Roche SARS-CoV-2 molecular test granted first FDA Emergency Use Authorization for PCR testing of both symptomatic and asymptomatic individuals at the point of care

- This is the first SARS-CoV-2 real-time RT-PCR test authorised for use in screening and testing asymptomatic and symptomatic individuals with results within 20 minutes, allowing health care professionals to take action quickly and confidently
- The new test offers broad SARS-CoV-2 strain coverage as monitored by Roche's ongoing variant surveillance program providing further reassurance with healthcare decisions
- The test, which runs on the **cobas**® Liat® System, will also be available in markets accepting the CE mark, and it reinforces Roche's continued commitment to address the COVID-19 public health crisis.

Basel, 18 June 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the **cobas**® SARS-CoV-2 Nucleic acid test for use on the **cobas**® Liat® System. This singleplex test is the first real-time reverse transcriptase polymerase chain reaction (RT-PCR) test that can identify SARS-CoV-2 infection within 20 minutes.

The cobas SARS-CoV-2 test is the first RT-PCR test that screens within 20 minutes both asymptomatic and symptomatic persons, enabling quick, informed decisions at the point of care. The test is for use at a wide range of point-of-care settings, including but not limited to emergency and primary care, physician offices and screening locations, enabling greater access for patients. At launch, the test will also be available in markets accepting the CE mark.

"We learn more about COVID-19 everyday and Roche continues to develop solutions that will help healthcare systems around the world slow and eventually defeat this pandemic. We are pleased that we can now provide a test to enable healthcare professionals to identify both asymptomatic and symptomatic infected individuals at the point of care," said Ian Parfrement, Head of Point of Care for Roche Diagnostics Solutions. "Preventing further spread of the virus is crucial for public health and the continued safe reopening of our communities worldwide."

Individuals infected with the SARS-CoV-2 virus may not always show symptoms of COVID-19.[1] However, they can still spread the infection, which is why a test that can be used to screen asymptomatic people is important in the fight against the virus. The test offers broad strain coverage of SARS-CoV-2 variants providing further reassurance with clinician-care decisions.

The test will be available in July.

About the cobas Liat System

Utilising PCR technology, the cobas Liat System fully automates the testing process, simplifies workflow and enables healthcare providers to perform molecular testing in a variety of point-of-care settings with speed, reliability and minimal training. Definitive results are generated in 20 minutes or less to aid in patient care decisions. In addition to the existing tests for SARS-CoV-2 & influenza A/B, influenza A/B & RSV, Strep A and C. diff, assays for other infectious diseases are in development. More information is available at www.cobasliat.com.

The cobas Liat System is commercially available in select markets.

About SARS-CoV-2 (COVID-19)

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 type which has not previously been identified in humans.[2]

Signs of infection may 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.

To control the spread of the infection, WHO recommends regular hand washing, covering mouth and nose when coughing and sneezing and avoiding close contact with anyone showing symptoms of respiratory illness.

About Emergency Use Authorization status

The cobas SARS-CoV-2 Test for use on the cobas Liat system has not been FDA cleared or approved. It has been authorised by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories. The test has been authorised only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. It is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of in vitro diagnostics for detection of SARS-CoV-2 virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorisation is terminated or revoked sooner.

About Roche's response to the COVID-19 pandemic

The COVID-19 pandemic continues to evolve globally with varying developments from country to country and we are partnering with healthcare providers, laboratories, authorities and

organisations to help make sure that patients receive the tests, treatment and care they need. This new test is an additional step in Roche's fight against the COVID-19 pandemic, which has already included:

- Launching COVID-19 diagnostic tests for active infection and the detection of antibodies in patients who have been exposed to the virus,
- Investigating treatments from our existing portfolio to better understand their potential to treat patients with COVID-19,
- Increasing manufacturing and supply chain capacity to meet product demand across our portfolio within the wider context of COVID-19 treatment, and
- Ensuring the supply of our existing medicines and diagnostics to patients around the world under exceptional conditions.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March 2020 we received FDA Emergency Use Authorization for a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, which is also available in countries accepting the CE Mark. On 3 May 2020, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorization and is available in markets accepting the CE mark. Also in June of last year we received an FDA EUA for the Elecsys® IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19, as well as launching Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic. In July of 2020, we added a Rapid Antibody Test, with SD Biosensor as manufacturing partner, to the portfolio that allows the detection of antibodies against COVID-19 at the point of care. In addition, we also launched a Rapid Antigen Test in September and a lab-based Antigen Test in December.* Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

Roche is actively involved in understanding the potential of the existing portfolio and is researching options for the future. Roche has an ongoing clinical trial program evaluating the role of Actemra©/RoActemra© (tocilizumab) in COVID-19 pneumonia. On 29 July 2020 Roche announced that the COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality. The study was the first global, randomised, double-blind, placebo-controlled phase III trial investigating Actemra/RoActemra in this setting. Roche remains committed to continuing the Actemra/RoActemra clinical trial programme in COVID-19 to further explore Actemra/RoActemra in other treatment settings, including in combination with an antiviral. In addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations. On 19 August 2020, Roche announced a partnership with Regeneron to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to

people around the globe. On 18 October 2020, Roche announced a collaboration with Atea Pharmaceuticals to develop a potential oral treatment for COVID-19 patients.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

** Roche v-TAC, the Rapid Antibody Test, the Rapid Antigen Test and the lab-based Antigen Test are not available for sale in the U.S.*

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

[1] Walsh KA, Jordan K, Clyne B, Rohde D, Drummond L, Byrne P, et al. SARS-CoV-2 detection, viral load and infectivity over the course of an infection. J Infection. 2020;81(3):357–71.
[2] https://www.who.int/health-topics/coronavirus. Accessed 05Jun2020

Roche Diagnostics Global Communications
Elizabeth.Baxter@Roche.com
Mobile: +1 (925) 523 - 8812

Roche Diagnostics US Communications
jo_lynn.garing@roche.com
Mobile: +1 (317) 363-7286