



cobas[®] pure integrated solutions
Simplicity meets Excellence

For the use only of registered medical practitioners or a hospital or a laboratory

cobas[®]



01 cobas e 402 analytical unit¹

Up to **120 Immunochemistry** tests per hour
28 reagent positions

02 Sample Supply unit¹

Up to **50** samples direct loading
Up to **50** samples direct unloading
STAT port

03 cobas c 303 analytical unit¹

Up to **450 photometric** tests per hour
Up to **450 ISE** tests per hour
Up to **750 tests** per hour
(mixed mode photometric and ISE)
42 reagent positions

A row of white diagnostic analyzers with blue-tinted glass covers, arranged in a laboratory. The background is a blurred view of a modern lab with large windows and greenery outside.

cobas® pure integrated solutions

Simplicity meets Excellence

Today more than ever, the importance of accurate and timely diagnostics is clearly understood. The journey from blood collection to the final test result, however, requires the highest level of dedication, expertise and diligence of the laboratory staff.

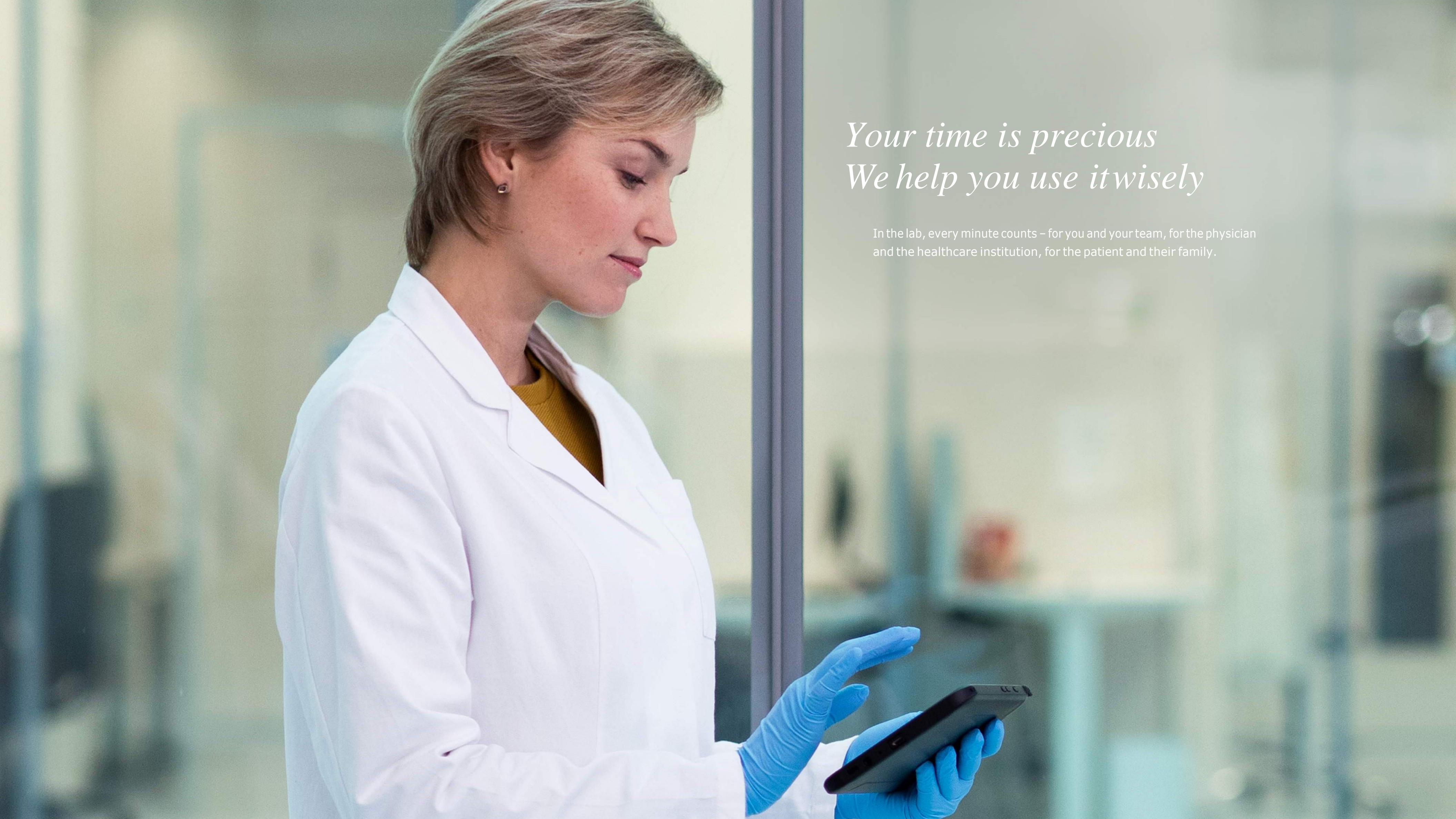
To support you in this, Roche has developed innovative integrated solutions renowned for quality and excellence.

