

Roche expands automated mass spectrometry menu with antibiotics drug monitoring CE mark approval offering industry's broadest in vitro diagnostic menu

- **With this approval, Roche's automated mass spectrometry platform now offers the industry's broadest in vitro diagnostic menu with 39 tests, including tests for therapeutic drug monitoring for immunosuppressants and antibiotics, as well as steroid hormones and vitamin D metabolites.**
- **The comprehensive menu brings the sensitivity and specificity of gold-standard testing into routine labs for a wide range of the most frequently tested targets.**
- **The fully automated solution replaces labour-intensive manual workflows, reducing turnaround times and supporting faster, standardised, high-quality care.**

Basel, 11 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has secured CE Mark approval for its mass spectrometry reagent pack for antibiotics drug monitoring. This establishes Roche's in-vitro diagnostics (IVD) menu as the broadest available for any automated mass spectrometry platform, including already 39 of the most frequently tested targets.

"When patients get results sooner, we increase the likelihood that they will get the right treatment," said Matt Sause, CEO of Roche Diagnostics. "With a comprehensive menu for automated mass spectrometry, we are giving clinicians and laboratories the tools to make faster, more precise diagnoses, reducing the time from sample to result. This approach also allows clinicians to better monitor the effectiveness of drug therapies and to optimise antibiotic use, a vital step in combating the major global healthcare challenge of antimicrobial resistance."

The cobas® Mass Spec solution Ionify® reagent portfolio includes tests for therapeutic drug monitoring for immunosuppressants and antibiotics, along with steroid hormones and vitamin D metabolites. These tests will enable laboratories to transition from labour-intensive and manual operation to a fully automated, standardised, easy to use solution.¹⁻³ Roche remains committed to expanding this menu with additional assays in the coming years, including the first panel in drugs of abuse testing and further expanding the menu of therapeutic drug monitoring parameters.

The cobas Mass Spec solution is currently available in selected markets accepting the CE mark, as well as other markets including the United Kingdom, Canada and Japan. In parallel, Roche achieved "moderate complexity" categorisation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) of the first analyte in the US. As the first mass

spectrometry assay to receive this designation, it marks a significant step toward broadening clinical utility across routine laboratories by eliminating the need for specialists to run the assay. Roche is continuously working with regulatory authorities around the world to further expand system and assay availability.

About the cobas Mass Spec solution

The high specificity, sensitivity and accuracy of mass spectrometry is considered the diagnostic 'gold standard' for various clinical situations, for example, measurements of steroid hormones in endocrinology, vitamin D testing, the monitoring of immunosuppressants and therapeutic drugs. The cobas Mass Spec solution combines the unmatched sensitivity and specificity of mass spectrometry with a fully automated, integrated, and standardised workflow, making this traditionally complex analytical method accessible to routine laboratories.

As part of the trusted cobas ecosystem, the cobas Mass Spec solution can integrate seamlessly with Roche's clinical chemistry, immunochemistry, and laboratory IT systems, enabling laboratories to fully streamline workflows.

In July 2025, the cobas Mass Spec solution was awarded the Best New Clinical Diagnostics Instrumentation of 2024 in the Scientists' Choice Awards® 2025. The Awards were first introduced in 2007 by SelectScience, with nominations collected and assessed by their editors and the most popular nominations put to vote among their readership of scientists.

For more information about the cobas Mass Spec, please visit diagnostics.roche.com/MassSpec

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 personalised 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.

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References

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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD

Phone: +41 79 407 72 58

Sileia Urech

Phone: +41 79 935 81 48

Nathalie Altermatt

Phone: +41 79 771 05 25

Lorena Corfas

Phone: +41 79 568 24 95

Simon Goldsborough

Phone: +44 797 32 72 915

Karsten Kleine

Phone: +41 79 461 86 83

Kirti Pandey

Phone: +49 172 6367262

Yvette Petillon

Phone: +41 79 961 92 50

Dr Rebekka Schnell

Phone: +41 79 205 27 03

Roche Investor Relations

Dr Bruno Eschli

Phone: +41 61 68-75284

e-mail: bruno.eschli@roche.com

Dr Sabine Borngräber

Phone: +41 61 68-88027

e-mail: sabine.borngraeber@roche.com

Dr Birgit Masjost

Phone: +41 61 68-84814

e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com