

cobas[®] pure integrated solutions*
Simplicity meets Excellence

*In development and not commercially available



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

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 mustard-colored top, blue nitrile gloves, and a small stud earring, is looking down at a black tablet computer she is holding with both hands. She is standing in a modern laboratory with large glass windows in the background. The lab equipment and shelves are visible but out of focus. The lighting is bright and even.

*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 reaction time.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

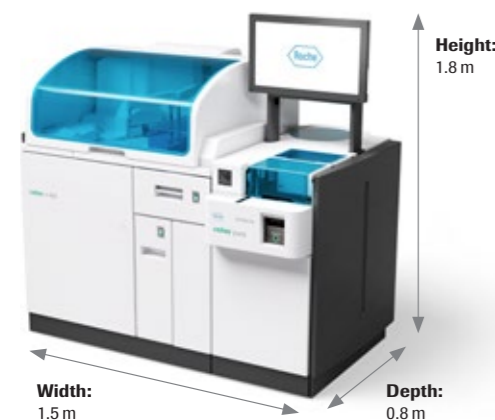
*For a common, daily routine workload, as compared to **cobas** 6000 <501|601> Mid Volume Commercial Lab



*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.

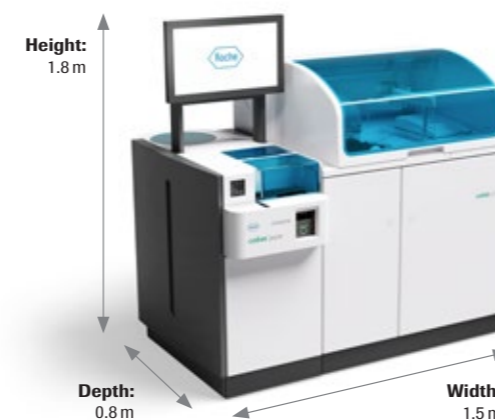
*Three compact configurations**



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



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



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

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

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

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.



No preparing



No mixing



No waiting



No pre-opening

Take out of the fridge

Load 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}

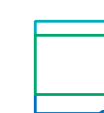
Immunochemistry⁵



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.

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

Immunochemistry

Single-use AssayTip

Single-use AssayCup

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.

99 % uptime⁷

* 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 days/Mean time between repair visit) × (Mean time for repair visit + Travel Time)⁷

