Roche User Group 2019

cobas® pure integrated solutions
The next Serum Work Area solution from Roche

Ian Mackay    RDNZ
Serum Work Area Systems Portfolio

Today and tomorrow – current roadmap

Integration level
- Integrated automation
- Connected automation
- Standalone automation
- Standalone SWA
- Virtual automation
- Standalone

Throughput
- cobas® 8000 modular analyzer series
- cobas® 6000 analyzer series
- cobas® 4000 analyzer series
Serum Work Area Systems Portfolio

Today and tomorrow – current roadmap

Integration level
- Integrated automation
- Connected automation
- Standalone automation
- Standalone SWA
- Virtual automation
- Standalone

Throughput

- cobas® 4000 analyzer series
- cobas® 6000 analyzer series
- cobas® pro integrated solutions
- cobas® 8000 modular analyzer
- cobas® 800x
- cobas® pure integrated solutions

Connected
- Standalone
- Virtual

Standalone
- SWA
- automation

Standalone
## cobas® SWA instrument portfolio

### Evolving the portfolio

<table>
<thead>
<tr>
<th>Instrument Series</th>
<th>Volume Description</th>
<th>Tests/hour</th>
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<tbody>
<tr>
<td><strong>cobas® 8000 modular analyzer series</strong></td>
<td>High to extra high volume</td>
<td>Up to 8,100</td>
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<td><strong>cobas® pro integrated solutions</strong></td>
<td>Medium to high volume</td>
<td>Up to 2,200</td>
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<td><strong>cobas® 6000 analyzer series</strong></td>
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<td><strong>cobas® pure integrated solutions</strong></td>
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<tr>
<td><strong>cobas® 4000 analyzer series</strong></td>
<td>Low volume</td>
<td>Up to 530</td>
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</table>
cobas® pure integrated solutions
The next Serum Work Area solution from Roche

**cobas e 402**
*IM Module*
- Up to 120 tests/hour
- 28 reagent positions

**cobas c 303**
*CC module incl. ISE*
- Up to 450 photometric tests/hour
- Up to 450 ISE test/hour
- Up to 750 tests/hour in a mixed mode
- 42 reagent positions

**Sample Buffer**
100 samples capacity

**Footprint**
2m² for SWA configuration

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**Immunochrometry**

**Serum Work Area**

**Clinical chemistry**
cobas® pure integrated solutions
Addressing the needs of various lab settings

**Lab Settings**

- **Small hospital labs**
- **Small private labs**
- **Networks**

**Features**

- **Reliability and Precision**
- **Compact size**
- **Less hands on time**
- **Suitability for both specialized and routine testing**
- **Seamless performance and usability across network organizations**
Reduced system preparation and hands on time

Reduced maintenance

Intelligent reagent loading

Automated calibration
Free up staff time with significantly reduced maintenance efforts

Automated maintenance

- Up to 70% less daily hands-on time for maintenance
- Automating the vast majority of daily manual tasks
- Only 6 minutes daily operator intervention
- Providing step-by-step guidance for less frequently performed maintenance actions

Maintenance effort

Time spent on value added tasks

Up to 70% less daily hands on time for maintenance
Ensure continuous operation with a predictive loading list

- Less time spent on planning supplies for the day
- Eliminate the risk of interruptions caused by supply shortage
Save time and effort with cobas® AutoCal

Lot-specific contribution

Instrument-specific contribution

Automated adjustment of the calibration curve

Up to 56% less calibration events
cobas® AutoCal – reducing calibration effort in the lab

Full physical calibration on Roche master instrument

Signal/concentration pairs transferred to Reagent Container File

Signal

Concentration

RCF Lot 1
cobas® AutoCal – reducing calibration effort in the lab

First installation of assay at customer lab – one-time full physical calibration

Slope and Intercept are calculated, and stored for the specific instrument and test

\[ Y = ax + b \]
cobas® AutoCal – reducing calibration effort in the lab

Each new lot contains an updated RCF with new signal values for the re-calculation of the signals at the customer site.

Linear transformation of master calibration curve to the instrument.

\[ Y = ax + b \]

Signal (master) vs. Calculated signal (customer)
Which parameters support cobas® Autocal?

Calibration stability determines which parameters will support AutoCal

70% of routine testing parameters

Routine parameters account for 80% of test volume

Calibration stability over shelf life

Instrument stability over lifetime

New instrument calibration only if sensitive parts like sample syringe stepper motor exchanged

No influence on calibration if following exchanged—cuvettes, lamp, probes, syringes, wash station nozzles
Maximize instrument uptime with Roche Remote CareGiver

Remote Support
Resolve issues faster with remote diagnostics and screen sharing

Proactive Maintenance
A.I.-powered machine learning algorithms for instrument-specific insights

Digital Updates
Experience faster remote software and assay updates

Faster issue resolution
cobas pure footprint

Immunochemistry
≈ 1.2 m² footprint

Serum Work Area
≈ 2.0 m² footprint

Clinical chemistry
≈ 1.2 m² footprint

Width:
1.5 m

Height:
1.4 m

Depth:
0.8 m

Width:
2.45 m

Height:
1.4 m

Depth:
0.8 m

Width:
1.5 m

Height:
1.4 m

Depth:
0.8 m
Maximize reagent utilization with longest onboard stability

Up to 6 months onboard stability
**cobas c 303**: 42 reagent positions

Up to 4 months onboard stability
**cobas e 402**: 28 reagent positions

Channel capacity matching both routine and specialized testing needs

STAT & Routine application using the same reagent pack
Ready to use reagents

No preparing

No mixing

No waiting

No pre-opening

Take out of the fridge ➔ Load onto the analyzer
Enable error-free handling with RFID-tagged reagents and consumables

Efficient and reliable scanning

Traceability
Ensure peace of mind for your team with reliable and safe solutions

**Sample**
- Liquid Level Detection
- Foam detection
- Clot detection

**Reagent**
- Liquid Level Detection
- Foam detection

**Clinical Chemistry**
- Carryover evasion program
- Ultrasonic Mixing of sample and reagent

**Immunochrometry**
- Single-use AssayTip
- Single-use AssayCup
cobas® harmonised integrated solutions

Consistent operation and simple training

Consistent results across locations

Same technologies

Same assay menu

Delivering seamless design today and into the future
Asia Manufacturing site
To meet Asia Pacific's growing demand Roche has invested in a new, best in class reagent manufacturing facility in the Suzhou Industrial Park in Suzhou, China.

Using state of the art equipment to optimise manufacturing automation, the new site will bring a reliable supply of products that adhere to the same global quality and compliance standards as all of our manufacturing sites.
Asia Manufacturing Site

The most important aspects you need to know about AMS

- Products made in China serve the same high quality standards as in Europe
- Roche Suzhou follows China FDA (CFDA) guidelines and ISO 13485.
Asia Manufacturing Site

The most important aspects you need to know about AMS

Sustainability

• Designed to meet the highest environmental standards

• Solar panel roof installations to cover 78% of the energy needs of the building

• Treatment of waste water
**Timelines and Activities at Souzhou**

*The products*

100 products – 42 clinical chemistry and 58 immunoassays

- Secure supply using two manufacturing sites
- Begin to supply some products at the end of this year and through 2020
- E2G in planning phase – start from 2021
### Diagnostics Operations Suzhou

*Label change as consequence of Manufacturer Change*

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Diagnostics Operations Suzhou
Product Label

The Global Material No will change in the last 3 digits

Made in China
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Doing now what patients need next