cobas® 6000 analyzer series

Flexibility you can build on

Roche

cobas®

Life needs answers

cobas® 6000 analyzer series

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.

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

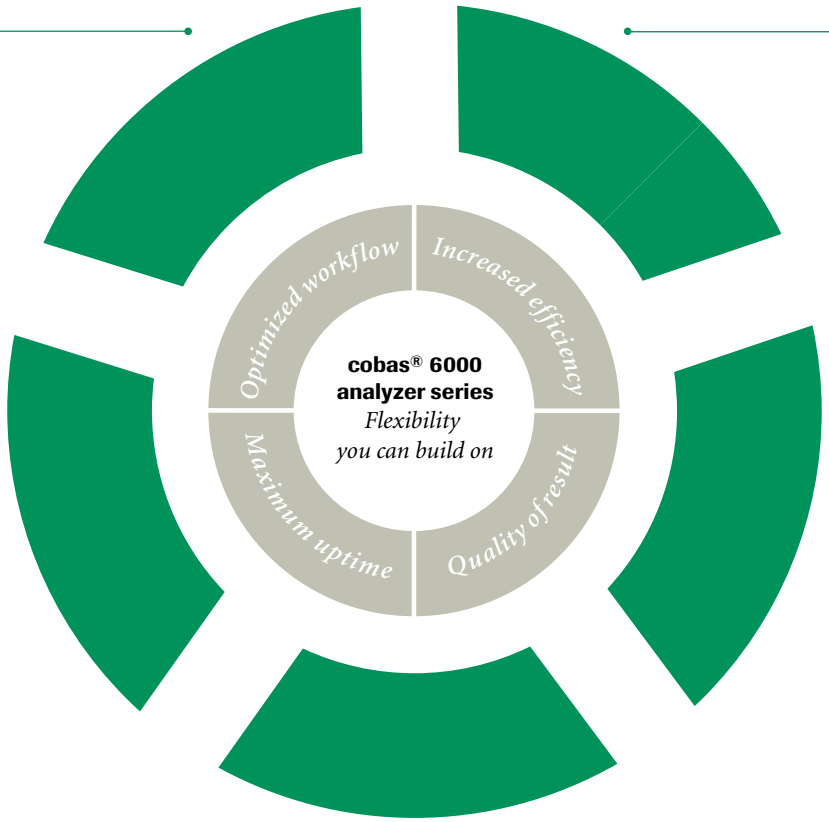
cobas® 6000 analyzer series

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:

Seamless implementation

Flexible consolidation



Proven system performance

Unique reagent concept

Superior analytical standards

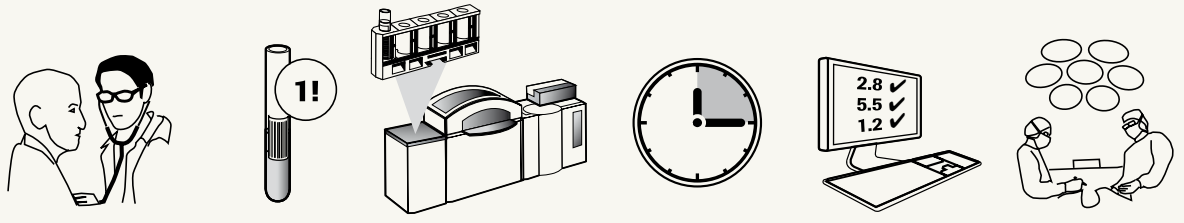
"With the cobas 6000, routine and STAT tests have been combined in a single analyzer. We can offer a broader menu and reduce the number of instruments"

Dr. Pier Mario Gerthoux, Italy

Flexible consolidation
Ready for the unexpected

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
- Seamlessly integrates pre- and post-analytical solutions
- Can expand existing system configurations onsite



