also had a minimum sample volume requirement, it was less than Dimension® RxL. During the same observation time as used above, only 6 out of a total of 83 total tubes or just 7% required micro-cups.

The client found a statistical difference between the before and after scenarios. There were three times fewer micro-cups required for the **cobas**® 6000 analyzer series than Dimension® RxL, resulting in time savings of one hour per day due to the omission of manual aliquotting. Additional advantages observed by the staff were less consumable usage, fewer patient identification errors, and avoidance of sample contamination.

Test consolidation

Workstation consolidation helped the laboratory to dramatically reduce any non-value adding activities. Overall, this resulted in savings of approximately 380 hours per month or 4556 hours per year, which translates to more than 2 full-time equivalents (FTEs) (Figure 3).

Specifically these savings were realized due to more efficient quality control, less time loading/unloading samples and performing QC/calibration, and less frequent maintenance of equipment. The client noted that these time savings have enabled staff to focus on value-added activities within the laboratory.

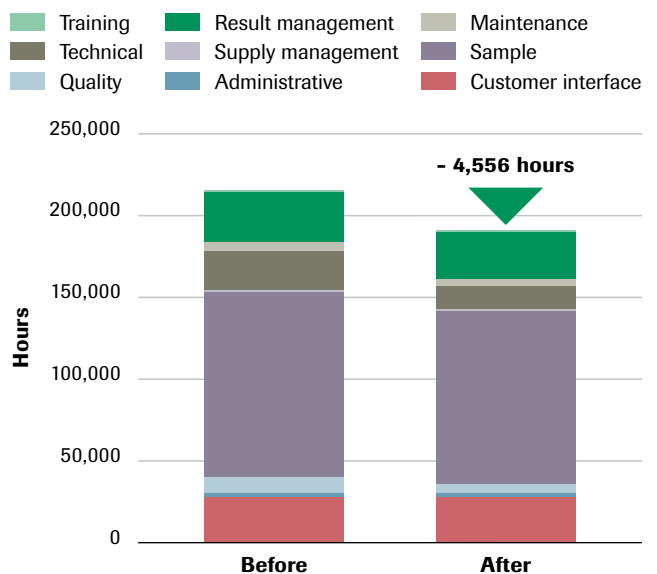


Fig. 3: Annualized staff activity comparison in hours

Lower operating costs

The implementation of the **cobas**® 6000 analyzer series resulted in lower operating costs.

Before: Monthly reagent and consumable costs averaged \$368,354. Staff FTEs averaged 9.75 with 0.25 in overtime.

After: Monthly reagent and consumable costs averaged \$246,174 and FTEs averaged 9.41 with 0.05 in overtime.

The client realized a significant reduction of over 30% in operating costs, totaling \$ 1.4 Mio. in annualized cost savings. While no overall labor savings were realized due to the decision to redeploy staff to other activities, the laboratory realized a significant opportunity savings.

Unique reagent concept

The implementation of the **cobas**® 6000 analyzer series introduced a new reagent concept, which was considered to be convenient and cost effective.

Ready to use reagents

Before: Dimension® RxL reagents, controls and calibrators required a variety of storage needs: room temperature, freezer and refrigeration. Once loaded, an extra step of hydrating Dimension RxL reagents was necessary and slowed the analyzers significantly. Additional storage was needed for Lithium and HbA1c reagents as well.

After: The **cobas c** and **cobas e** reagent packs required no preparation with the exception of one third party assay for special use. The compact reagent pack size resulted in one less refrigerator needed for storage of reagents. Once the reagent was loaded on the analyzer, it was immediately ready to use.

The ready-to-use **cobas c** and **cobas e** packs meant less time spent on reagent preparation. Overall time savings were 20 minutes in preparation per day or 122 hours per year.

Reagent loading on the fly

Before: Dimension® RxL required reagent reconstitution on board the analyzer with hydrating packs. Due to the amount of time needed for this step, the task of reagent loading would fall on the night shift so that there would be minimal impact on the workflow. Nevertheless, during each shift additional reagent kits needed to be loaded due to the small packaging size and test volume.

After: Loading and unloading of **cobas c** and **cobas e** packs were performed during normal operation. However, most reagent loading was performed just once and was sufficient for the complete day due to larger package sizes. The client noted that the afternoon and evening shift needed to load reagents only 1-2 times per week.

Overall time savings with **cobas c** and **cobas e** packs were 23 minutes per day or 140 hours per year. For the shifts with less staff coverage, reagent handling was considered easier due to infrequent reagent loading.

Superior analytical performance

The **cobas**® 6000 analyzer series also contributed to reducing the cost of quality. The client evaluated the impact on its staff's activities dedicated to ensuring quality by documenting the time spent on activities such as error prevention, result inspection and appraisal, and result correction.

Reduced cost of quality

Before: Annualized staff activities dedicated to ensuring quality totaled 48,875 hours.

After: Annualized staff activities dedicated to ensuring quality totaled 39,595 hours, a time saving of over 9,000 hours or 4.5 FTEs (Figure 4).

The implementation of the **cobas**® 6000 analyzer series had a significant impact in reducing the cost of quality by reducing staff activity dedicated to ensuring quality by 19%.

