Media Release

Roche's first respiratory test powered by TAGS technology receives FDA clearance for SARS-CoV-2, Influenza A, Influenza B and RSV

- **Used with the cobas® 5800, 6800 and 8800 systems, cobas Respiratory 4-flex simultaneously detects and differentiates the four most common respiratory viruses, helping to ensure confidence in diagnosis.**
- **The new cobas Respiratory 4-flex offers an innovative syndromic PCR testing solution, providing labs flexibility in customizing their menu panel.**
- **The customized panel test includes a "digital reflex"* option that allows for additional results to be obtained from the same test run, beyond the initial reported results.**

INDIANAPOLIS, August 4, 2025 – Roche today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance for the **cobas**® Respiratory 4-flex. This is the first FDA-cleared assay utilizing Roche's innovative TAGS (Temperature-Activated Generation of Signal) technology, designed to streamline respiratory testing, and to ensure timely and accurate diagnoses for patients.

The new test provides accurate PCR results for the four most common respiratory viruses: SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus (RSV). This enables physicians to promptly initiate targeted treatment plans to improve patient care. The test consolidates these four key targets into a single, efficient assay, simplifying laboratory workflows and optimizing resource use. It integrates seamlessly with Roche's **cobas** 5800, 6800 and 8800 molecular lab instruments.

"The **cobas** Respiratory 4-flex assay offers a significant technological advancement that empowers labs to address evolving respiratory testing demands now and in the future," said Brad Moore, President and CEO of Roche Diagnostics North America. "The expanded testing capabilities, enabled by TAGS technology, will allow labs to deliver reliable and relevant patient testing, while also optimizing healthcare resources."

With its customizable testing menu, **cobas** Respiratory 4-flex enables laboratories to tailor testing to physician orders and patient needs, reducing the need for repeat healthcare visits and

tests. The test includes a “digital reflex”* option, which allows for additional testing from the same sample. For example, if the physician requests influenza A and B and the results are negative, a digital reflex can request results for SARS-CoV-2 or RSV, focusing on relevant tests for the patient. While raw data for all targets is generated and available, only requested results are analyzed and reported, ensuring targeted and efficient testing.

“Our goal for the Respiratory 4-flex is to allow labs to customize testing based on clinical needs, patient symptoms, which are often similar, and to better support a constantly shifting respiratory landscape,” said Denise Heaney, Ph.D., Chief Medical Partner, Molecular Solutions and Infectious Disease at Roche Diagnostics. “TAGS technology allows for the detection of more targets on a high-throughput platform, which supports diagnostic stewardship while reaching a broader patient population.”

This launch 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.

TAGS (Temperature-Activated Generation of Signal) technology

Leveraging Roche’s innovative TAGS technology, cobas Respiratory 4-flex lays the groundwork for future expanded testing capabilities. Developed by Roche scientists, TAGS technology uses multiplex polymerase chain reaction (PCR) testing, combined with color, temperature and data processing, to enable the detection and differentiation of multiple targets within a single optical channel.

About cobas Respiratory 4-flex

The **cobas** Respiratory 4-flex runs on the **cobas** 5800, 6800 and 8800 systems. The test offers qualitative detection and differentiation of SARS-CoV-2, influenza A and B, and respiratory syncytial virus (RSV) in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection, along with clinical and epidemiological risk factors.

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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*Digital Reflex for **cobas** Respiratory 4-flex will be available at launch on the **cobas** 5800 system only. Digital Reflex for **cobas** Respiratory 4-flex will be available on the **cobas** 6800/8800 systems with software version 2.0, which is in development and not available in the U.S.

For Further Information

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