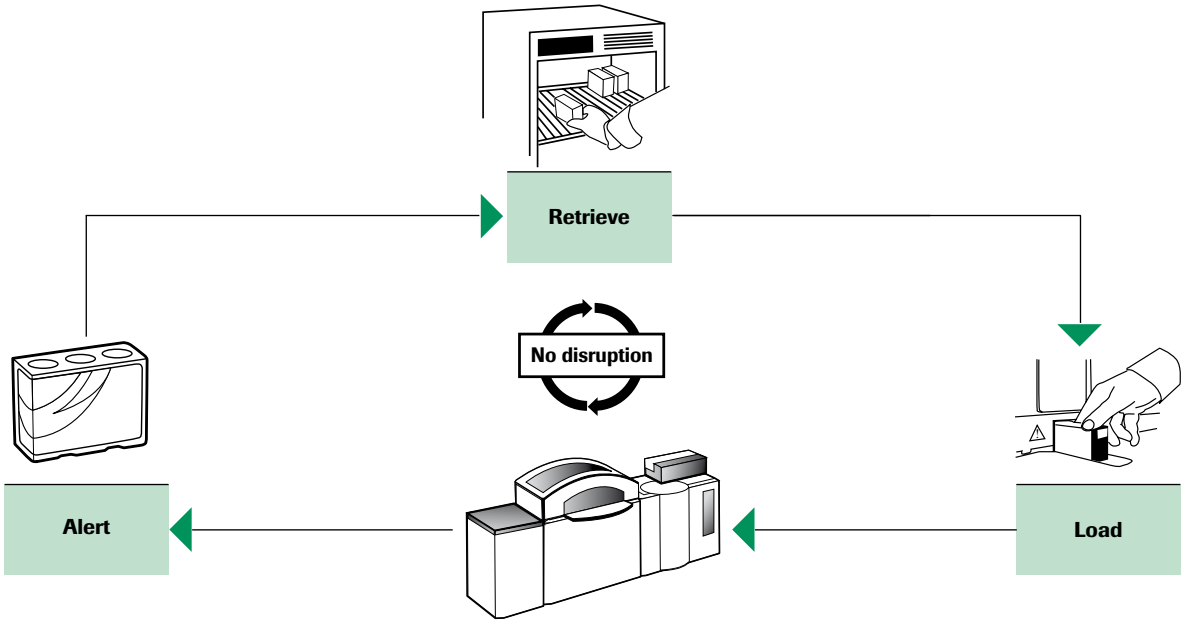
*"The lab has already seen a 20% savings in reagent costs in the first 4 months of operation…
The size of cobas reagent packs is very small so we don't need as much storage space as we did previously"*

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.

- One grip handling without preparation for most reagents
- "On the fly" loading of chemistry reagents during operation
- Interchangeable with other **cobas** Serum Work Area systems
- Economic usage with high stabilities and convenient kit sizes



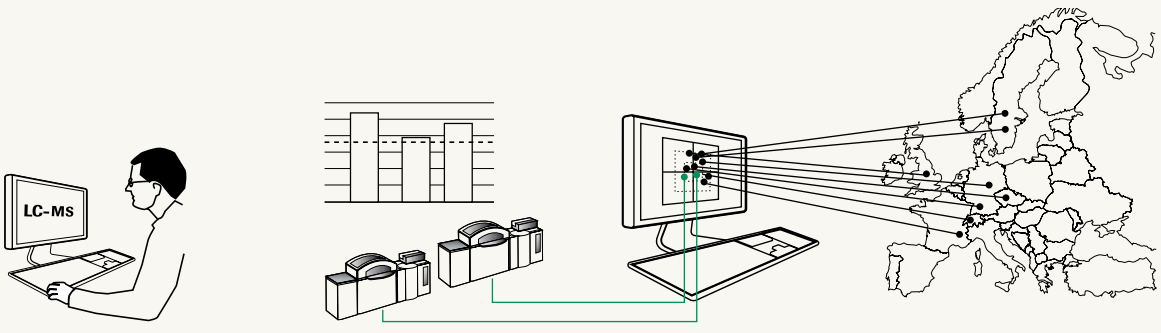
"We looked at the competition but we felt that Roche has the best system. We performed studies for precision and accuracy on Roche tests. We also discussed with colleagues in other labs and found the quality to be very high"

Dr. Pier Mario Gerthoux, Italy

Superior analytical standards
Right the first time

High performing labs stake their reputation on quality. The trust of their clinicians is paramount. The **cobas** 6000 analyzer series inspires trust and confidence by reaching superior standards of analytical performance.