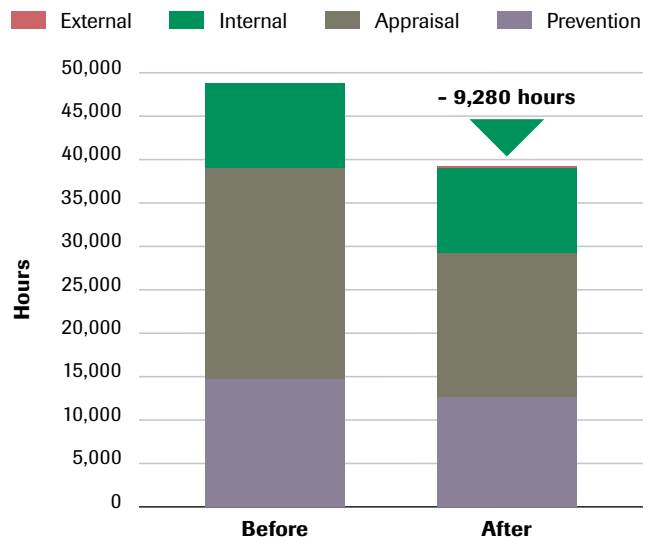


Fig. 4: Annualized staff activity comparison in hours dedicated to ensuring quality

“Consolidation resulted in savings of approximately 380 hours per month, which translates to more than 2 FTEs.”

“Annualized staff activities dedicated to ensuring quality was reduced by the equivalent of 4.5 FTEs.”

Proven system performance

The implementation of the **cobas**[®] 6000 analyzer series contributed to the laboratory’s responsiveness by improving system reliability and uptime.

Before: In a five month period Dimension[®] RxL analyzers had 27 incidents of service calls, with many issues requiring multiple service visits with multiple days of analyzer downtime.

After: In a five month period, the **cobas** analyzers had only 10 service calls with minimal impact on downtime.

Service calls ranged from 1 hour to 7 hours, not counting system downtime prior to the arrival of the service technician. Using a 4 hour average, this would equate to 259 hours per year in the before scenario and 96 hours per year in the after scenario, a dramatic reduction of over 60%. This represents a system uptime of 99% for a lab operating 24 hours a day, 365 days per year. Thus, while the age of the system should also be noted as a contributing factor, the **cobas**[®] 6000 analyzer series was considered to be more reliable with less service calls and unexpected downtime.

Conclusion

Today’s laboratories are faced with providing broad menus, increased expectations from providers and a diminishing workforce. In addition, the medical community is under scrutiny for patient safety. As a result of this site evaluation, Fairview Cleveland Clinic maintains that the cobas[®] 6000 analyzer series is the solution to these challenges.

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CH-6343 Rotkreuz
Switzerland
www.cobas.com

Substantially low cardiac testing TAT

cobas[®] 9-minute cardiac STAT applications provide fast and reliable results, significantly reducing test TAT

Facility: Florida Hospital, Central Florida

Profile: 8-campus hospital network

Number of beds: 2,188

Number of emergency cases: 337,146 per year

Challenge: Improve accuracy and speed of cardiac STAT tests

Solution: **cobas[®]** 6000 analyzer series and **cobas[®]** 8000 modular analyzer series 9-minute cardiac STAT applications

Introduction

The labs at Florida Hospital want to provide the highest-quality, fastest, most appropriate diagnostic testing to ensure that their patients receive excellent care. But when technologists needed to frequently re-run critical values for cardiac STAT tests, lab managers knew it was time to look for a new system. Cardiac patients could lose heart muscle with every minute of delay caused due to inaccurate, unreliable STAT test results. Lab managers and directors decided to meet as a team to search for the best possible solution. Their goals were simple:

1. Reduce turnaround times (TAT) for cardiac STAT tests,
2. Complete at least 90% of their cardiac STAT tests within 45 minutes of receiving the order from the ED.

While each hospital's lab had different volumes of and needs with testing, each hospital had an equal say in what laboratory equipment they would choose as a network. They chose the **cobas** 6000 analyzer series and **cobas** 8000 modular analyzer series (**cobas** 6000/8000) 9-minute cardiac STAT application, helping both labs to reach their internal testing goals.

Key conclusion

Delivering fast turnaround times is essential in cardiac STAT testing so that physicians can quickly diagnose, treat and/or transfer patients as the case may be. As Susana Savino, Lab Administrative Director explains, "Every minute saved equals a better heart outcome." Since switching to **cobas**, both campuses have experienced significant reduction in TAT for cardiac STAT testing. The decrease in TAT is palpable and statistically significant.

The Florida Hospital system has a goal of delivering 90% of its cardiac STAT lab results to the Emergency Department in less than 45 minutes from request receipt. This is even more stringent standard than CMS guidelines for a 60 minute or less TAT for troponin from patient arrival to result availability. Prior to **cobas**, many campuses were able to meet the 60-minute TAT goal as per the CMS guidelines but were not able to meet the 45-minute internal goal. Since adopting **cobas** 6000/8000, Florida Hospital is proud to announce that they are now meeting the 45-minute TAT goal.



cobas[®]

Life needs answers

Detailed results

Quantitative data were gathered and analyzed to measure the performance of the hospitals before and after implementation of the **cobas**[®] 6000 analyzer series and **cobas**[®] 8000 modular analyzer series with the 9-minute cardiac STAT applications. Metrics include cardiac STAT test Troponin, pro-BNP, and CK-MB TATs.

