

Media Release

Roche expands mass spectrometry menu to include steroid assays receiving CLIA ‘moderate complexity’ designation

- **Roche’s Ionify® steroid assays join its Vitamin D Total test as the latest mass spectrometry tests to receive CLIA ‘moderate complexity’ classification.**
- **The expanded steroid menu brings the sensitivity and specificity of mass spectrometry – the diagnostic gold standard – into routine clinical laboratories.**
- **The CLIA classification broadens access to advanced testing through a fully automated and standardized workflow on the cobas® i 601 analyzer.**

INDIANAPOLIS, March 18, 2026 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has categorized its Ionify® steroid assays for mass spectrometry as “moderate complexity” under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This designation marks an important step toward expanding access to advanced diagnostic testing, which has historically been limited to highly specialized laboratories due to complex workflows and the need for expert operators.

The Ionify® steroid assays include Estradiol, DHEA, DHEA-S, Progesterone, 17-Hydroxyprogesterone and Androstenedione, which run on Roche’s **cobas® i 601** analyzer as part of the [cobas® Mass Spec solution](#). By combining the sensitivity and specificity of mass spectrometry with a standardized, easy-to-use workflow, the **cobas® Mass Spec** solution streamlines complex testing and helps reduce variability across laboratories.

“This technology fundamentally transforms mass spectrometry, moving it from an intricate specialty process to a seamless engine for routine diagnostics,” said Brad Moore, President and CEO, Roche Diagnostics North America. “By delivering a broad and expanding mass spectrometry menu with automation and standardization, we are empowering laboratories to operate more efficiently and enabling clinicians to make critical decisions sooner – helping ensure the right treatment reaches the right patient without delay.”

The Ionify® steroid assays, together with the previously launched Ionify® 25-Hydroxy Vitamin D total assay, form the growing U.S. portfolio for the **cobas® Mass Spec** solution with a CLIA “moderate complexity” designation. This classification significantly broadens accessibility,

enabling laboratories to routinely offer clinical mass spectrometry assays without the need for specialized operators. Roche remains committed to expanding this menu and maintains an active pipeline of future clinical mass spectrometry assays currently in development and under regulatory review to further extend system and assay availability.

About the cobas® Mass Spec solution

Mass spectrometry is widely regarded as the diagnostic gold standard for a range of clinical applications, including the measurement of steroid hormones in endocrinology and 25-hydroxyvitamin D testing. The **cobas**® Mass Spec solution combines the high specificity, sensitivity and accuracy of mass spectrometry with a fully automated, integrated, and standardized workflow – making this traditionally complex analytical method accessible to routine laboratories.

In July 2025, the **cobas**® Mass Spec solution received the “Best New Clinical Diagnostics Instrumentation of 2024” award in the Scientists' Choice Awards® 2025. Established in 2007 by SelectScience, the awards recognize innovations nominated and voted on by the global scientific community.

For more information about **cobas**® Mass Spec, please visit go.roche.com/ClinicalMassSpec.

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.



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