cobas® pure integrated solutions is the newest member of the **cobas®** family of systems which is designed to deliver excellence, while at the same time simplifying your daily work. **cobas® pure** combines clinical chemistry, immunochemistry and ISE testing on a footprint of just 2 square meters, giving access to our broad menu of more than 230 parameters – including many unique high medical value assays to labs who have to deal with limited space.

To simplify daily operation, **cobas® pure** comes with new features that minimize the hands on work for the operators, thus saving precious time.

To ensure simple and effective work for network organizations, **cobas® pure** provides fully standardized results and operation to **cobas® pro** integrated solutions – Roche's latest analyzer designed for larger labs.

Because simplifying any step of the journey can help deliver fast and accurate diagnosis.

A female scientist with short blonde hair, wearing a white lab coat over a yellow top and blue gloves, is looking down at a tablet computer she is holding. She is standing in a laboratory with shelves of equipment in the background.

*Your time is precious
We help you use it wisely*

In the lab, every minute counts – for you and your team, for the physician and the healthcare institution, for the patient and their family.





*Empower your physicians
to take action faster*

Standards are being raised across health systems, as patient and physician satisfaction and fast clinical decision making are becoming more prominent quality metrics. Choosing an analyzer that supports short and predictable turnaround times at peak times is a key to meet these standards.

Get answers fast with short and predictable turnaround times

cobas® pure integrated solutions is designed to support fast and predictable turnaround times across all assays.

93% of Roche immunoassays have reaction time of 18 minutes or less, with STAT assays having just 9 min reactiontime.²

To offer full transparency, **cobas® pure integrated solutions** allows the operator to see the time to result per sample and per test as well as the time to last result on all ordered tests.

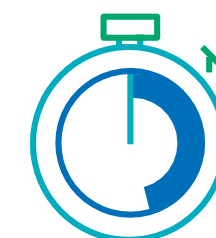
Roche reaction times²



9 minutes




18 minutes



27 minutes





Benefit from reduced system preparation and hands-on time

Free up staff time with reduced hands-on maintenance efforts


With **cobas® pure** integrated solutions, every effort has been made to reduce hands-on maintenance tasks to a minimum. The new and smart concept of self-operating maintenance executes maintenance tasks automatically in the background and reduces the manual burden of daily maintenance to 8 min.¹

Save time and costs with cobas® AutoCal

The clinical chemistry module of **cobas® pure** integrated solutions comes with a significantly simplified calibration concept – automated calibration. With **cobas® AutoCal**, new reagent lots for the majority of clinical chemistry tests are calibrated automatically, without the need for manual calibration. This can lead to 56% less calibration events, saving up to 105 hours of hands-on time yearly.*³

* For a common, daily routine workload, as compared to **cobas** 6000 <501|601> Mid Volume Commercial Lab





*Your space is limited
We help you make the best of it*

cobas® pure integrated solutions is designed to deliver true productivity for your lab and access to our complete Serum Work Area assay menu on a compact footprint of just 2 square meters.