Lab staff and administrators have been extremely pleased with the results. “We quantify everything... and we noticed that the ED TATs were faster than before and kept getting faster as we got used to the new system,” continues Savino.

Average TAT decreased – adopted in the Orlando campus

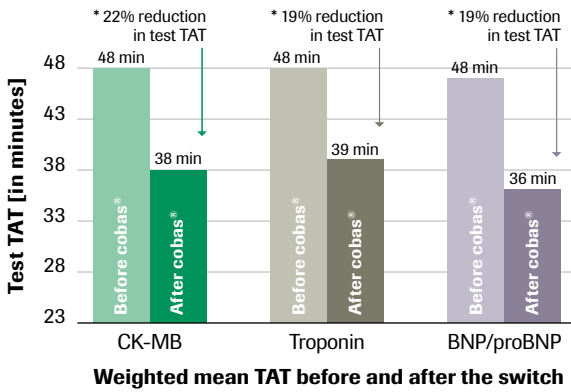


Figure 1

Average TAT decreased – adopted in the Kissimmee campus

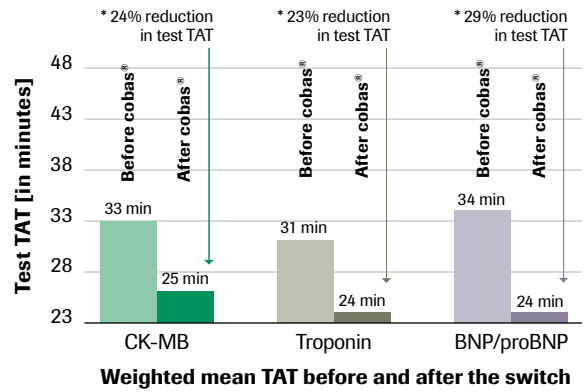


Figure 2

NOTE: A weighted mean was used to account for the fluctuating volume of tests per month. The month in which the switch was made to the **cobas** 9-min cardiac test application was excluded from the analysis because the switch occurred mid-month.

* Indicates significant differences at the 0.05 significance level.

Both campuses are now able to meet or come close to their internal gold standard target of completing 90% of their cardiac STAT tests under 45 minutes.

Goal average % complete in 45 minutes with cobas 9-min cardiac STAT application is 90%

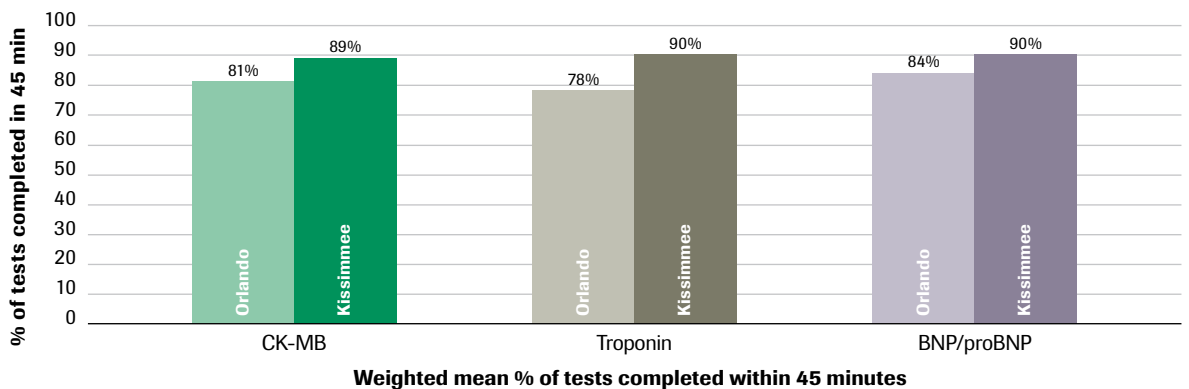


Figure 3

Other benefits for Florida Hospital:

In addition to the faster TAT, Florida Hospital has achieved many other improvements from adopting the **cobas** 6000/8000 systems. Namely:

- 1. Accurate, reliable results** – Patrick O’Sullivan comments, “Our staff has noticed the increase in reliability of the tests... they’ll say they get the exact same result every time – that speaks well for the consistency of the assay. The staff is really pleased because they truly care about quality patient care.”
- 2. Workflow efficiency and resource optimization** – The **cobas** 6000/8000 systems have created efficiencies in lab staff time, and reduced the number of repeat tests and hence reagent use. After installing the new systems, Savino quickly noticed a significant reduction in the amount of reagents they have to order – resulting in direct cost savings – both in terms of materials and also staff time.

