

## Roche transforms mass spectrometry diagnostics with launch of cobas® Mass Spec solution

- Roche launches its cobas® Mass Spec solution, bringing mass spectrometry to the routine clinical lab
- Clinical mass spectrometry testing offers unparalleled sensitivity and specificity, providing clinicians with additional diagnostic insights<sup>1</sup>
- cobas Mass Spec solution will offer a fully automated, integrated and standardised workflow with IVDR-compliant assays

Basel, 18 December 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received CE mark approval for its cobas® Mass Spec solution including the cobas® i 601 analyser and the first Ionify® reagent pack of four assays for steroid hormones<sup>2</sup>. The CE mark is the first milestone in the global launch of the cobas Mass Spec solution, using in-house innovation to bring automated, integrated and standardised clinical mass spectrometry testing to routine laboratories worldwide. Following launch, the cobas Mass Spec solution will roll out a menu offering of more than 60 analytes for testing of steroid hormones, vitamin D metabolites, immunosuppressant drugs (ISD), therapeutic drug monitoring (TDM) and drugs of abuse testing (DAT).

“The cobas Mass Spec solution will fundamentally change the field of clinical diagnostics,” said Matt Sause, CEO of Roche Diagnostics. “The solution would make fully standardised clinical mass spectrometry more broadly available with the potential to improve patient care worldwide. For example, in breast cancer patients receiving hormone therapy, mass spectrometry can help physicians detect subtle changes in therapeutic response earlier, allowing for timely adjustments to treatment.”

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. Examples of how mass spectrometry can benefit healthcare systems include the effective and responsible use of antibiotics and ongoing monitoring of disease progression and treatment. The high specificity of testing can provide greater levels of clarity to physicians, enabling more timely treatment decisions for patients.

New, proprietary chemistry technology developed by Roche makes commercial automation possible, with a workflow that is much more environmentally sustainable than current methods. Until now, mass spectrometry has only been offered by specialist laboratories due to the low level of automation, integration and standardisation and the high complexity of the workflows that require highly skilled operators. This has resulted in great variability between different laboratories and long processing times.

The cobas Mass Spec solution will be part of Roche's established cobas® pro integrated solutions which allows for full integration into clinical chemistry and immunochemistry testing as well as lab automation and IT.

For more information, please visit [diagnostics.roche.com/MassSpec](https://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](https://www.roche.com).

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### References

[1] Hristova, J., & Svinarov, D. (2022). Enhancing precision medicine through clinical mass spectrometry platform. *Biotechnology & Biotechnological Equipment*, 36(1), 107–117. <https://doi.org/10.1080/13102818.2022.2053342>

[2] Notified Body 0123

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