Roche announces the filing for FDA Emergency Use Authorization for SARS-CoV-2 Rapid Antigen Test, allowing healthcare professionals to make fast decisions at the point of care

- **Test is designed to provide healthcare professionals reliable, quick results, typically ready in 15 minutes for people with symptoms of COVID-19, to allow fast, informed treatment decisions**
- **At launch, Roche expects to have tens of millions of tests available per month in the United States**
- **Small, instrument-free testing kit is designed to be affordable and enable convenient use by healthcare professionals at various point-of-care locations or in resource-limited settings**
- **Test is designed for use with a nasal swab to allow quick and convenient sample collection and minimally-invasive testing experience for patients**

INDIANAPOLIS, 8 February 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the submission for Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a SARS-CoV-2 Rapid Antigen Test that is designed for use by healthcare professionals in point-of-care settings with patients experiencing symptoms of COVID-19.

The test is designed to help healthcare professionals quickly identify a SARS-CoV-2 infection, typically in 15 minutes, in people exhibiting symptoms of the virus. It uses a simple nasal swab sample and comes in a small, convenient kit that does not require laboratory instruments, so it can be used at various point-of-care locations close to the patient and in settings where healthcare resources are limited. The test is highly beneficial where timely decisions are needed and PCR tests are not readily available.

"As the COVID-19 pandemic persists, it's becoming more and more important to increase access to testing for all patients in multiple settings, particularly at the point of care," said Matt Sause, President & CEO of Roche Diagnostics North America. "This new rapid antigen test will provide a much needed resource to the healthcare system, as broad access to testing will be critical for re-opening our society."

To accompany the test launch, Roche will offer NAVIFY® Pass, a digital solution that includes mobile applications for healthcare providers and test recipients to share diagnostic results in real time with interested parties. The application is easy to configure and helps streamline healthcare provider digital operations.

Roche expects to have tens of millions of SARS-CoV-2 Rapid Antigen Tests available per month in the United States at launch, with the capacity to produce additional volumes as needed to help address

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pandemic testing demand. The launch is a partnership with SD Biosensor Inc., with whom Roche has a global distribution agreement and launched the SARS-CoV-2 Rapid Antigen Test and the SARS-CoV-2 Rapid Antibody Test in countries accepting the CE mark in 2020.

This test will be a valuable addition to the comprehensive Roche diagnostic portfolio to help healthcare systems combat COVID-19 through testing in the laboratory and at the point of care. Currently, this portfolio includes molecular, serology and digital solutions that help diagnose and manage COVID-19 during the initial stages of infection, during the recovery phase, as well as following the resolution of infection.

About antigen testing

An antigen test detects proteins that are structural or functional components of a pathogen and are thus very specific to that pathogen.[1] In this case, the test would provide a qualitative "yes/no" answer on the presence of the pathogen in the patient sample and can be offered as a rapid strip test that is performed at the point of care. If the target antigen is present in sufficient concentrations in the sample, it will bind to specific antibodies and generate a visually detectable signal on the test strip, typically with results ready in 15 minutes.[2]

In general, antigen tests have a high specificity, though are not as sensitive as molecular tests that amplify the target viral DNA or RNA sequence in order to generate a quantifiable signal to indicate the presence of the virus in a sample. Therefore, to make up for the potential decrease in sensitivity of an antigen test, negative results should be analyzed together with additional patient factors, such as COVID-19 exposure history, clinical symptoms, additional test results to help guide the diagnosis and subsequent treatment of the patient.

About Roche's response to the COVID-19 pandemic

To address the global COVID-19 healthcare crisis, Roche has launched a growing number of diagnostic solutions that help detect and diagnose the infection in patients, as well as providing digital support to healthcare systems. Roche also continues to identify, develop and support potential therapies that can play a role in treating the disease.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. Roche continues to work with healthcare providers, laboratories, authorities and organizations to help make sure that patients continue to receive the tests, treatment and care they need during these challenging times.

The Roche portfolio of COVID-19 solutions includes:

- **cobas**® SARS-CoV-2 Test - a high-volume molecular test to detect the virus that causes COVID-19, (FDA Emergency Use Authorization (EUA) and available in countries accepting the CE Mark)

- Elecsys® Anti-SARS-CoV-2 Test - a laboratory-based antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid protein (FDA EUA and CE Mark)
- Elecsys® IL-6 - an IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
- **cobas**® SARS-CoV-2 & Influenza A/B Test - a high-volume molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both (FDA EUA and CE Mark)
- Elecsys® Anti-SARS-CoV-2 S Test - a second antibody test, aimed at measuring antibody response to the spike protein, to help assess a patient's immune response and support the development of convalescent plasma therapy (FDA EUA and CE Mark)
- SARS-CoV-2 & Influenza A/B Test for **cobas**® Liat System - a point-of-care molecular PCR test that simultaneously detects and differentiates between SARS-CoV-2 and influenza A/B infections to support urgent triage and diagnosis (FDA EUA and CE Mark)

About SD Biosensor
SD Biosensor is a global bio-diagnostic company that provides in vitro products engrafted with innovative technologies. Established in 2010, SD Biosensor has successfully launched diagnostics of blood glucose, glycated hemoglobin, and cholesterols globally, and with innovative products, are striving to become a leading global in vitro diagnostic company.

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognized as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

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The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.

The SARS-CoV-2 Rapid Antigen test is not available for sale in the US.

References

[1] European Centre for Disease Prevention and Control. Diagnostic testing and screening for SARS-CoV-2. 2020. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing. Accessed February 2021.
[2] https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19

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