- 3. Seamless transition** – The staff at Florida Hospital labs together with Roche personnel worked hard to transition from their old system to the new **cobas** system. Thanks to their hard work, it was seamless. Savino explains, “We went live across all campuses with the new cardiac markers, it was just like we flipped a switch, it was so smooth, we had absolutely no issues.” The Florida Hospital labs engaged with the hospital’s Medical and Scientific Affairs team to educate staff clinicians on the new cut-off points for cardiac markers (Troponin T and NT-proBNP) in a highly collaborative process.
- 4. Transferring patients** – At the Kissimmee campus, success is also measured by the time it takes from a cardiac patient’s initial arrival in the ED to the time they meet with the ED cardiologist for confirmatory diagnostics: “door-to-balloon time”. As a small campus that needs to appropriately triage and transfer patients when needed, they proudly report a door-to-balloon time of less than 90 minutes [See Figure 4].

Fast and appropriate triage helps the site achieve a door-to-balloon time of less than 90 minutes

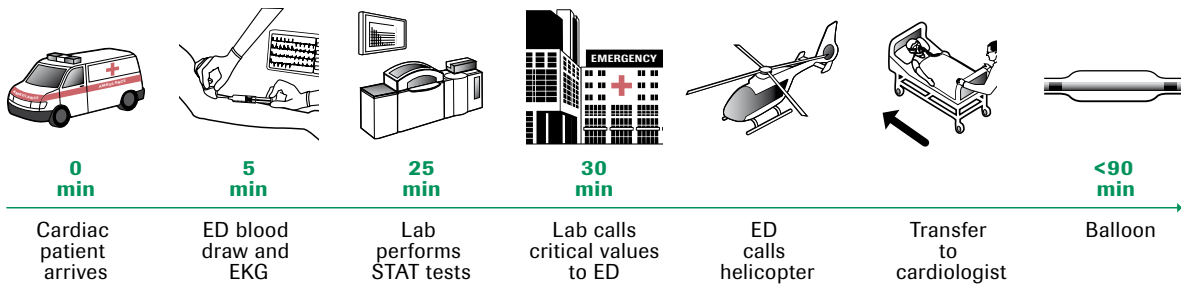


Figure 4

Pre-transition

- Campuses evaluated multiple options and made a joint decision
- Roche provided hands-on training with lab staff on site and in Indianapolis
- Labs worked with Medical & Scientific Affairs to create pocket reference cards to educate clinician stakeholders re: new key cardiac marker parameters and appropriate cut-off values

During transition

- Roche continued to provide hands-on training to lab staff
- Lab services continued without any disruption or problems
- There were no reported complaints from clinicians

Post-transition

- Roche remains responsive to any concerns that campus staff may bring up
- Roche engineers visit regularly to work through any issues and optimize sample retrieval
- Roche provides ongoing sales support and resources

Conclusions and observations:

Not only does the system meet today's goals, but it also meets projected future needs. "It's important to look at where the healthcare system is going down the road – 4 or 5 years from now," says O'Sullivan. "As our hospital and population grows, it's important to look at where we're going to be at the end of the life cycle of the equipment."

Having equipment which will continually provide fast results, high accuracy, and high throughput over time is the common thread across all the labs. According to Kathy McGinnis, Lab Technologist, "If I had to use three words to describe the **cobas** 8000 STAT cardiac markers, I would have to say, accuracy, reliability and one of the quickest tests around times". The **cobas** 6000/8000 systems have allowed Florida Hospital to achieve these goals and will continue to work hard to accommodate their growth and their future needs.

"As a laboratory administrator, I have a lot of things pulling at me and there's a lot of conflicting priorities and with a reliable immunochemistry system like the **cobas** system, it's one less thing I have to worry about. I can focus my attention on staffing issues or finance issues or quality improvement issues and I don't have to worry about those chemistry tests. It's a really great feeling knowing that it's one less stress I have." – Sarah Province, Assistant Laboratory Director.

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

Serum Work Area

Assay overview

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module	COBAS INTEGRA® 400 plus
Anemia				
Ferritin		•	•	•
Folate			•	
Folate RBC			•	
Iron	•	•		•
Iron Binding Capacity – Unsaturated		•		•
Soluble transferrin receptor		•		•
Transferrin		•		•
Vitamin B12			•	
Lactate Dehydrogenase	•	•		•
Bone				
N-MID Osteocalcin			•	
P1NP			•	
Phosphorus	•	•		•
PTH			•	
PTH (1-84)			•	
PTH STAT			•	
β-CrossLaps			•	
Vitamin D total			•	
Cardiac				
Apolipoprotein A1		•		•
Apolipoprotein B		•		•
Cholesterol	•	•		•
CK	•	•		•
CK-MB	•	•		•
CK-MB (mass)			•	
CK-MB (mass) STAT			•	
CRP hs	•	•		•
Cystatin C		•		•
D-Dimer	•	•		•

