# Media & Investor Release

## Roche receives FDA clearance with CLIA waiver for its first molecular point-of-care test for the detection of Bordetella infections, including whooping cough (pertussis)

- **The cobas® liat point-of-care test delivers PCR results in just 15 minutes, enabling healthcare providers to act quickly to prevent severe complications and onward transmission.**
- **This test detects and differentiates between three types of Bordetella pathogens that can cause similar cough symptoms, ensuring patients receive the right diagnosis at the earliest opportunity.**
- **Early diagnosis can reduce the risk of complications and severe disease in vulnerable groups such as infants and the elderly by enabling faster, more precise care decisions.**

BASEL and INDIANAPOLIS, December 2, 2025 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its first point-of-care test for the detection of Bordetella infections, including whooping cough (pertussis), has been granted U.S. Food and Drug Administration (FDA) 510(k) clearance and Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver. The groundbreaking PCR test uses the **cobas® liat** system to deliver results in just 15 minutes at the point of care. This speed enables physicians to diagnose patients during their consultation and take immediate action to provide appropriate antibiotics that can prevent severe complications and onward transmission.

Pertussis is a global burden, affecting people of all ages but can be more severe in children, causing an estimated 24.1 million cases and 170,000 deaths annually.[1] A major diagnostic challenge is that early symptoms are often indistinguishable from other respiratory illnesses.

"Faster and more accurate clinical decisions are critical for reducing the risk of severe complications and ultimately stopping the transmission of Bordetella infections," said Matt Sause, CEO of Roche Diagnostics. "This new test allows clinicians to quickly make a definitive and precise diagnosis to ensure patients get the right treatment earlier."

The test not only detects Bordetella infections but also differentiates between three key species: *B. pertussis*, the cause of classic whooping cough; *B. parapertussis*, which causes a milder pertussis-like illness; and *B. holmesii*, an emerging pathogen increasingly associated with pertussis-like symptoms and potential diagnostic challenges.

Whooping cough has a cyclical prevalence that typically peaks in severity every three to five years.[2] With a surge underway,[3] the increase in cases has been further amplified by interruptions in routine vaccinations during the COVID-19 pandemic, along with waning

immunity and vaccine hesitancy. These factors have driven infections across all age groups, including older children and adults, where symptoms can be less typical and harder to recognise.

Bordetella infections, including whooping cough, pose a significant challenge for clinicians because their early symptoms resemble those of other respiratory infections. Accurately identifying Bordetella among these conditions is essential to delivering the right treatment and ensuring timely intervention.

## About cobas® liat

The point-of-care (POC) test is delivered using the **cobas® liat** system, already used by healthcare professionals worldwide for point-of-care diagnostics. The compact system delivers PCR definitive results in 20 minutes or less to aid in patient-care decisions. This new assay expands the **cobas® liat** system's capabilities, complementing existing solutions for the detection of SARS-CoV-2, Influenzas A and B, Respiratory Syncytial Virus (RSV), and Group A Streptococcus (Strep A). By enabling clinicians to test for a range of conditions during the patient consultation, the system empowers faster, more decisive care decisions and reduces reliance on central laboratory facilities.

## 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.

## References

1. Yeung KHT, Duclos P, Nelson EAS, Hutubessy RCW. An update of the global burden of pertussis in children younger than 5 years: a modelling study. Lancet Infect Dis. 2017;17(9):974-980. doi:10.1016/S1473-3099(17)30390-0.
2. U.S. Centers for Disease Control and Prevention. "About Whooping Cough Outbreaks."
3. U.S. Centers for Disease Control and Prevention. "Pertussis Surveillance and Trends."

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