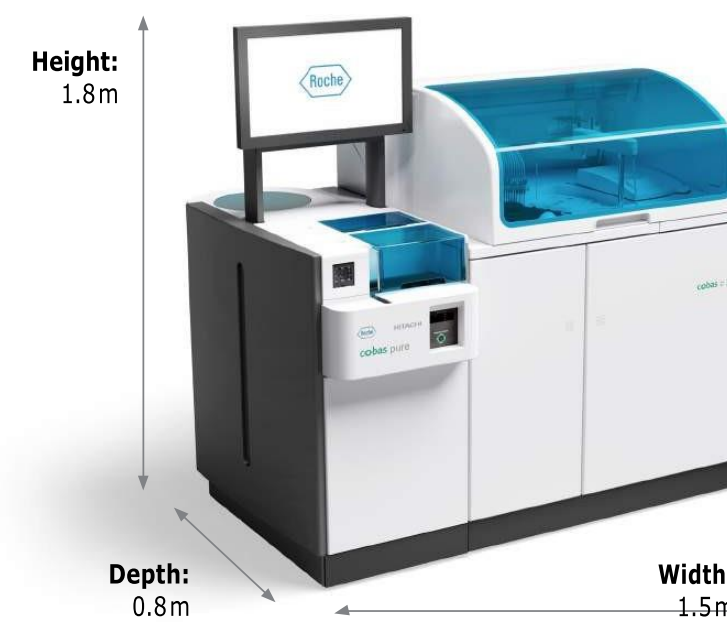
*Three compact configurations**



Immunochemistry Configuration
Footprint $\approx 1.2 \text{ m}^2$



Serum Work Area Configuration
Footprint $\approx 2.0 \text{ m}^2$



Clinical Chemistry Configuration
Footprint $\approx 1.2 \text{ m}^2$

*The width and depth dimensions shown here are the floor(footprint) dimensions⁴



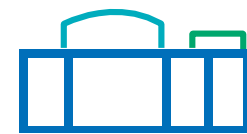
Consolidate clinical chemistry & immunochemistry on a single platform



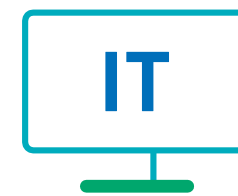
One
sample tube for all CC &
IM tests to handle