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module	COBAS INTEGRA® 400 plus
Cardiac				
Digitoxin		•	•	•
Digoxin		•	•	•
HDL Cholesterol direct	•	•		•
Homocysteine	•	•		•
Hydroxybutyrat Dehydrogenase		•		•
LDL Cholesterol direct	•	•		•
Lipoprotein (a)		•		•
Myoglobin		•	•	•
Myoglobin STAT			•	
NT-proBNP			•	
NT-proBNP STAT			• ¹	
Troponin I			• ¹	
Troponin I STAT			•	
Troponin T hs			•	
Troponin T hs STAT			•	
Coagulation				
AT III		•		•
D-Dimer	•	•		•
Drugs of Abuse Testing				
Amphetamines (Ecstasy)		•		•
Barbiturates		•		•
Barbiturates (Serum)				•
Benzodiazepines		•		•
Benzodiazepines (Serum)				•
Cannabinoids		•		•
Cocaine		•		•
Ethanol		•		•
LSD		• ²		•
Metamphetamine		•		•



Life needs answers

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module COBAS INTEGRA® 400 plus
Drugs of Abuse Testing			
Methadone		•	•
Methadone metabolites (EDDP)		•	•
Methaqualone		•	•
Opiates		•	•
Oral Fluids Amphetamines		•	
Oral Fluids Cocaine		•	
Oral Fluids Metamphetamines		•	
Oral Fluids Opiates		•	
Oral Fluids Phencyclidine		•	
Oxycodone		• ³	•
Phencyclidine		•	•
Propoxyphene		•	•
Endocrinology			
Amylase – pancreatic	•	•	•
Amylase – total	•	•	•
ACTH			•
Anti-Tg			•
Anti-TPO			•
Anti-TSH-R			•
Calcitonin			•
Cortisol			•
C-Peptide			•
FT3			•
FT4			•
hGH			•
Hydroxybutyrate Dehydrogenase		•	•
Insulin			•
<i>Insulin like growth factor</i> ⁴			•
Lipase	•	•	•
PTH STAT			•
T3			•
T4			•
Thyreoglobulin (TG II)			•
Thyreoglobulin confirmatory			•
TSH			•
T-uptake			•
Fertility			
<i>Anti Muellerian Hormone</i> ⁴			•
DHEA-S			•
Estradiol			•
FSH			•
hCG			•
hCG plus beta			•
LH			•
Progesterone			•
Prolactin			•

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module COBAS INTEGRA® 400 plus
Fertility			
SHBG			•
Testosterone			•
Hepatology			
Alkaline phosphatase (IFCC)	•	•	•
Alkaline phosphatase (opt.)		• ³	•
ALT/GPT with Pyp		•	•
ALT/GPT without Pyp	•	•	•
Ammonia	•	•	•
Anti-HCV			•
AST/GOT with Pyp	•	•	•
AST/GOT without Pyp	•	•	•
Bilirubin – direct	•	•	•
Bilirubin – total	•	•	•
Cholinesterase Acetyl		• ³	
Cholinesterase Butyryl		•	•
Gamma Glutamyl Transferase	•	•	•
Glutamate Dehydrogenase		•	•
HBeAg			•
HBsAg			•
Lactate Dehydrogenase	•	•	•
Infectious Diseases			
Anti-HAV			•
Anti-HAV IgM			•
Anti-HBc			•
Anti-HBc IgM			•
Anti-HBe			•
HBeAg			•
Anti-HBsAg			•
HBsAg			•
HBsAg confirmatory			•
HBsAg quantitative			•
Anti-HCV			•
<i>Chagas</i> ⁴			•
CMV IgG			•
CMV IgG Avidity			•
CMV IgM			•
CRP (Latex)	•	•	•
HIV combi PT			•
HIV-Ag			•
HIV-Ag confirmatory			•
HSV-1 IgG			•
HSV-2 IgG			•
<i>HTLV 1 & 2</i> ⁴			•
Rubella IgG			•
Rubella IgM			•
<i>Syphilis</i> ⁴			•

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module COBAS INTEGRA® 400 plus
Infectious Diseases			
Toxo IgG			•
Toxo IgG Avidity			•
Toxo IgM			•
TPLA (Syphilis)		• ⁶	
Inflammation			
Anti-CCP			•
ASLO		•	•
C3c		•	•
C4		•	•
Ceruloplasmin		•	•
CRP (Latex)	•	•	•
Haptoglobin		•	•
IgA		•	•
IgE			•
IgG		•	•
IgM		•	•
Immunglobulin A CSF ⁵		•	
Immunglobulin M CSF ⁵		•	
Interleukin 6			•
Kappa light chains		•	•
Kappa light chains free		• ³	•
Lambda light chains		•	•
Lambda light chains free		• ³	•
Prealbumin		•	•
Procalcitonin			•
Rheumatoid factor		•	•
α1-Acid Glycoprotein		•	•
α1-Antitrypsin		•	•
Metabolic			
Bicarbonate (CO ₂)	•	•	•
Calcium	•	•	•
Chloride	•	•	•
Fructosamine		•	•
Glucose	•	•	•
HbA1c (hemolysate)	•	• ³	•
HbA1c (whole blood)	•	• ³	•
Insulin			•
Lactate	•	•	•
LDL Cholesterol direct	•	•	•
Magnesium	•	•	•
Potassium	•	•	•
Sodium	•	•	•
Total Protein	•	•	•
Triglycerides	•	•	•
Triglycerides Glycerol blanked		•	
Vitamin D			•

