Roche receives FDA Emergency Use Authorization for new test to measure the level of SARS-CoV-2 antibodies

- **Elecsys® Anti-SARS-CoV-2 S test specifically detects antibodies against the SARS-CoV-2 spike protein**
- **The spike protein is the target of many COVID-19 vaccines in development**
- **This test may help identify recovering patients who could potentially be serum and plasma donors for developing treatments for COVID-19**

Basel, 2 December 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that its Elecsys® Anti-SARS-CoV-2 S antibody test has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The serology (blood) test can be used to measure the level of antibodies in people who have been exposed to the SARS-CoV-2 virus. The EUA in the United States follows the launch of the Elecsys® Anti-SARS-CoV-2 S antibody test for markets accepting the CE Mark announced on 18 September.

The new test targets antibodies that are directed against the region of the novel coronavirus known as the spike protein, specifically the area that enables the virus to bind to a host cell receptor, which is required for the virus to enter the host cell.[1,2] Many current candidate vaccines aim to induce an antibody response against the SARS-CoV-2 spike protein. Tests that quantify antibodies to the spike protein could be used to measure the level of that response and track that measurement over time. The test provides a numerical result describing the concentration of antibodies from 0.40-250 U/mL as well as a qualitative result.

“Since the start of this pandemic, our focus has been to bring effective diagnostic testing solutions to the fight against COVID-19,” said Thomas Schinecker, CEO of Roche Diagnostics. “Antibody tests like these will play a critical role in measuring a person’s vaccine-induced immune response”.

In addition to its role in helping to measure a patient’s immune response, the test may help guide the allocation of plasma donations from recovered COVID-19 patients to current patients by identifying donors that have antibodies to SARS-CoV-2 virus. Convalescent plasma therapy is an investigational procedure that separates and removes the plasma from a patient’s blood. This plasma is then replaced with plasma from a donor to give the ill patient antibodies to help fight the virus.

The laboratory-based Elecsys Anti-SARS-CoV-2 S test runs on Roche’s widely available cobas e analyzers and is the latest addition to Roche’s growing 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 healthcare professionals diagnose COVID-19 and provide optimal patient care during the initial stages of infection and the recovery phase, as well as following the resolution of infection.

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About SARS-CoV-2
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus (SARS-CoV-2) is a new strain which has not previously been identified in humans.

Signs of infection include respiratory symptoms such as cough, shortness of breath, difficulty breathing and fever. In more severe cases, pneumonia, severe acute respiratory syndrome, kidney failure and death can occur.[3]

About the Elecsys® Anti-SARS-CoV-2 S test
The Elecsys® Anti-SARS-CoV-2 S test is an immunoassay for the in vitro determination of antibodies to SARS-CoV-2. Through a blood sample, the test can measure antibodies to the spike protein of the coronavirus, which could signal whether a person has been already infected. The test has both a high negative percent agreement (NPA) of 99.98% (N=5991) and positive percent agreement (PPA) of 96.6% (N=233), 15 days or later after diagnosis with a PCR test. With this test, Roche also showed titer development over time for patient samples ranging >100 days following a reactive PCR result, with no samples showing a decline of titers below the reactive range. Additionally, across panels of potentially cross-reactive samples (N=1100) from endemic human coronaviruses, infectious respiratory diseases, other infectious diseases, auto-immune and liver related diseases, the test demonstrated zero cross-reactivity. This test has been authorized only for the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens.

Clinical laboratories can run these tests on Roche's cobas e analyzers which are widely available around the world. These fully automated systems can provide antibody test results in approximately 18 minutes, with a test throughput of up to 300 tests/hour, depending on the analyzer.[4]

About Roche's response to the COVID-19 pandemic
To address the global COVID-19 healthcare crisis, Roche has developed 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:

- a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, (FDA Emergency Use Authorization (EUA) and available in countries accepting the CE Mark)
- a SARS-CoV-2 laboratory-based antibody test, aimed at detecting the presence of antibodies in the

blood targeting the nucleocapsid (FDA EUA and CE Mark)
- an IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
- 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)
- a second SARS-CoV-2 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
- 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 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 personalised 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 twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

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.

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[2] Hoffmann, Markus et al. (2020). Cell. 81(2):271-280.e8
[3] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
[4] Full specifications of the Roche immunoassay systems, including throughput, can be found on our diagnostics.roche.com website

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