Media Release

Roche receives FDA 510(k) clearance for cobas® c703 and cobas® ISE neo, next-generation analytical units enhancing efficiency and capability for laboratories

- **The cobas® c 703 and cobas® ISE neo analytical units deliver higher testing capacity and increased automation, helping to improve laboratory workflows and advance patient care.**
- **High-throughput efficiency, with up to 2,000 tests per hour on cobas® c 703 and up to 70 reagent positions for testing optimization.**
- **The new cobas® ISE neo analytical unit delivers up to 1,800 tests per hour and reduces hands-on time through automated maintenance.**

INDIANAPOLIS, March 30, 2026 – Roche announced today the U.S. Food and Drug Administration (FDA) 510(k) clearance of its newest analytical units – the **cobas®** c 703 and **cobas®** ISE neo. As part of the scalable and modular **cobas®** pro integrated solutions, these additions deliver advanced lab-automation capabilities designed to help address some of today's most pressing laboratory challenges, including staff shortages, limited space and growing test volumes.

"Laboratories are the indispensable engine of modern healthcare, and Roche wants to partner in addressing staffing-shortage challenges and an ever-increasing demand for testing," said Brad Moore, President and CEO of Roche Diagnostics North America. "Roche is investing in solutions that help labs process more samples than ever – without sacrificing performance. The high-volume clinical chemistry and enhanced automation of the **cobas®** c 703 and **cobas®** ISE neo analytical units will streamline workflows, one test at a time."

These new units reflect Roche's commitment to leading with science and delivering transformative diagnostic solutions that simplify operations and support faster clinical decision-making. With more than 4,000 **cobas®** analyzers installed across the U.S., Roche provides laboratories with a standardized platform capable of scaling access to testing quickly and effectively.

cobas® c 703 analytical unit

The new **cobas®** c 703 is engineered to double the clinical chemistry throughput[1] on **cobas®** pro integrated solutions, delivering up to 2,000 tests per hour and 70 reagent positions. Its expanded reagent capacity enables more high-value tests to run continuously, reducing reagent reloads and improving workflow efficiency. Monthly operator maintenance further enhances uptime and productivity.

cobas® ISE neo analytical unit

The **cobas**® ISE neo analytical unit, with up to 1,800 tests per hour, delivers more efficient ISE testing, reducing hands-on time through automated maintenance. The **cobas**® ISE neo system delivers more tests per reagent bottle, minimizing plastic waste and reducing logistical efforts compared to previous-generation systems. Monthly maintenance supports consistent uptime, helping laboratories manage higher volumes with fewer manual steps.

Together, these units automate tasks traditionally performed manually, supporting laboratories facing staffing shortages while increasing test capacity and accelerating turnaround times.

About cobas® pro integrated solutions

Launched in the U.S. in 2020, **cobas® pro** integrated solutions is a modular, scalable system to meet mid- to very-high-volume clinical chemistry and immunochemistry testing needs. The platform drives efficiency through intelligent sample routing, fast STAT assay incubation times, the broadest test menu on an integrated platform, and industry-leading reagent onboard stability.[2] **Key features include:**

- **cobas**® SonicWash, ultrasonic probe cleaning to help ensure sample integrity
- Full standardized and shared reagents with **cobas**® **pure** integrated solutions, enabling flexible staff assignment and minimal training

With **cobas**® **pro** integrated solutions, the required sample volume per test has been reduced by 43% on average compared to previous-generation systems.[3] Additionally, the plastic generated per test result has been reduced by up to 78% due to smaller reagent pack sizes and a higher number of tests per pack.[4]

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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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.

References

1. Internal data on file
2. Internal data on file
3. Reduction is a comparison to **cobas**® c 501 module, part of **cobas**® 6000 analyzer series
4. Reduction is a comparison to **cobas**® e 601 module, part of **cobas**® 6000 analyzer series

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