Media Release

Roche achieves first CLIA 'Moderate Complexity' categorization for Ionify® 25-Hydroxy Vitamin D total test

- First mass spectrometry-based test system for total 25-Hydroxyvitamin D to receive CLIA 'Moderate Complexity' designation in the U.S.
- Expands access to advanced testing with a fully automated, standardized workflow on the **cobas**® i 601 analyzer
- Marks an important step in broadening the clinical utility of mass spectrometry testing across routine labs

INDIANAPOLIS, September 18, 2025 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has categorized its Ionify® 25-Hydroxy Vitamin D total assay as "Moderate Complexity" under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This represents the first time a mass spectrometry-based test has achieved this designation, opening access to a broader range of clinical laboratories.

The assay runs on Roche's **cobas**® i 601 analyzer, part of the **cobas**® Mass Spec solution. By combining mass spectrometry's sensitivity and specificity with a standardized, easy-to-use workflow, the **cobas**® Mass Spec solution streamlines complex testing and reduces variability across labs. Traditionally, these tests have been confined to highly specialized labs due to complex workflows and the need for expert operators.

"Achieving this level of automation for a mass spectrometry assay is a breakthrough for routine diagnostics," said Brad Moore, President and CEO, Roche Diagnostics North America. "It will allow more labs to deliver highly accurate results efficiently, helping clinicians make better-informed decisions and ultimately improving patient care."

The Ionify 25-Hydroxy Vitamin D total assay is the first in Roche's planned U.S. pipeline for the **cobas**® Mass Spec solution. Roche already offers a broad menu of mass spectrometry assays in countries accepting the CE mark, with additional launches anticipated globally.

Roche's proprietary chemistry enables scalable automation with a workflow that is faster, more reproducible and more environmentally sustainable than conventional mass spectrometry methods. This reduces variability across labs and helps minimize the need for outsourcing advanced testing.

For more information, please visit go.roche.com/USMassSpec or visit Roche's booth at the upcoming Mass Spectrometry & Advances in the Clinical Lab (MSACL) Conference in Montreal, Canada, from September 21-26, 2025.

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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