Media & Investor Release

Roche receives FDA clearance with CLIA waiver for cobas® liat molecular tests to diagnose sexually transmitted infections at the point of care

- **More than 1 million curable sexually transmitted infections (STIs) are acquired every day worldwide in people 15–49 years old, most of which are asymptomatic.[1]**
- **FDA CLIA-waived tests broaden access to accurate, easy-to-use diagnostics for all patients in decentralized settings like urgent care centers, retail clinics, and community health venues.**
- **The tests use highly sensitive, gold-standard PCR technology, providing results in 20 minutes to allow healthcare providers to confidently diagnose and determine appropriate treatment in the same visit.**

Basel, 22 January 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance and Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver for its cobas® liat sexually transmitted infection (STI) multiplex assay panels. These panels, including tests for chlamydia and gonorrhea (CT/NG) and chlamydia, gonorrhea and *Mycoplasma genitalium* (CT/NG/MG), enable clinicians to diagnose and differentiate between multiple STIs with a single sample. These tests will be exclusively available in the U.S. market in the coming months, with commercialisation under CE mark expected to follow shortly.

“Rapid molecular point-of-care testing can revolutionise the clinical management of STIs in decentralised and community-based healthcare settings, enabling informed treatment strategies, better health outcomes for patients, and contain further spread by providing timely diagnosis.” said Matt Sause, CEO Roche Diagnostics.

More than 1 million people worldwide acquire an STI every day. Common STIs often present overlapping symptoms and can frequently be asymptomatic, making diagnosis challenging, when relying solely on symptoms. *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are among the most prevalent STIs. If untreated, these infections can lead to serious health complications, including pelvic inflammatory disease (PID), urethritis, ectopic pregnancy, infertility, and an increased risk of HIV infection.[1] Additionally, *Mycoplasma genitalium* (MG) is an emerging sexually transmitted pathogen affecting both males and females, with untreated infections resulting in severe health issues such as PID and infertility.[2]

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Comprehensive Point-of-Care Solutions

The cobas liat CT/NG and cobas liat CT/NG/MG STI assay tests further expand and complement Roche's broad portfolio of lab-level solutions to help diagnose and address patients' needs at the point of care. The test-to-treat approach can help combat potentially high loss to follow-up rates, making treatment more likely. Testing at the point of care can help reduce unnecessary antibiotic usage, facilitate targeted treatment strategies, improve healthcare efficiency and cost, and ultimately enhance the patients' short and long-term health outcomes.[3-5]

About the cobas liat system

The cobas liat system utilises gold-standard PCR technology to provide results in 20 minutes or less. The cobas liat assays are CLIA waived*, enabling healthcare professionals to perform molecular testing in a variety of near-patient settings with speed, reliability and minimal training. The cobas liat system is a closed system, reducing contamination risks and enhancing the reliability of results. The cobas liat CT/NG and CT/NG/MG assays complement existing tests for the cobas liat system. These include singleplex and multiplex assays for a variety of pathogens such as SARS-CoV-2, influenza A, influenza B, Strep A., and C. diff. These assays are easily added to a testing programme by connecting the cobas liat system to cobas infinity edge to remotely schedule software and assay script updates, and to provide remote troubleshooting in all patient-care settings. Connected cobas liat instruments streamline testing workflow and reduce instrument maintenance time. Assays for other infectious diseases are currently in development. The cobas liat system is commercially available in select markets.

**C. diff has been cleared by the FDA for use by authorised laboratories under CLIA to perform moderate complexity testing.*

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.

References

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[5] Point of Care Testing. NIH STATPEARLS. Published May 29, 2023.

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