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

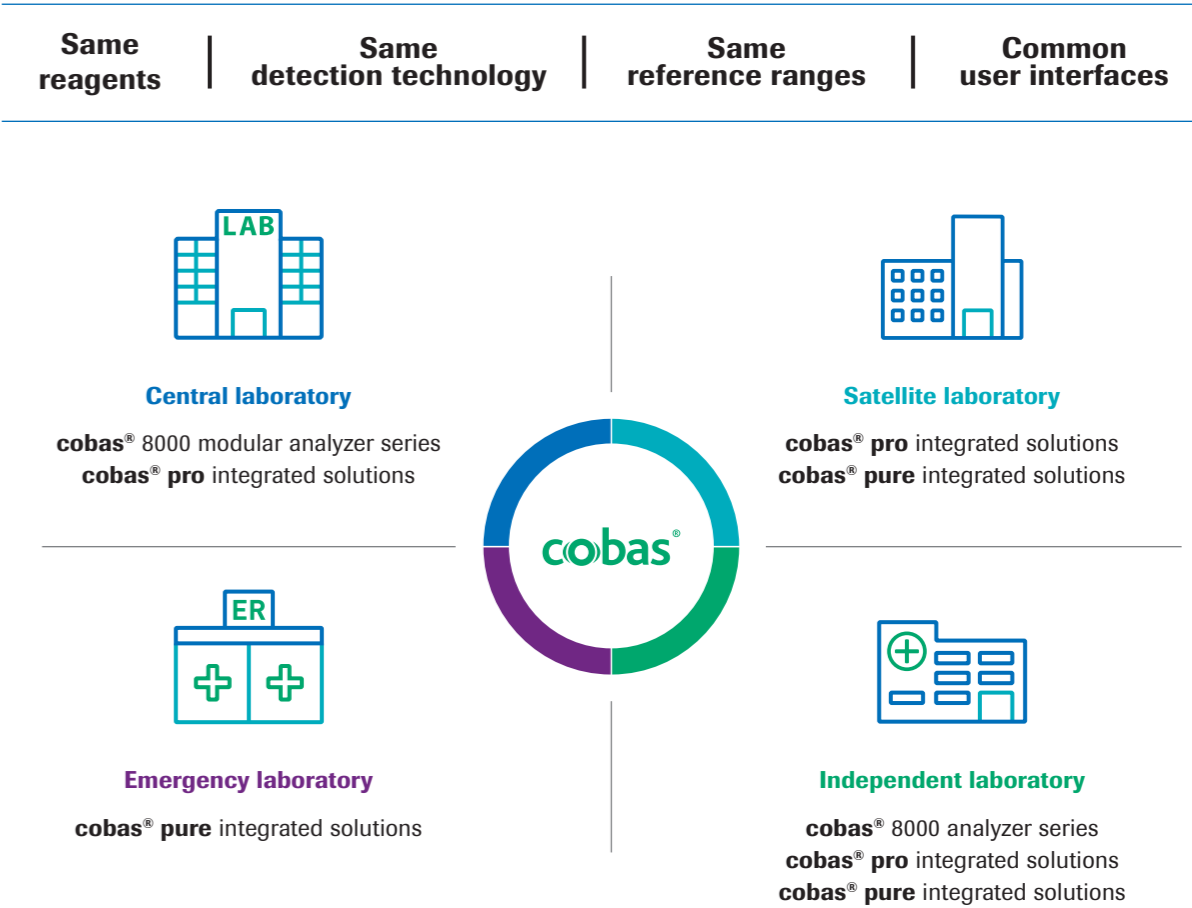
Same reagents and detection technology mean standardized reference ranges which improve the speed and accuracy of care.

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.





*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

Consistent, standardized results

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

Designed for convenience

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

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

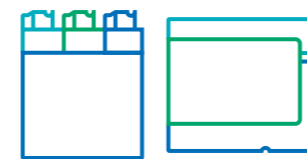


cobas® pure integrated solutions



cobas® pro integrated solutions

Delivering seamless design today and into the future



**Shared reagents
packs**



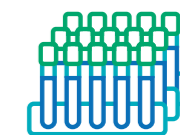
**Consistent
results**



**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	800	1,750 mm	200 kg
	17.7	31.5	70.0 inch	441 lb
cobas c 303 (incl. ISE) analytical unit	1,000	800	1,375 mm	400 kg
	39.4	31.5	54.1 inch	882 lb
cobas e 402 analytical unit	1,000	800	1,375 mm	400 kg
	39.4	31.5	54.1 inch	882 lb
SWA System Configuration <c 303 SSU e 402>	2,450	800	1,750 mm	1,000 kg
	96.5	31.5	70.0 inch	1,764 lb

cobas [®] pure integrated solutions	
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	≤ 5 m
	≤ 16 feet	≤ 16 feet
Conductivity	≤ 1.0 µS/cm	≤ 1.0 µS/cm
Water pressure	50 to 340 kPa	50 to 340 kPa
	0.5 to 3.4 bar	0.5 to 3.4 bar
Water temperature	> 12 °C	≥ 12 °C
	> 53.6 °F	≥ 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 flow rate	< 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	≤ 1/200 or ≤ 0.5% inclination
	Bearing load ≥ 5 kN/m²	Bearing load ≥ 5 kN/m²
Ambient temperature	0 – 2,000 m above sea level 18 – 32 °C (64.4 – 89.6 °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)	> 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 reagent system	
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 sampling system	
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 reaction system	
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

