# Media & Investor Release

## Roche four-in-one molecular test for SARS-CoV-2, Influenza A/B viruses and RSV receives U.S. FDA Emergency Use Authorization

- **The test uses highly sensitive PCR technology, requiring only a single nasal-swab sample to provide rapid, accurate qualitative detection and differentiation among four of the most prevalent respiratory viruses for which differential diagnosis can drive appropriate treatment.**
- **It enables healthcare professionals to make confident clinical decisions and promptly determine appropriate treatment, with definitive results reported in just 20 minutes.**
- **The test expands Roche's extensive molecular point-of-care testing portfolio, offering greater flexibility to meet testing needs amid evolving regional prevalence of respiratory infections.**

BASEL, June 10, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its **cobas® liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test, an automated, multiplex, real-time polymerase chain reaction (RT-PCR) assay on the **cobas® liat** system. Producing results in just 20 minutes on a compact analyzer suitable for most healthcare settings, the test uses either a single nasopharyngeal or anterior nasal-swab sample to confirm or rule out infection with SARS-CoV-2, influenza A virus, influenza B virus and respiratory syncytial virus (RSV).

"Diagnostics play a critical role in the fight against respiratory illness," said Matt Sause, CEO of Roche Diagnostics. "We are proud to provide this innovative test to address the significant burden placed on healthcare systems. Now, healthcare professionals will be able to detect and differentiate these respiratory viruses within a single patient visit, enabling improved public health outcomes."

Introducing rapid multiplex PCR diagnostic tests into near-patient care environments such as emergency departments, urgent care facilities and physician office labs has the potential to provide swift and precise results, expediting clinical decision-making processes. This approach can help reduce unnecessary antibiotic usage, facilitate targeted treatment strategies, and ultimately enhance patient outcomes and healthcare system efficiency.[1-6]

According to the U.S. Centers for Disease Control and Prevention (CDC), respiratory diseases in the United States reached high levels during the most recent autumn and winter seasons, with SARS-CoV-2 causing the most emergency department visits.[7] Hospitalizations due to respiratory illness place a strain on hospitals and can result in delayed diagnosis and treatment for patients.[8] In the 2023-2024 respiratory season, infants, children, and adults ages 65 and older were observed to have the highest rates of emergency department visits and hospitalizations caused

by SARS-CoV-2, influenza and RSV.[9,10] Nationwide, the percentage of recent total deaths due to these respiratory viruses was highest among patients 65 and older.[11]

The **cobas liat** SARS-CoV-2, Influenza A/B & RSV -nucleic acid test authorized for emergency use further expands and complements Roche's broad portfolio of single and multiplex tests intended to help diagnose and address the needs of patients presenting with symptoms of respiratory illness, including the following assays: **cobas**® SARS-CoV-2, **cobas**® Strep A, **cobas**® SARS-CoV-2 & Influenza A/B, and **cobas**® Influenza A/B & RSV for use on the **cobas liat** system. In 2025, Roche intends to seek FDA 510(k) clearance and a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver in the United States for the new test, with plans for commercial launch in other markets worldwide following CE-IVDR approval.

### About the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test[12]

The **cobas liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test is an automated rapid multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus, influenza B virus and respiratory syncytial virus (RSV) RNA in anterior nasal (nasal) swab and nasopharyngeal swab specimens collected from individuals with signs and symptoms of respiratory tract infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza and RSV can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The **cobas liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A, influenza B and RSV viral RNA in clinical specimens and are not intended to detect influenza C virus. SARS-CoV-2, influenza A, influenza B and RSV RNA are generally detectable in nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A, influenza B and/or RSV RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definitive cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, influenza B and/or RSV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

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The **cobas liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test is intended for use by trained operators specifically instructed in the use of the **cobas liat** system and the **cobas liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test. The **cobas liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test is only for use under the Food and Drug Administration's Emergency Use Authorization.

## About the cobas liat system

The **cobas liat** system combines the **cobas liat** analyzer – an automated nucleic acid test instrument – with **cobas liat** assay tubes to fully automate the testing process, simplify workflows and enable healthcare professionals to perform molecular testing in a variety of near-patient settings with speed, reliability and minimal training. The system performs reagent preparation, target enrichment, inhibitor removal, nucleic acid amplification, polymerase chain reaction (PCR) amplification, real-time detection and result interpretation to automate the detection and quantification of nucleic acid targets in a biological sample in a single, closed tube. Definitive results are generated in 20 minutes or less to aid in patient care decisions. The **cobas liat** SARS-CoV-2, Influenza A/B & RSV Assay complements existing tests for SARS-CoV-2 & Influenza A/B, Influenza A/B & RSV, Strep A, and Cdiff. Assays for other infectious diseases are currently in development. More information is available here. The **cobas liat** system is commercially available in select markets.

## 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.

In recognizing our endeavor to pursue a longterm perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifthteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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 roche.com.

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## References

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[9] Centers for Disease Control and Prevention. Respiratory Illnesses. Groups Most Impacted—Emergency Department Visits. Published February 9, 2024. Accessed February 13, 2024.

[10] Centers for Disease Control and Prevention. Respiratory Illnesses. Groups Most Impacted—Hospitalizations. Published February 9, 2024. Accessed February 13, 2024.

[11] Centers for Disease Control and Prevention. Respiratory Illnesses. Groups Most Impacted—Deaths. Published May 24, 2024. Accessed May 28, 2024.

[12] This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and RSV, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

## For Further Information

**Roche Diagnostics U.S. Media Relations**

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us.mediarelations@roche.com

**Gina Goodenough**
Phone: 1-317-734-7171
gina.goodenough@roche.com

**Jennifer Hoopingarner**
Phone: 1-317-797-9741
jennifer.hoopingarner@roche.com