

Roche granted FDA clearance for cobas pure integrated solutions for low- to mid-volume laboratories

- Roche's new compact and modular system is designed to simplify daily operations, increase lab productivity, and support the delivery of better patient care through automation of manual tasks.
- cobas® pure integrated solutions brings together three diagnostic technologies on a single platform to optimize space and resources in low- to mid-volume laboratories. The system also integrates seamlessly within health networks with cobas® pro integrated solutions in their mid- to large-volume labs.
- With a footprint of about 21 square feet, the new system will provide access to a broad menu of more than 186 tests¹ across a wide-range of disease areas, including infectious diseases, oncology and cardiology.²

INDIANAPOLIS, September 19, 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the [cobas® pure](#) integrated solutions, the next generation of innovation in the cobas family of Serum Work Area solutions. The new compact and modular solution combines three technologies – clinical chemistry, immunoassay and Ion-Selective Electrode (ISE) diagnostic testing – on a single platform, helping to optimize space and resources for low- to mid-volume labs to support the delivery of the best patient care.

Built on the latest technology, **cobas pure** integrated solutions focuses on the automation of manual tasks, reducing the hands-on maintenance time of technicians to just five minutes per day.² This can help to improve the productivity of lab personnel while also supporting fast delivery of patient results and clinical decision-making.

Laboratory testing provides essential information for the prevention, diagnosis, treatment and management of disease. This helps patients receive the best care and highest quality outcomes. The **cobas pure** system delivers test results in short and predictable turnaround times using low-volume patient samples.

“The **cobas pure** integrated solutions marks a significant milestone in evolving standardization in lab diagnostics,” said Matt Sause, president and CEO of Roche Diagnostics North America. “Lab professionals are charged with providing life-impacting results quickly, accurately and efficiently. This system delivers a broad menu of medical assays while simplifying operations and reducing hands-on time for laboratorians so that they can focus on the tasks that matter most.”

With a footprint of about 21 square feet, **cobas pure** integrated solutions is up to 30% smaller than previous generation systems.²⁻⁵ It is able to perform up to 870 tests per hour with access to Roche's full clinical chemistry and immunochemistry assay menu. Within the first year after launch, the menu will include more than 186 diagnostic tests² across a wide-range of disease areas such as infectious diseases, oncology and cardiology. The system will enable low- to mid-volume labs to make better use of their space and expand their offering of high medical value tests for the benefit of patients.

Furthermore, to ensure effective and efficient work within healthcare networks, the **cobas pure** system operates seamlessly with Roche's **cobas pro** integrated solutions for mid- to high-volume labs. Standardization helps labs do more work on fewer instruments, deliver consistent results and facilitate flexible staffing strategies through features including consolidated workflows, shared reagent packs, standard reference ranges and common system interfaces.

The **cobas pure** integrated solutions launched in countries accepting the CE mark in March 2021.

About the cobas pure integrated solutions

cobas pure integrated solutions is the newest member of the cobas family of systems and combines clinical chemistry, immunoassay and ISE diagnostic testing on a single platform for low- to mid-volume testing needs. In addition, cobas pure integrated solutions comes with a number of innovations including automated maintenance, automated calibration and ready-to-use reagents that help simplify the overall operation of the lab.²

With **cobas pure** integrated solutions, the required sample volume per test has been reduced on average by 43% compared to previous generation systems.^{6,7} Additionally, the plastic generated per test result has been reduced by up to 78% due to smaller reagent pack sizes with higher number of tests per pack.^{7,8}

To learn more about **cobas pure** integrated solutions system, please visit:

<https://diagnostics.roche.com/us/en/products/systems/cobas-pure-integrated-solutions.html>

To learn more about cobas pro integrated solutions, please visit:

<https://diagnostics.roche.com/us/en/products/systems/cobas-pro-integrated-solutions.html>

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded

medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalized healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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References

- [1] Roche clinical chemistry and immunochemistry assay menu: Roche data on file
- [2] cobas pure integrated solutions User Guide
- [3] cobas® 4000 analyzer series including cobas® e 411 analyzer rack system and cobas® c 311 analyzer
- [4] cobas e 411 analyzer Operator's Manual
- [5] cobas c 311 analyzer Operator's Manual
- [6] Data based on a comparison to a cobas c 501® module, part of the cobas® 6000 analyzer series
- [7] cobas 6000 analyzer series Operator's Manual
- [8] Data based on a comparison to a cobas® e 601 module, part of the cobas 6000 analyzer series

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