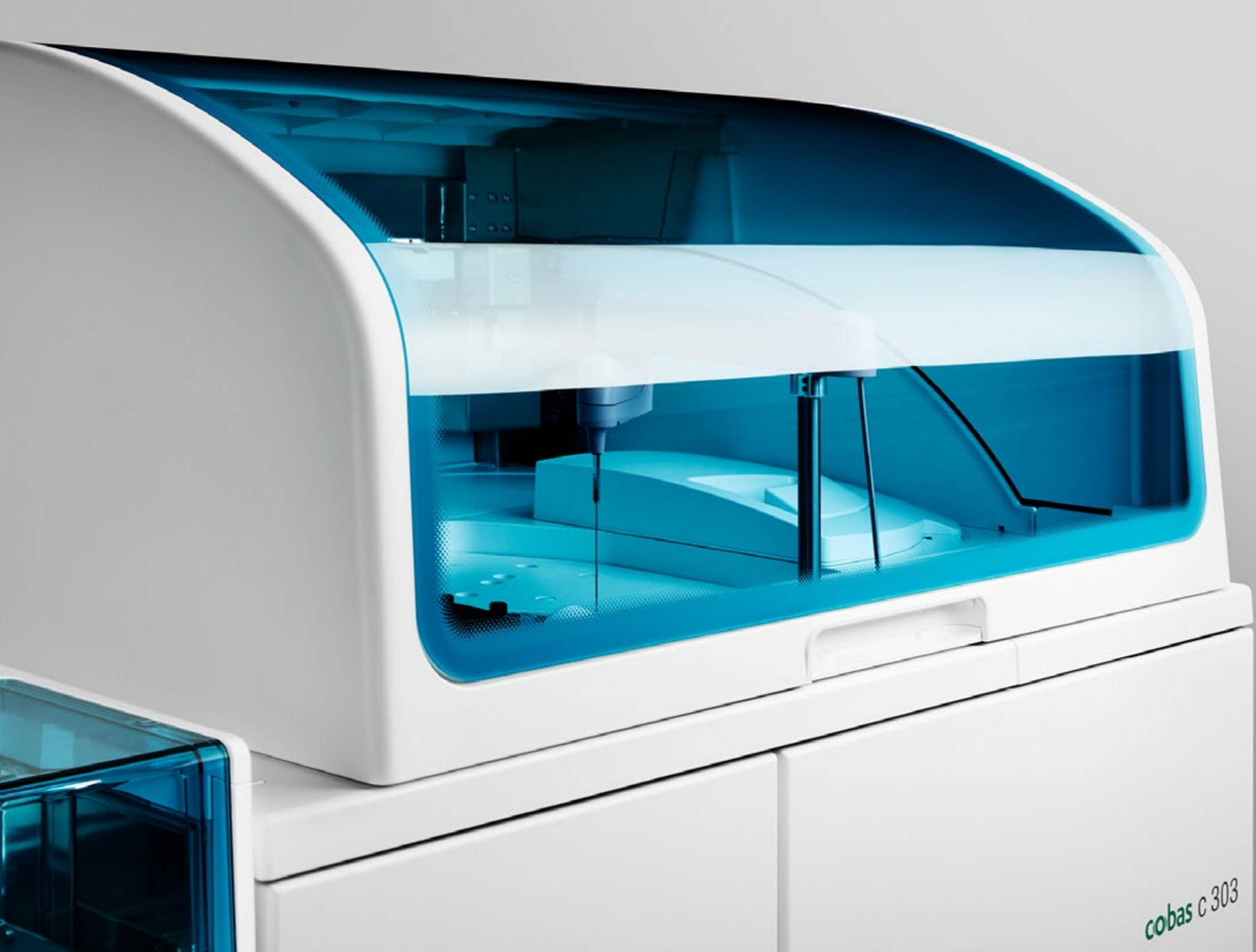
ISE unit (integrated in the c 303 analytical unit*)

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

* 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

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



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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