- 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



Methodological traceability | **Benchmarking** | **Peer comparison** | **Network standardization**

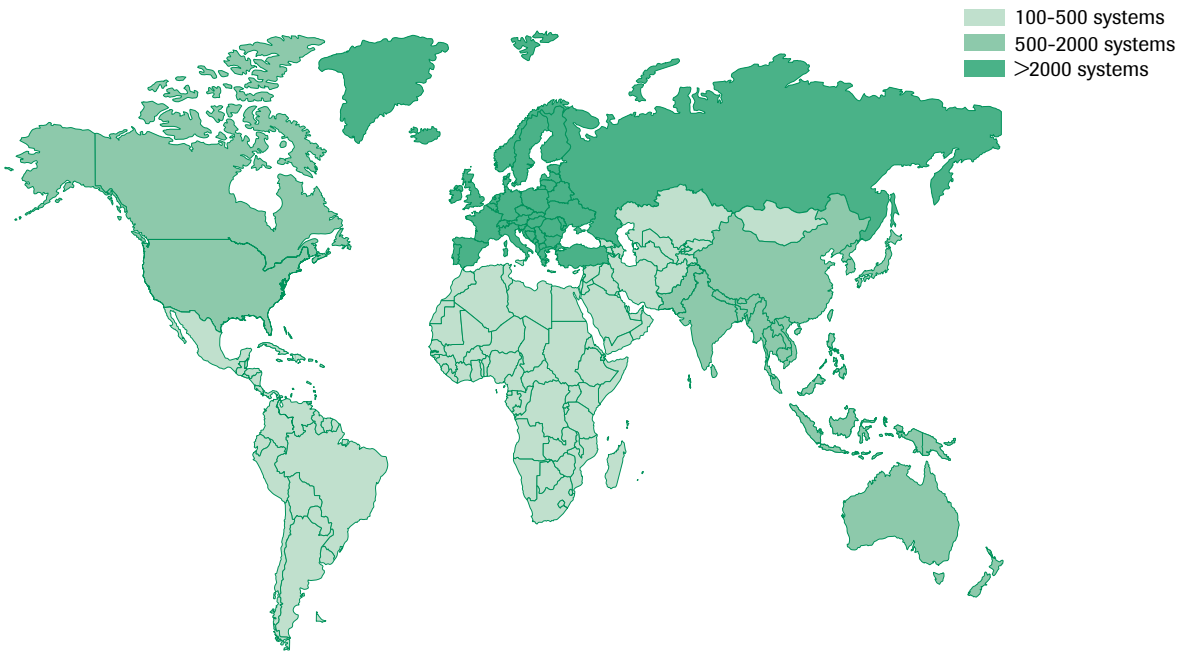
"Our experience has shown the Roche analyzers to be very robust and require low maintenance" *Dr. Jos Pouwels, The Netherlands*

Proven system performance
Maximum system uptime

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

- Partnership with Hitachi: 30 years as a total solution provider
- Over 4,000 systems and over 6,000 modules installed in over 40 countries
- Greatly reduced and automated maintenance
- Over 99% observed system uptime*

** Source: Internal Roche US service reports*



"The other thing that Roche offered that the other companies didn't offer was project management. They stood by us and did all the project management including all the installation drawings. That allowed me to keep running the lab rather than having to line up third party resources"

Gwin Filleman MBA, MT(ASCP), USA

Seamless implementation

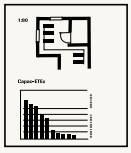
With you every step of the way

High performing labs cannot afford complex installations and long ramp-up periods. Roche's team of experienced lab process consultants and engineers ensure the **cobas** 6000 analyzer series is seamlessly implemented and well supported.

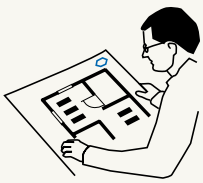
- Tailor-made solutions through work-process consultations
- Optimum lab design within challenging environmental constraints
- Experienced project management for seamless implementation
- Timely and efficient routine service and support

Work process consultation

Simulation tools



Lab design



Project management

After sales support

cobas® 6000 analyzer series

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

"The range of tests offered by Roche was the most extensive and with analyzers and reagents from one company, they were well ahead in terms of total scope of supply"

Dr. rer. nat. Reinhard Dreisch, Germany

cobas modular platform *Flexibility you can build on*

With the **cobas** modular platform (**cobas** 4000 and 6000 analyzer series and **cobas** 8000 modular analyzer series) Roche has developed a platform concept based on a common architecture that delivers tailor-made solutions for diverse workload and testing requirements.
The **cobas** modular platform is designed to reduce the complexity of laboratory operation and provide efficient and compatible solutions for network co-operation.