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module COBAS INTEGRA® 400 plus
Oncology			
Acid phosphatase		•	•
AFP			•
CA 125			•
CA 15-3			•
CA 19-9			•
CA 72-4			•
Calcitonin			•
CEA			•
Cyfra 21-1			•
hCG plus beta			•
HE4			•
Kappa light chains free		• ³	•
Lambda light chains free		• ³	•
NSE			•
proGRP			•
PSA free			•
PSA total			•
SCC ⁴			•
S-100			•
Thyreoglobulin (TG II)			•
Thyreoglobulin confirmatory			•
β ₂ -Microglobulin		•	
Renal			
Albumin (BCG)	•	•	•
Albumin (BCP)		•	•
Albumin immunologic	•	•	•
Creatinin (enzymatic)	•	•	•
Creatinin (Jaffe)	•	•	•
Cystatine C		•	•
PTH			•
PTH (1-84)			•
Total Protein	•	•	•
Total Protein, Urine/CSF		•	•
Urea/BUN	•	•	•
Uric acid	•	•	•
α ₁ -Microglobulin		•	•
β ₂ -Microglobulin		•	
Therapeutic Drug Monitoring			
Acetaminophen (Paracetamol)		•	•
Amikacin		•	•
Carbamazepine		•	•
Barbiturates		•	•
Barbiturates (Serum)			•
Cyclosporine A			• ⁵
Digitoxin		•	•
Digoxin		•	•

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module	COBAS INTEGRA® 400 plus
Therapeutic Drug Monitoring				
Everolimus ⁴			•	
Gentamicin		•		•
Lidocaine				•
Lithium		•		ISE
Mycophenolic acid		•		•
NAPA		•		•
Phenobarbital		•		•
Phenytoin		•		•
Primidone				•
Procainamide		•		•
Quinidine		•		•
Salicylate		•		•
Sirolimus ⁴			•	
Tacrolimus ⁵			•	
Theophylline		•		•
Tobramycin		•		•
Valproic Acid		•		•
Vancomycin		•		•
Women Health				
Anti Muellierian Hormone ⁴			•	
AFP			•	
β-Crosslaps			•	
Estradiol			•	
FSH			•	

¹ not on cobas e 411

² not on cobas c 311

³ not on cobas c 701 and c 702

⁴ in development

⁵ launch in 2013

⁶ only on cobas c 501 and c 502

	cobas c 111 analyzer	cobas modular platform: c module	cobas modular platform: e module	COBAS INTEGRA® 400 plus
Women Health				
free βhCG			•	
hCG			•	
hCG plus beta			•	
hCG STAT			•	
HE4			•	
LH			•	
N-MID Osteocalcin			•	
PAPP-A			•	
PIGF			•	
sFlt-1			•	
P1NP			•	
Progesterone			•	
Prolactine			•	
SHBG			•	
Testosterone			•	
CMV IgG			•	
CMV IgG Avidity			•	
CMV IgM			•	
Rubella IgG			•	
Rubella IgM			•	
Toxo IgG			•	
Toxo IgG Avidity			•	
Toxo IgM			•	

Product availability may vary from country to country.

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CH-6343 Rotkreuz
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Serum Work Area

Clinical chemistry and homogeneous immunoassays

	cobas c 111 analyzer	cobas c 311 analyzer	cobas c 501 and c 502 modules	cobas c 701 and c 702 modules	COBAS INTEGRA® 400 plus
Anemia					
Ferritin		•	•	•	•
Iron	•	•	•	•	•
Iron Binding Capacity - Unsaturated		•	•	•	•
Soluble transferrin receptor		•	•	•	•
Transferrin		•	•	•	•
Lactate Dehydrogenase	•	•	•	•	•
Bone					
Phosphorus	•	•	•	•	•
Cardiac					
Apolipoprotein A1		•	•	•	•
Apolipoprotein B		•	•	•	•
Cholesterol	•	•	•	•	•
CK	•	•	•	•	•
CK-MB	•	•	•	•	•
CRP hs	•	•	•	•	•
Cystatin C		•	•	•	•
D-Dimer	•	•	•	•	•
Digitoxin		•	•	•	•
Digoxin		•	•	•	•
HDL Cholesterol direct	•	•	•	•	•
Homocysteine	•	•	•	•	•
Hydroxybutyrat Dehydrogenase		•	•	•	•
LDL Cholesterol direct	•	•	•	•	•
Lipoprotein (a)		•	•	•	•
Myoglobin		•	•	•	•
Coagulation					
AT III		•	•	•	•
D-Dimer	•	•	•	•	•

	cobas c 111 analyzer	cobas c 311 analyzer	cobas c 501 and c 502 modules	cobas c 701 and c 702 modules	COBAS INTEGRA® 400 plus
Drugs of Abuse Testing					
Amphetamines (Ecstasy)		•	•	•	•
Barbiturates		•	•	•	•
Barbiturates (Serum)					•
Benzodiazepines		•	•	•	•
Benzodiazepines (Serum)					•
Cannabinoids		•	•	•	•
Cocaine		•	•	•	•
Ethanol		•	•	•	•
LSD			•	•	•
Metamphetamine		•	•	•	•
Methadone		•	•	•	•
Methadone metabolites (EDDP)		•	•	•	•
Methaqualone		•	•	•	•
Opiates		•	•	•	•
Oral Fluids Amphetamines			•	•	
Oral Fluids Cocaine		•	•	•	
Oral Fluids Metamphetamine		•	•	•	
Oral Fluids Opiates		•	•	•	
Oral Fluids Phencyclidine		•	•	•	
Oxycodone		•	•		•
Phencyclidine		•	•	•	•
Propoxyphene		•	•	•	•
Endocrinology					
Amylase – pancreatic	•	•	•	•	•
Amylase – total	•	•	•	•	•
Hydroxybutyrat Dehydrogenase		•	•	•	•
Lipase	•	•	•	•	•
T4					•



