# Roche receives FDA authorisation for testing of asymptomatic people with the cobas SARS-CoV-2 Test to help control the spread of COVID-19

- **Asymptomatic spread of SARS-CoV-2 infections is a significant contributor of ongoing COVID-19 transmission**
- **The high-throughput, highly sensitive cobas SARS-CoV-2 Test under FDA Emergency Use Authorisation can now be used to test individual or pooled samples from people without symptoms or other reasons to suspect COVID-19**
- **Accurate, reliable and early detection of SARS-CoV-2 in potentially exposed individuals can help limit the spread of disease**

Pleasanton, 17 May 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that its **cobas®** SARS-CoV-2 Test for use on the widely available, high-throughput **cobas®** 6800/8800 Systems has received Emergency Use Authorisation (EUA) from the U.S. Food and Drug Administration (FDA) for testing individuals without symptoms or reasons to suspect COVID-19. This authorisation supports the guidance update from the U.S. Centers for Disease Control and Prevention (CDC) to expand SARS-CoV-2 testing to include people without symptoms[1] in an effort to reduce the spread of disease, and applies to pooled samples containing up to and including six individual samples.

A study conducted by the CDC has shown that transmission of COVID-19 by individuals who do not exhibit symptoms is estimated to be responsible for more than half of all infected cases.[2] This presents a significant public health challenge as symptom-based testing alone is not sufficient to effectively control the spread of COVID-19.

“One of the key strategies to reduce COVID-19 transmission is to stop the silent spread of disease early,” said Cindy Perettie, Head of Molecular Lab, Roche Diagnostics Solutions. “Expanding highly sensitive testing to include people who are at risk of exposure but do not show symptoms will help guide contact tracing, isolation and surveillance requirements, which are crucial for public health and the safe reopening of communities.”

Asymptomatic testing with the cobas SARS-CoV-2 Test is also available in countries accepting the CE mark. In 2020 Roche enabled 160 million molecular SARS-CoV-2 tests on the company’s platforms in an extraordinary scale-up effort, and the company continues to develop innovative diagnostic solutions to help healthcare professionals understand and manage the disease.

**About Emergency Use Authorisation status**
The cobas SARS-CoV-2 Test 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 moderate and high-complexity tests. 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

**F. Hoffmann-La Roche Ltd** 4070 Basel Switzerland | Group Communications Roche Group Media Relations | Tel. +41 61 688 88 88 www.roche.com

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 SARS-CoV-2 (coronavirus)**
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 recently identified in humans.

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

**About cobas SARS-CoV-2 Test**
cobas SARS-CoV-2 for use on the cobas 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider, and those without symptoms or other reasons to suspect COVID-19. cobas SARS-CoV-2 is for use only under Emergency Use Authorization (EUA) in laboratories certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.

This test is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens. Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive or presumptive positive result must be tested individually prior to reporting a result. Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing. Testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 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 viruses.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, recent exposures and epidemiological information. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. cobas SARS-CoV-2 is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the

techniques of real-time PCR and on the use of the cobas 6800/8800 Systems. cobas SARS-CoV-2 is only for use under the Food and Drug Administration's Emergency Use Authorization.

**About the cobas 6800/8800 Systems**
When every moment matters, the fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms. With proven performance, absolute automation and unmatched flexibility delivering unparalleled throughput 24/7— cobas 6800/8800 Systems are designed to ensure a lab's long-term sustainability and success … now, more than ever. Learn more now: www.cobas68008800.com

**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 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.



**References**
[1] Overview of Testing for SARS-CoV-2 (COVID-19). Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/php/testing/expanded-screening-testing.html. Accessed 3 Mar 2021.
[2] Johansson MA, Quandelacy TM, Kada S, et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. JAMA Netw Open. 2021;4(1):e2035057. Published 2021 Jan 4. doi:10.1001/jamanetworkopen.2020.35057
[3] Coronavirus. World Health Organization. https://www.who.int/health-topics/coronavirus. Accessed 18 Jan 2021.

**Media Contact:**

**F. Hoffmann-La Roche Ltd** 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

Elizabeth Baxter
Elizabeth.Baxter@Roche.com
925.523.8812

Mike Weist
mike.weist@roche.com
317.371.0035