One
set of results
to track



One
platform to manage
and to be trained on



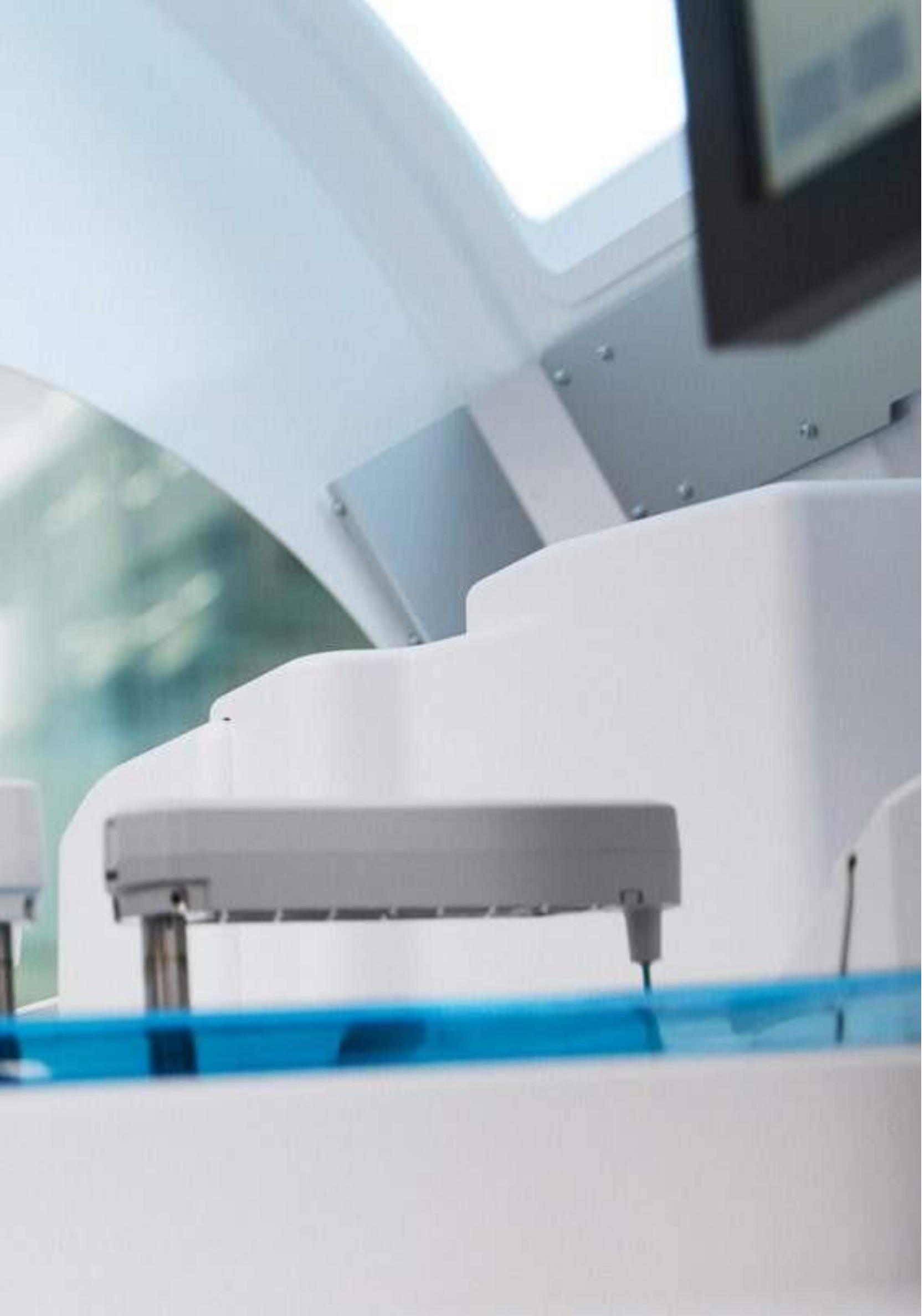
One
user interface to
interact with



One
manufacturer to
partner with

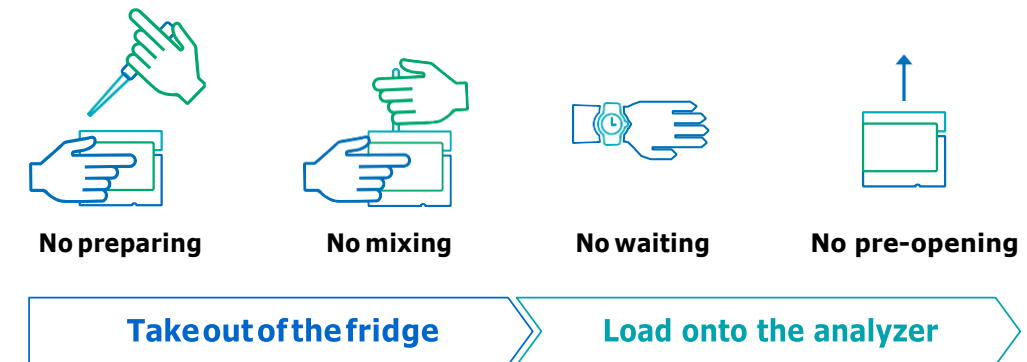
A female scientist with short blonde hair, wearing a white lab coat over a yellow top, is working in a laboratory. She is wearing blue gloves and holding a black reagent carrier with several white vials. She is looking down at the carrier. In the background, there is a large window with a grid pattern and a piece of laboratory equipment with a blue tray.

*Increase productivity with our
improved reagent carriers in clinical
chemistry and immunochemistry*



Ready to use reagents

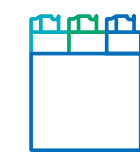
cobas® pure uses the latest reagent generation from Roche – **cobas e** pack green and **cobas c** pack green. These reagents do not require any preparation, mixing, waiting or pre-opening. The operator can simply take them out of the fridge and load them directly onto the analyzer.



Industry's leading onboard stability

Using space intelligently is about achieving the highest output within the existing space. The average onboard stability for the immunochemistry reagents is 110 days, with 98% of the assays having an onboard stability of 4 months. The average on board stability for clinical chemistry is 137 days, with 57% of the reagents having an onboard stability of 6 months.^{5,6}

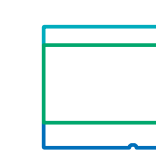
Immunochemistry⁵



cobas e
pack green

- Up to 4 months onboard stability
- ≈ 3 times longer average onboard stability compared to previous generation systems


Clinical chemistry⁶



cobas c
pack green

- Up to 6 months onboard stability
- ≈ 2 times longer average onboard stability compared to previous generation systems





*Your team is pushed to their limits
We help them focus on the tasks that matter*

Whilst the pressure to deliver continuously increases, keeping your team engaged and focused on value-adding tasks can be difficult but is of paramount importance for your lab's success. The **cobas® pure** integrated solutions is designed to eliminate hurdles that may cause unnecessary stress.

Safety of results¹

Disposable AssayTips/AssayCups

cobas pure immunochemistry analytical unit utilizes single-use disposable AssayTips and AssayCups to completely eliminate the risk of sample carry over.

Carryover evasion program

The sample probes on the **cobas pure** clinical chemistry analytical unit are rinsed

inside and outside with deionized water each time after dispensing a sample. Additionally, for applications that are sensitive to sample carryover, special wash can be programmed for an extra wash of reagent probes, sample probes and reaction cells with basic and acidic wash solutions.