Life needs answers

	cobas c 111 analyzer	cobas c 311 analyzer	cobas c 501 and c 502 modules	cobas c 701 and c 702 modules	COBAS INTEGRA® 400 plus
Endocrinology					
T-uptake					•
Hepatology					
Alkaline phosphatase (IFCC)	•	•	•	•	•
Alkaline phosphatase (opt.)		•	•		•
ALT/GPT with Pyp		•	•	•	•
ALT/GPT without Pyp	•	•	•	•	•
Ammonia	•	•	•	•	•
AST/GOT with Pyp	•	•	•	•	•
AST/GOT without Pyp	•	•	•	•	•
Bilirubin - direct	•	•	•	•	•
Bilirubin - total	•	•	•	•	•
Cholinesterase Acetyl		•	•		
Cholinesterase Butyryl		•	•	•	•
Gamma Glutamyl Transferase	•	•	•	•	•
Glutamate Dehydrogenase		•	•	•	•
Lactate Dehydrogenase	•	•	•	•	•
Infectious Diseases					
CRP (Latex)	•	•	•	•	•
TPLA (Syphilis)			•		
Inflammation					
ASLO		•	•	•	•
C3c		•	•	•	•
C4		•	•	•	•
Ceruloplasmin		•	•	•	•
CRP (Latex)	•	•	•	•	•
Haptoglobin		•	•	•	•
IgA		•	•	•	•
IgG		•	•	•	•
IgM		•	•	•	•
Immunglobulin A CSF ¹		•	•	•	
Immunglobulin M CSF ¹		•	•	•	
Kappa light chains		•	•	•	•
Kappa light chains free		•	•	•	•
Lambda light chains		•	•	•	•
Lambda light chains free		•	•	•	•
Prealbumin		•	•	•	•
Rheumatoid factor		•	•	•	•
α1-Acid Glycoprotein		•	•	•	•
α1-Antitrypsin		•	•	•	•
Metabolic					
Bicarbonate (CO ₂)	•	•	•	•	•
Calcium	•	•	•	•	•
Chloride	•	•	•	•	•
Fructosamine		•	•	•	•
Glucose	•	•	•	•	•

	cobas c 111 analyzer	cobas c 311 analyzer	cobas c 501 and c 502 modules	cobas c 701 and c 702 modules	COBAS INTEGRA® 400 plus
Metabolic					
HbA1c (hemolysate)	•	•	•		•
HbA1c (whole blood)	•	•	•		•
Lactate	•	•	•	•	•
LDL Cholesterol direct	•	•	•	•	•
Magnesium	•	•	•	•	•
Potassium	•	•	•	•	•
Sodium	•	•	•	•	•
Total Protein	•	•	•	•	•
Triglycerides	•	•	•	•	•
Triglycerides Glycerol blanked		•	•	•	
Oncology					
Acid phosphatase		•	•	•	•
Kappa light chains free		•	•		•
Lambda light chains free		•	•		•
β ₂ -Microglobulin		•	•	•	
Renal					
Albumin (BCG)	•	•	•	•	•
Albumin (BCP)		•	•	•	•
Albumin immunologic	•	•	•	•	•
Creatinin (enzymatic)	•	•	•	•	•
Creatinin (Jaffe)	•	•	•	•	•
Cystatine C		•	•	•	•
Total Protein	•	•	•	•	•
Total Protein, Urine/CSF		•	•	•	•
Urea/BUN	•	•	•	•	•
Uric acid	•	•	•	•	•
α ₁ -Microglobulin		•	•	•	
β ₂ -Microglobulin		•	•	•	
Therapeutic Drug Monitoring					
Acetaminophen (Paracetamol)		•	•	•	•
Amikacin		•	•	•	•
Carbamazepine		•	•	•	•
Barbiturates		•	•	•	•
Barbiturates (Serum)					•
Cyclosporine					•
Digitoxin		•	•	•	•
Digoxin		•	•	•	•
Gentamicin		•	•	•	•
Lidocaine					•
Lithium		•	•	•	ISE
Mycophenolic acid		•	•	•	•
NAPA		•	•	•	•
Phenobarbital		•	•	•	•
Phenytoin		•	•	•	•
Primidone					•

	cobas c 111 analyzer	cobas c 311 analyzer	cobas c 501 and c 502 modules	cobas c 701 and c 702 modules	COBAS INTEGRA[®] 400 plus
Therapeutic Drug Monitoring					
Procainamide		•	•	•	•
Quinidine		•	•	•	•
Salicylate		•	•	•	•
Theophylline		•	•	•	•
Tobramycin		•	•	•	•
Valproic Acid		•	•	•	•
Vancomycin		•	•	•	•

