Roche begins shipments of first 400,000 COVID-19 tests to laboratories across US to begin patient testing under FDA Emergency Use Authorization

- Broad network of labs will use automated cobas SARS-CoV-2 Test to process high volume of patient samples sent from across US
- First available commercial test kit for novel coronavirus will enable labs to expand and expedite testing to meet urgent medical needs

INDIANAPOLIS, March 16, 2020—Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has begun shipping the first allotment of its cobas® SARS-CoV-2 Test for COVID-19 (coronavirus) to a network of hospital and reference laboratories across the U.S. to enable automated, high-volume patient testing. Shipping of the initial 400,000 test kits began Friday, March 13, and will be completed this week. Roche plans to ship an additional 400,000 tests per week to the laboratory testing sites across the nation that are set up to run the test immediately under the guidelines of the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

"We are grateful to the FDA for accelerating the process to grant Emergency Use Authorization for this test," said Matt Sause, president and CEO of Roche Diagnostics North America. "We began shipping test kits immediately so labs could start to offer high-volume testing as soon as possible and give more patients access to reliable diagnostics. Together, we can help combat this serious disease."

Under the EUA, the cobas SARS-CoV-2 Test is intended for the qualitative detection of SARS-CoV-2, the virus that causes COVID-19 disease, in patients who meet COVID-19 clinical and/or epidemiological criteria for testing. The test uses nasopharyngeal or oropharyngeal swab samples (taken from the back of the nose or throat).

The test kits are being sent to a network of more than 30 hospital and reference laboratories in the U.S. that already have the required instrumentation in place and have the ability to...
implement high-volume testing immediately. Roche consulted with government agencies to ensure that the test distribution prioritizes labs with the broadest geographic reach and highest patient impact. Healthcare providers across the entire U.S. can send patient samples to these laboratories for processing.

The labs run the test on Roche’s fully automated cobas® 6800 and cobas® 8800 Systems, which can process up to 384 results (cobas 6800 System) and 960 results (cobas 8800 System) in an 8-hour shift. After the lab starts the test, results are available in about three-and-a-half hours.

The test can only be ordered by a medical professional, so patients who have symptoms consistent with COVID-19 should go to their healthcare provider for evaluation.

More information for healthcare providers, patients and the general public is available at diagnostics.roche.com. Technical information about the test is available at cobas SARS-CoV-2 Test.

About Emergency Use Authorization Status

The cobas SARS-CoV-2 Test has not been FDA cleared or approved. It has been authorized 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 authorized 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 authorized for the duration of the declaration that circumstances exist justifying the authorization 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 authorization is terminated or revoked sooner.

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 eleventh 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 or diagnostics.roche.com.

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