Ultrasonic Mixing

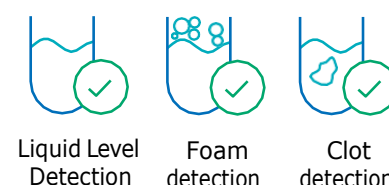
The **cobas pure** clinical chemistry analytical unit features ultrasonic mixing for non-contact mixing of sample and reagent to eliminate the risk of carryover during this event.

Reliability

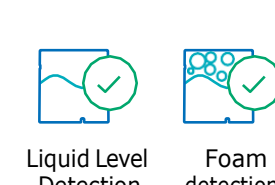
cobas® pure integrated solutions is designed to deliver the reliability that Roche is known for. With more than 75,000 analytical units globally, the **cobas** family of solutions demonstrates a distinctive uptime* of more than 99%.⁷ Having a reliable analyzer means less interruption of services and less time spent on troubleshooting, thus higher productivity with more predictable turnaround times.

*Uptime: Percentage of the time when system is up and running vs. the time the system is not running due to unplanned incidents.
Calculation: $(365 \text{ days} / \text{Mean time between repair visit}) \times (\text{Mean time for repair visit} + \text{Travel Time})^7$

Sample



Reagent



Clinical Chemistry



Immunochemistry



99 % uptime⁷






Bring more confidence to your team with reliable and safe solutions

Unplanned downtime and lack of confidence in results are some of the most stressful things that can happen in the lab. They shift attention to time-consuming, hands-on workarounds or sample reruns which can affect staff morale and motivation.

Additionally, they pose risks to the quality of results and the lab's reputation. With **cobas® pure integrated solutions** we deliver distinctive reliability through sound system architecture and confidence in the results through various safety features.



*Enable your team to work more
efficiently through standardized
solutions*

Lab standardization enables you to do more work on fewer instruments, through consolidation of workflow, systems and reagents. Standardization also provides efficient and compatible solutions for network cooperation.



Essential benefits of standardization

Improved speed and accuracy of care

Same reagents and detection technology mean standardized reference ranges which improve the speed and accuracy of care.

Simplified training and staff allocation

Common user interfaces between our **cobas**[®] systems simplify training and allow for flexible staff allocation as healthcare centers are consolidating into larger integrated health networks.

Optimized patient management

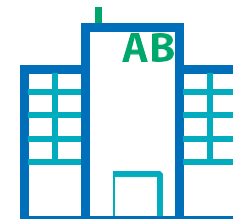
Consistent results over time and across different locations enable optimized patient management.

**Same
reagents**

**Same
detection technology**

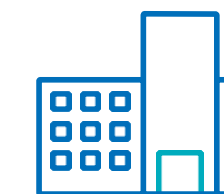
**Same
reference ranges**

**Common
user interfaces**



Central laboratory

cobas[®] 8000 modular analyzer series
cobas[®] **pro** integrated solutions



Satellite laboratory

cobas[®] **pro** integrated solutions
cobas[®] **pure** integrated solutions



Emergency laboratory

cobas[®] **pure** integrated solutions



Independent laboratory

cobas[®] 8000 analyzer series
cobas[®] **pro** integrated solutions
cobas[®] **pure** integrated solutions





*Your future is unpredictable
We help you succeed through continuous
access to innovations*

Choosing the right solution and vendor to partner with is not a small undertaking – it is a choice that impacts your lab's ability to fulfill performance and quality standards but also your ability to remain competitive. At Roche we believe in the power of innovation to advance and improve diagnostics – for a better future of the patients and your lab.

*Support better outcomes by
delivering greater medical value*





Focused innovation of our assay portfolio

Extending evidence base

Extending the evidence-base for existing assays through clinical studies to generate higher awareness and broader access to innovation.

New claims for existing assays

Generating new claims for existing assays for a wider range of application.

Discovery of new assays

Menu expansion in the areas of unmet medical needs to help clinicians improve outcomes for their patients.

Bring Personalized Healthcare to clinical practice

Supporting better patient care, contributing to health economics and empowering labs to play a greater role in medical decision making.