¹ launch in 2013

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

Serum Work Area

Heterogeneous immunoassays

	cobas e 411 analyzer cobas e 601 and e 602 modules	
Anemia		
Ferritin	•	•
Folate	•	•
Folate RBC	•	•
Vitamin B12	•	•
Bone		
N-MID Osteocalcin	•	•
P1NP	•	•
PTH	•	•
PTH (1-84)	•	•
PTH STAT	•	•
β-CrossLaps	•	•
Vitamin D total	•	•
Cardiac		
CK-MB (mass)	•	•
CK-MB (mass) STAT	•	•
D-Dimer	•	•
Digitoxin	•	•
Digoxin	•	•
Myoglobin	•	•
Myoglobin STAT	•	•
NT-proBNP	•	•
NT-proBNP STAT		•
Troponin I		•
Troponin I STAT	•	•
Troponin T hs	•	•
Troponin T hs STAT	•	•
Endocrinology		
ACTH	•	•
Anti-Tg	•	•

	cobas e 411 analyzer cobas e 601 and e 602 modules	
Endocrinology		
Anti-TPO	•	•
Anti-TSH-R	•	•
Calcitonin	•	•
Cortisol	•	•
C-Peptide	•	•
FT3	•	•
FT4	•	•
hGH	•	•
Insulin	•	•
<i>Insulin like growth factor¹</i>	•	•
PTH STAT	•	•
T3	•	•
T4	•	•
Thyreoglobulin (TG II)	•	•
Thyreoglobulin confirmatory	•	•
TSH	•	•
T-uptake	•	•
Fertility		
<i>Anti Mullerian Hormone¹</i>	•	•
DHEA-S	•	•
Estradiol	•	•
FSH	•	•
hCG	•	•
hCG plus beta	•	•
LH	•	•
Progesterone	•	•
Prolactin	•	•
SHBG	•	•
Testosterone	•	•



Life needs answers

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analyzer
cobas e 601 and
e 602 modules

Hepatology

HBeAg	•	•
HBsAg	•	•
Anti-HCV	•	•

Infectious Diseases

Anti-HAV	•	•
Anti-HAV IgM	•	•
Anti-HBc	•	•
Anti-HBc IgM	•	•
Anti-HBe	•	•
HBeAg	•	•
Anti-HBs	•	•
HBsAg	•	•
HBsAg confirmatory	•	•
HBsAg quantitative	•	•
Anti-HCV	•	•
<i>Chagas</i> ¹	•	•
CMV IgG	•	•
CMV IgG Avidity	•	•
CMV IgM	•	•
HIV combi PT	•	•
HIV-Ag	•	•
HIV-Ag confirmatory	•	•
HSV-1 IgG	•	•
HSV-2 IgG	•	•
<i>HTLV 1 & 2</i> ¹	•	•
Rubella IgG	•	•
Rubella IgM	•	•
Syphilis ¹	•	•
Toxo IgG	•	•
Toxo IgG Avidity	•	•
Toxo IgM	•	•

Inflammation

Anti-CCP	•	•
IgE	•	•
Interleukin 6	•	•
Procalcitonin	•	•

Metabolic

Insulin	•	•
Vitamin D	•	•

Oncology

AFP	•	•
CA 125	•	•
CA 15-3	•	•
CA 19-9	•	•

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Oncology

CA 72-4	•	•
Calcitonin	•	•
CEA	•	•
Cyfra 21-1	•	•
hCG plus beta	•	•
HE4	•	•
NSE	•	•
proGRP	•	•
PSA free	•	•
PSA total	•	•
<i>SCC</i> ¹	•	•
S-100	•	•
Thyreoglobulin (TG II)	•	•
Thyreoglobulin confirmatory	•	•

Renal

PTH	•	•
PTH (1-84)	•	•

Therapeutic Drug Monitoring

Cyclosporine A ²	•	•
Digitoxin	•	•
Digoxin	•	•
<i>Everolimus</i> ¹	•	•
<i>Sirolimus</i> ¹	•	•
Tacrolimus ²	•	•

Women Health

<i>Anti Muellerian Hormone</i> ¹	•	•
AFP	•	•
β-Crosslaps	•	•
Estradiol	•	•
FSH	•	•
free βhCG	•	•
hCG	•	•
hCG plus beta	•	•
hCG STAT	•	•
HE4	•	•
LH	•	•
N-MID Osteocalcin	•	•
PAPP-A	•	•
PIGF	•	•
sFlt-1	•	•
P1NP	•	•
Progesterone	•	•
Prolactine	•	•
SHBG	•	•

cobas e 411
analyzer
cobas e 601 and
e 602 modules

Women Health

Testosterone	•	•
CMV IgG	•	•
CMV IgG Avidity	•	•
CMV IgM	•	•
Rubella IgG	•	•
Rubella IgM	•	•
Toxo IgG	•	•
Toxo IgG Avidity	•	•
Toxo IgM	•	•

¹ in development

² launch in 2013

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