Common applications and analytical technologies
- Ensures comparable patient results
- Combines routine and innovative testing

Common reagent concept
- Simplifies logistics
- Allows efficient use of reagents

Common user interface
- Requires less training
- Supports staff flexibility

MODULAR *PRE-ANALYTICS* **EVO** *Optimizing workflow efficiency*

Proven and reliable Total Lab Automation with expert consultancy services:
- Compact configurations and flexible design ensure seamless connection to the **cobas** 6000 analyzer series
- Centrifugation, decapping, aliquotting, labeling, recapping and sorting functionalities reduce manual tasks and standardize pre-analytical processes
- Support of both primary and secondary workflow handling facilitates shorter and more predictable turnaround times

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cobas® 6000 analyzer series

cobas e 601 assay menu

Thyroid function
Anti-TG
Anti-TPO
Anti-TSHR
Calcitonin[1]
FT3
FT4
T3
T4
T-Uptake
Tg
Tg hs[1]
TSH

Fertility / hormones
ACTH
C peptide
Cortisol
DHEA-S
Estradiol
FSH
hCG+β
hCG STAT
Insulin
LH
Progesterone
Prolactin
SHBG
Testosterone

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

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

Infectious diseases
Anti-HAV total
Anti-HAV IgM
Anti-HBc
Anti-HBc IgM
Anti-HBe
Anti-HBs
Anti-HCV
HBeAg
HBsAg
HBsAg confirmatory
HBsAg quantification
CMV IgG
CMV IgM
CMV IgG Avidity
HSV-1
HSV-2
HIV Antigen
HIV Antigen confirmatory
HIV combi
HIV combi PT
Rubella IgG
Rubella IgM
Toxo IgG
Toxo IgM

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Maternal care
free β hCG
PAPP-A
PlGF
sFLT-1

Rheumatoid Arthritis
Anti-CCP

Anemia
Ferritin
Folate
RBC Folate
Vitamin B12

Critical care
IL6
BRAHMS PCT
S100

Bone markers
β-CrossLaps
Vitamin D3 (25-OH)
Intact PTH
N-MID Osteocalcin
P1NP
PTH STAT

Others
IgE

[1] *Assays currently under development*
Last Update 02/2011

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cobas® 6000 analyzer series

cobas c 501 assay menu

Substrates
Albumin (BCP+BCG)
Ammonia
Bicarbonate
Bilirubin-direct
Bilirubin-total
Calcium
Cholesterol
HDL Cholesterol
LDL Cholesterol
Creatinine enz.
Creatinine Jaffé
Fructosamine
Glucose
Iron
Lactate
Magnesium
Phosphorus
Total Protein
Total Protein U / CSF
Triglycerides
Triglycerides GB
UIBC
Urea / BUN
Uric Acid

Enzymes
ACP
ALP
ALT / GPT
Amylase-tot.
Amylase-pancr.
AST / GOT
Cholinesterase Acetyl
Cholinesterase Butyryl
Cholinesterase Dibucain
CK
CK-MB
GGT
GLDH
HBDH
LDH
Lipase

Electrolytes (ISE)
Chloride
Potassium
Sodium

Proteins
α1-Acid Glycoprotein
α1-Antitrypsin
α1-Microglobulin
β2-Microglobulin
Albumin (immuno.)
APO A1
APO B
ASLO
C3c
C4
Ceruloplasmin
CRP
CRP High Sensitivity
Cystatin C
Ferritin
Haptoglobin
HbA1c (whole blood + hemolysate)
Homocysteine[2]
IgA
IgG
IgM
Kappa Light chains
Freelite™ Human Kappa Free[2]
Lambda Light chains
Freelite™ Human Lambda Free[2]
Lipoprotein (a)
Myoglobin
Prealbumin
RF
Soluble Transferrin Receptor
Transferrin

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Drugs of abuse (DAT)
Amphetamines
Barbiturates
Benzodiazepines
Cannabinoids
Cocaine
LSD
Ethanol
Methadone
Methadone Methabolite (EDDP)
Methaqualone
Opiates
Oxycodone
Phencyclidine
Propoxyphene