Commitment to exceptional assay quality

Advanced assay design

- Outstanding precision across measuring range
- High sensitivity in areas where it matters
- Wider measuring ranges, fewer dilutions and repeats

Designed for convenience

- Short and predictable assay Turn Around Times
- Low sample volume
- No reagent preparation required

Consistent, standardized results

- Consistent patient results across all platforms
- Excellent lot-to-lot consistency
- Assays standardized against reference method or reference material

*Introducing the new generation
of solutions from Roche –
cobas® integrated solutions*



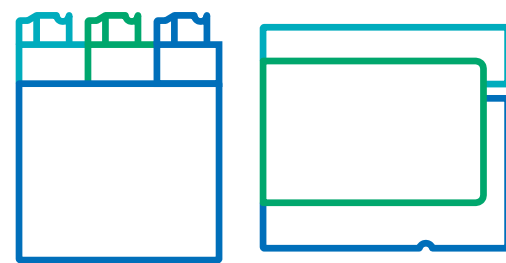


cobas® pure integrated solutions



cobas® pro integrated solutions

Delivering seamless design today and into the future



Shared reagents packs



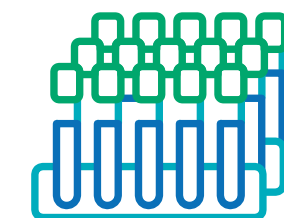
Consistent results



Consistent operation



Same technologies



Same assay menu



cobas[®] pure integrated solutions

General technical specifications

Dimensions and Weights

| | Width | Depth | Height | Weight |
|---|---------------|-------------|-----------------------|----------------------|
| Sample Supply Unit (SSU), (excl. STAT port and incl. touch screen monitor) | 450 17.7 | 800 31.5 | 1,750 mm 70.0 inch | 200 kg 441 lb |
| cobas c 303 (incl. ISE) analytical unit | 1,000 39.4 | 800 31.5 | 1,375 mm 54.1 inch | 400 kg 882 lb |
| cobas e 402 analytical unit | 1,000 39.4 | 800 31.5 | 1,375 mm 54.1 inch | 400 kg 882 lb |
| SWA System Configuration <c 303 SSU e402> | 2,450 96.5 | 800 31.5 | 1,750 mm 70.0 inch | 1,000 kg 1,764 lb |

Specifications of the electrical power supply

| | |
|------------------------|--|
| Distance to system | ≤ 5 m (16 feet) |
| Electrical supply | Single Phase AC 200 / 208 / 220 / 230 / 240 V 50 / 60 Hz |
| Max. power fluctuation | ≤ 10% |
| Power consumption | ≤ 4.0 kVA Whole System: < 4.0 kVA SSU: < 0.5 kVA cobas c 303 AU: < 1.5 kVA cobas e 402 AU: < 2.0 kVA |

cobas[®] pure integrated solutions

General technical specifications continued

| | cobas c 303 (incl. ISE) | cobas e 402 |
|--|--|--|
| Deionized water supply and consumption | | |
| Distance to instrument | ≤ 5 m ≤ 16 feet | ≤ 5 m ≤ 16 feet |
| Conductivity | ≤ 1.0 μS/cm | ≤ 1.0 μS/cm |
| Water pressure | 50 to 340 kPa 0.5 to 3.4 bar | 50 to 340 kPa 0.5 to 3.4 bar |
| Water temperature | > 12 °C > 53.6 °F | ≥ 12 °C ≥ 53.6 °F |
| Approx. deionized water consumption | max. 16 L/h | max. 12 L/h |
| Maximum liquid waste volumes | | |
| Highly concentrated liquid waste flow rate | < 1.2 L/h | ≤ 3 L/h |
| Diluted liquid waste flowrate | < 14.8 L/h | ≤ 10 L/h |
| Environmental conditions during operation | | |
| Maximum altitude above sea level | 3,000 m | 3,000 m |
| Floor conditions | ≤ 1/200 or ≤ 0.5% inclination Bearing load ≥ 5 kN/m ² | ≤ 1/200 or ≤ 0.5% inclination Bearing load ≥ 5 kN/m ² |
| Ambient temperature | 0–2,000 m above sea level 18–32 °C (64.4–89.6 °F) > 2,000 m above sea level 18–30 °C (64.4–86 °F) | 0–2,000 m above sea level 18–32 °C (64.4–89.6 °F) > 2,000 m above sea level 18–30 °C (64.4–86 °F) |
| Ambient temperature fluctuation | ≤ 2 °C/hour (≤ 3.6 °F/h) | ≤ 2 °C/hour (≤ 3.6 °F/h) |
| Ambient humidity | 30 – 85% | 30 – 85% |



cobas e 402 analytical unit

Specifications

Specifications of the reagentsystem

| | |
|-----------------------------|---------------------------|
| Reagent pack types | cobas e pack green |
| Reagent loading/ unloading | Manual |
| Reagent Identification | RFID |
| Capacity of reagent disk | 28 reagent packs |
| Reagent storage temperature | 5 - 10 °C (41 - 50 °F) |

