Media Release

Roche receives FDA 510(k) clearance for new cobas® eplex respiratory pathogen panel 3, enabling labs to customize respiratory testing for local patient needs

- **The new cobas®eplex RP3 panel detects up to 19 viruses and bacteria, with newly added *Bordetella pertussis* and improved inclusivity of influenza A and SARS-CoV-2 strains, from a single sample to inform timely patient management.**
- **Laboratories can optimize resources with up to five flexible panel configurations tailored to local disease prevalence and patient needs, enabled by cobas®eplex system software version 3.0 or higher.**
- **The streamlined workflow enhances operational efficiency, requiring less than one minute of hands-on time and delivering results in under two hours.**
- **The test expands the existing capabilities of cobas® eplex respiratory pathogen panel 2 (EUA).**

INDIANAPOLIS, November 2, 2026 – Roche announced today the U.S. Food and Drug Administration (FDA) 510(k) clearance of the **cobas® eplex** respiratory pathogen panel 3 (RP3). Designed for the automated **cobas® eplex** system, this flexible syndromic test offers up to five customizable panel configurations, enabling labs and clinicians to rapidly and accurately identify the cause of respiratory infections to help ensure timely and effective patient care.

During peak respiratory seasons, health systems face immense pressure to accurately differentiate viral and bacterial infections that often have overlapping symptoms. When clinicians have accurate and rapid respiratory results, they can reduce the number of tests and radiographs ordered, decrease unnecessary antibiotic use and decrease the length of time to discharge.[1]

"Timely and accurate respiratory testing in critical situations can guide life-saving interventions," said Dan Malarek, President and CEO, Roche Diagnostics North America. "The cobas® eplex RP3 panel gives laboratories the range of testing choices they need with quick turnaround times that can make a difference in patient care."

Diagnostic uncertainty creates challenges, particularly for high-risk populations – including the elderly, young children and the immunocompromised – who are at increased risk for severe complications.[2] The **cobas® eplex** RP3 panel addresses these challenges by providing rapid, actionable insights that facilitate efficient patient management and antibiotic stewardship.

About the cobas® eplex respiratory pathogen panel 3 (RP3)

The **cobas® eplex** respiratory pathogen panel 3 (RP3) simultaneously detects up to 19 viral and bacterial targets, with broad strain inclusivity, from a single nasopharyngeal swab sample. Like the RP2 panel (EUA),* the RP3 panel detects common pathogens, such as influenza A virus, RSV and SARS-CoV-2, with the addition of *Bordetella pertussis*, to broaden targeting of bacterial pathogens that can cause severe illness in high-risk patients. The **cobas® eplex** RP3 panel also has updated assays for influenza virus and SARS-CoV-2 to improve coverage of current and recently circulating strains. It enables laboratories to tailor testing strategies with up to five distinct panel configurations, aligning with local disease prevalence and specific patient population needs.

With an automated "sample-to-answer" workflow process, the test requires less than one minute of hands-on preparation time and supports 24/7 availability. It also delivers highly accurate, qualitative results in less than two hours.

This FDA clearance further expands Roche's respiratory portfolio, which includes a broad range of singleplex and multiplex assays for respiratory viral and bacterial infections, supporting patient testing needs across the continuum of care.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland, in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases, and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

All trademarks used or mentioned in this release are protected by law.

*__cobas__® __eplex__ RP2 has not been cleared or approved by the FDA. This test is authorized for use by qualified laboratories under an Emergency Use Authorization.

References

1. Rappo U, Schuetz AN, Jenkins SG, Calfee DP, Walsh TJ, Wells MT, Hollenberg JP, Glesby MJ. Impact of Early Detection of Respiratory Viruses by Multiplex PCR Assay on Clinical Outcomes in Adult Patients. J Clin Microbiol. Aug 2016;54(8):2096-103. doi: 10.1128/JCM.00549-16. Epub May 25, 2016. PMID: 27225406; PMCID: PMC4963510.
2. Centers for Disease Control. Accessed September 10, 2026.

For Further Information

Roche Diagnostics U.S. Media Relations
us.mediarelations@roche.com

Krystina Monaco
1-317-850-7521
krystina.monaco@roche.com

Lori McLaughlin
1-463-207-2395
lori.mclaughlin@roche.com