Therapeutic drug monitoring (TDM)
Acetaminophen
Amikacin
Carbamazepine
Cyclosporine [1]
Digitoxin
Digoxin
Gentamicin
Lidocaine [1]
Lithium
MPA-T
NAPA
Phenobarbital
Phenytoin
Procainamide
Quinidine
Salicylate
Theophylline
Tobramycin
Valproic Acid
Vancomycin

Others
D-Dimer
Anti-Thrombin III
TPLA-Trepanoma pallidum

[1] *Assays currently under development*
[2] *Partner Channel*
Last Update 02/2011

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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: **cobas e** 601 modules: **cobas c** 501 | **e** 601 modules:	 1 to 2 modules 1 to 2 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 1,000 up to 2,000 tests/hr 170 up to 340 tests/hr 1,170 up to 2,170 tests/hr	- overall - with **cobas c** 501 modules - with **cobas e** 601 modules - 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: Rack types: Tray: STAT port:	5 position rack, RD standard rack Routine, STAT, Control, Calibrator, Rerun (manual), Wash Tray with 15 racks/75 samples, RD standard tray STAT samples are processed with priority
Sample container types	Primary tubes: Sample cup: Micro cup: Cups on tube: False bottom tube (FBT):	5 to 10 mL; 16 x 100, 16 x 75, 13 x 100, 13 x 75 mm 2.5 mL 1.5 mL, (exception: **cobas e** 601 module) Cup on top of a 16 x 75/100 mm tube; Cup on top of one non standard tube 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: Sample cup: Micro cup (FBT):	700 µL 100 µL 50 µL
Sample barcode types	Code 128; Codabar (NW 7); Interleaved 2 of 5; Code 39	

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cobas® 6000 analyzer series
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 datastation 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^3, (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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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)**
- **Troponin I**
- **Myoglobin**
- **CK-MB**
- **NT-proBNP**
- **hCG**
- **Intra-operative PTH**

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

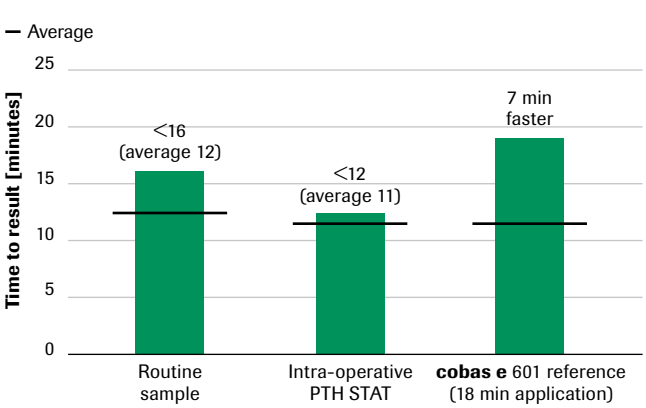

Fig. 1: Night shift scenario, MGH

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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).

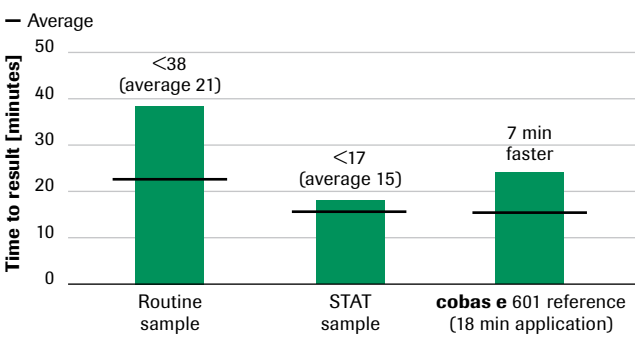

Fig. 2: Peak workload scenario, Regensburg

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 Panel[1] + 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).