Specifications of the samplingsystem

| | |
|---------------------------------|------------------------|
| Sampling cycle time | 30 seconds |
| Sample pipetting volume | 4 - 60 µL (1 µL steps) |
| Sample Liquid level detection | Available |
| Sample clot detection | Available |
| Sample air aspiration detection | Available |

Specifications of the reactionsystem

| | |
|------------------------------------|-------------------------------|
| Number of incubator disk positions | 38 |
| Reaction volume | 120 µL |
| Incubator temperature | 37°C ± 0.3°C (98.6°F ± 0.5°F) |
| Reaction times for tests | 9/18/27 min |
| Mixer | Vortex |

Specifications of the ECL measuring system

| | |
|---------------------------|--------------------|
| Measuring Cell | ECL measuring cell |
| Number of measuring cells | 1 |
| Maximum throughput* | 120 tests/hour |

*Throughput may differ based on the mix of test orders per sample

Excellent performance, simple to use and beautifully designed. The new Immunochemistry analyzer – cobas e 402 analytical unit.



The new cobas c 303 analytical unit – combining photometric and ISE testing on a footprint of just 1.2 square meters.



cobas c 303 analytical unit

Specifications

Specifications of the reagent system

| | |
|-----------------------------|---------------------------|
| Reagent pack types | cobas c pack green |
| Reagent loading/unloading | Manual |
| Reagent Identification | RFID |
| Capacity of reagent disk | 42 reagent packs |
| Reagent storage temperature | 5 – 15 °C (41 – 59 °F) |

Specifications of the sampling system

| | |
|---------------------------------|------------------------------|
| Sampling cycle time | 8 seconds |
| Sample pipetting volume | 1.0 – 25.0 µL (0.1 µL steps) |
| Sample Liquid level detection | Available |
| Sample clot detection | Available |
| Sample air aspiration detection | Available |

Specifications of the reaction system

| | |
|-----------------------------|--|
| Number of reaction cells | 128 |
| Reaction volume | 75 – 185 µL (detectable reaction volume) |
| Incubation bath temperature | 37.0 +/- 0.1 °C |
| Reaction time | 3 – 10 min (1 min steps) |
| Mixer | Ultrasonic |

Specifications of the photometric system

| | |
|---------------------------------------|--|
| Measurements per reaction cell/10 min | 46 |
| Photometer lamp | 12 V, 50 W |
| Photometer | Multiple wavelengths spectrophotometer |
| Maximum throughput* | Photometric only: 450 tests/hour ISE only: 450 tests/hour (150 samples/hour) Mixed mode Photometric & ISE: 750 tests/hour (300 photometric + 450 ISE tests/hour)** HbA1c only: 225 tests/hour |

* Throughput may differ based on the mix of test orders per sample

** The ISE unit and the c 303 photometric measuring unit share the same sample pipetter

ISE unit (integrated in the c 303 analytical unit*)

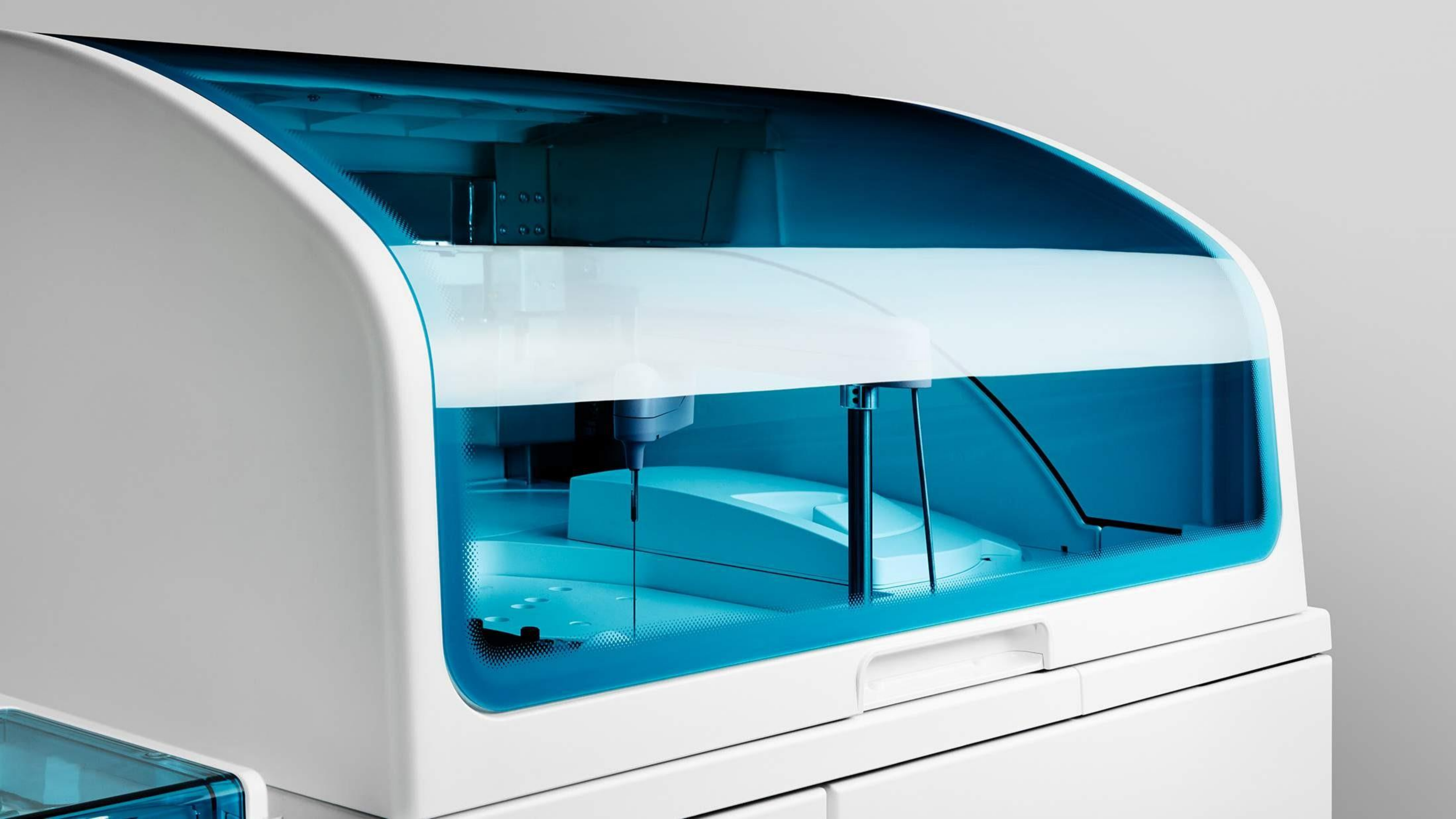
| |
|--|
| Applications |
| Sample types |
| Number of electrodes |
| Maximum throughput** |
| Sampling cycle time |
| Electrode handling |
| Sample Liquid level detection |
| Sample clot detection |
| Sample air aspiration detection |
| Sample pipetting volumes (serum/plasma/urine) |
| Reagent pipetting volumes per sample |

Specifications

| |
|--|
| Na ⁺ : Sodium |
| K ⁺ : Potassium |
| Cl ⁻ : Chloride |
| Serum/Plasma, Urine |
| Ion-selective electrodes: 3 (Na ⁺ , K ⁺ and Cl ⁻) |
| Reference electrode 1 |
| ISE only: 450 tests/hour (150 samples) |
| 24 seconds per sample for ISE |
| 2D barcode placed on the electrode package |
| Available |
| Available |
| Available |
| 15 µL For reruns of urine samples with a decreased sample volume after Test data alarm: 10 µL |
| DIL 780 µL |
| IS 720 µL |
| REF 130 µL |

* The ISE unit and the c 303 photometric measuring unit share the same sample pipetter

** Throughput may differ based on the mix of test orders per sample





References

- 1 *cobas® pure integrated solutions User Guide – Publication Ver 1.0 · Draft Ver 3.*
- 2 *Elecsys assay menu cobas pure – Analysis (source method sheets cobas e pack green).*
- 3 *cobas pure – AutoCal Estimated Time Savings – Internal Calculation.*
- 4 *cobas pure – footprint dimensions – Internal Document.*
- 5 *Elecsys assay menu cobas pure – Analysis (source method sheets cobas e pack green, CMP Database).*
- 6 *Clinical Chemistry assay menu cobas pure – Analysis (source method sheets cobas c pack green).*
- 7 *Roche Diagnostics Internal Reporting Data On File – GCS reporting / Product reports Q1/2020, CPS Finance Report from Tableau, ICB Q1 2020.*

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