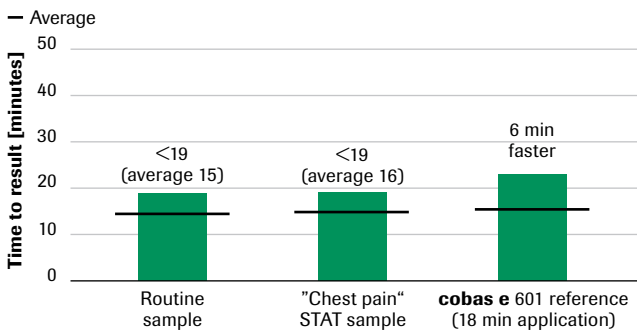

Fig. 3: Night shift scenario, Henri Mondor

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..."*

Prof. Dr. med. G. Schmitz, Regensburg

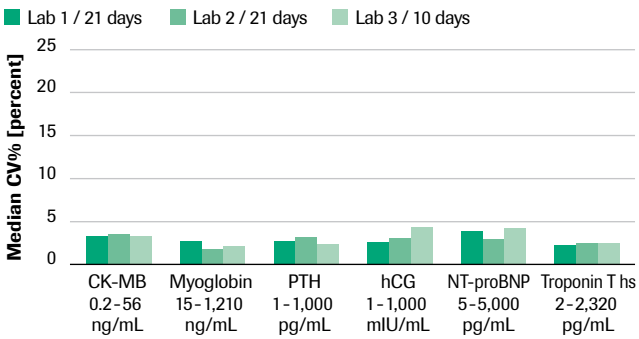

*Fig. 4: Total precision according to CLSI for 9 min STAT applications on the **cobas e** 601 module*

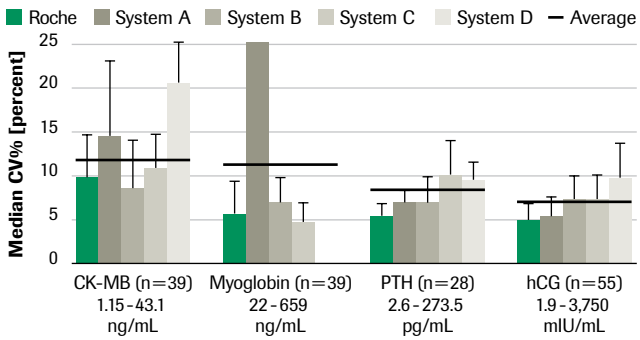

Fig. 6: Median CV% calculated using consolidated data from an external quality survey (2008 until January 2009)

Fast time to result

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

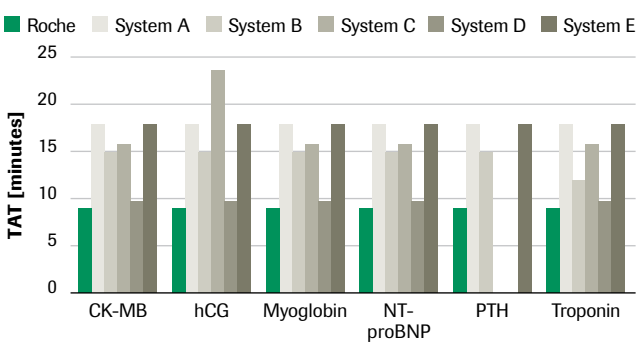

Fig. 5: Analytical time to result comparison of available STAT tests

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 guidelines[2] 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 recommendations[3] for turnaround time.

	C Tn T	C Tn I
Aid in the differential diagnosis of acute coronary syndrome (ACS) to identifiy acute myocardial infaction (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."

Dr. S. Moutereau, Henri Mondor

*"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).

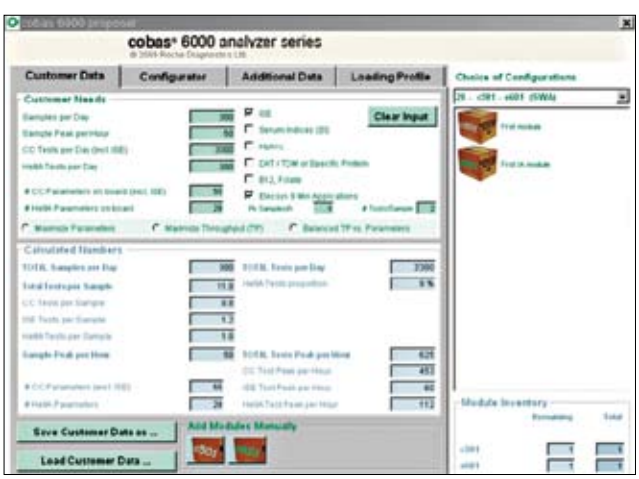

*Fig. 8: **cobas**® 6000 simulation tool*

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, CO_2, 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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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.

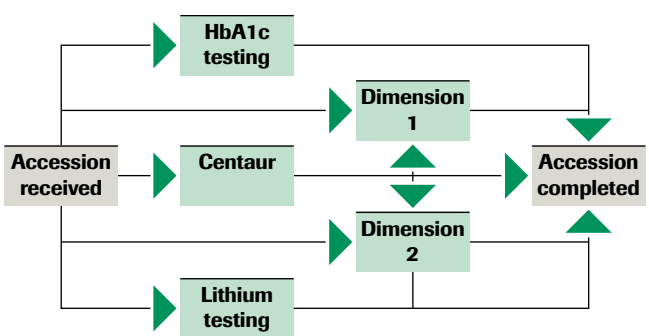

Fig. 1: Before scenario workflow

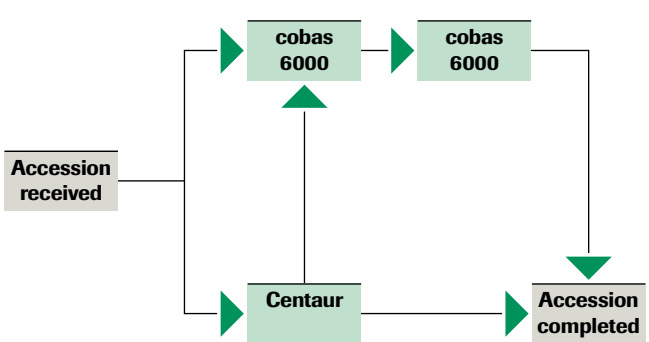

Fig. 2: After scenario workflow

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Life needs answers

"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.

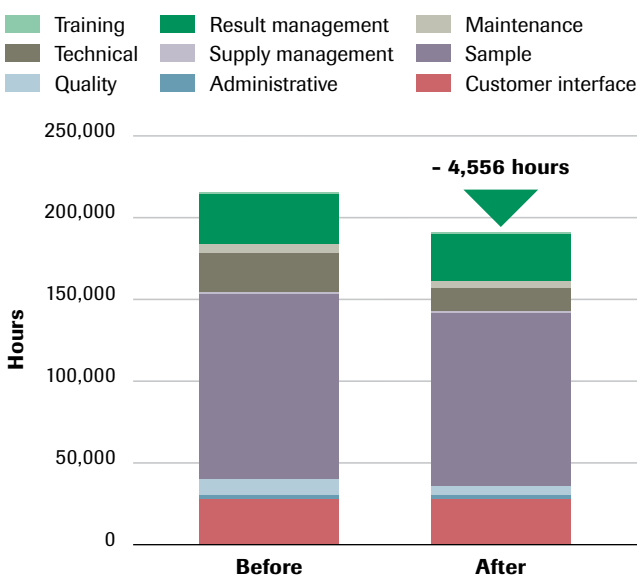

Fig. 3: Annualized staff activity comparison in hours

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%.

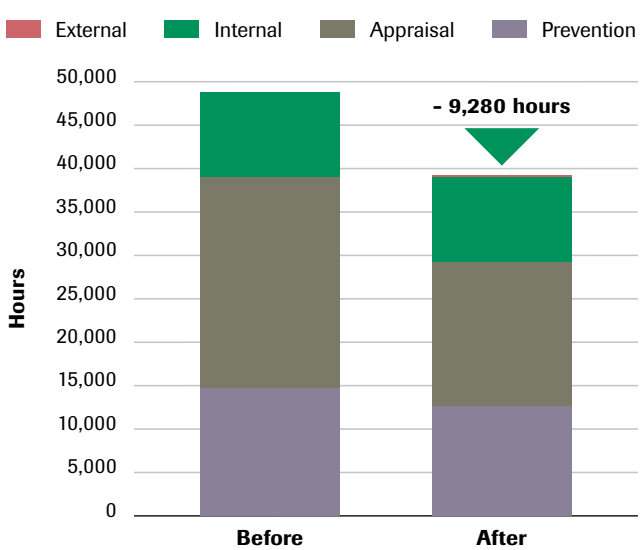

Fig. 4: Annualized staff activity comparison in hours dedicated to ensuring quality

"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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