

## **Roche highly accurate antibody test for COVID-19 goes live at more than 20 initial lab sites in the US**

### **LabCorp and other commercial labs will have the ability to perform more than 2 million tests per week by June**

INDIANAPOLIS, May 19, 2020—Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced its Elecsys® Anti-SARS-CoV-2 antibody test is live at more than 20 commercial and hospital lab sites throughout the United States, with plans in the next several weeks to increase to more than 200 commercial and hospital lab sites with the ability to perform millions of tests per week. The Elecsys® Anti-SARS-CoV-2 antibody test received Emergency Use Authorization from the FDA earlier this month.

“Roche is proud to make this highly accurate serology test available in the U.S. to determine if a person has developed antibodies to COVID-19,” said Matt Sause, President and CEO of Roche Diagnostics North America. “Reliable, high-quality antibody testing is essential to help us overcome this pandemic and will play an important role in getting people back to work. We are proud to partner with LabCorp in making this test available in the U.S.”

The Roche antibody test is uniquely designed to identify mature (high affinity) antibodies developed late in the immune response, significantly reducing the chance of a false positive result. It provides 99.8 percent specificity, which is greater than previously available antibody tests. This specificity is crucial to determine reliably if a person has been exposed to the virus and has developed antibodies. Tests with lower specificity and sensitivity can lead to a high number of misidentified cases in a population. A false positive result may put a patient at risk by indicating they have antibodies when they do not.

“Our long-standing relationship and collaboration with Roche enables us to introduce many innovative, high-quality tests for clinicians and patients, which is more important now than ever before,” said Dr. Brian Caveney, chief medical officer and president of LabCorp Diagnostics. “Roche’s

new antibody test allows LabCorp to provide more options and increase COVID-19 testing capacity as we support the country's response to the health crisis.”

Roche has more than 3,000 analyzers that perform the antibody test installed across the United States. Roche is distributing millions of tests per week to U.S. labs that can implement quickly, enable the broadest geographic reach and provide testing to areas hardest hit by COVID-19.

Roche is working to meet demand by scaling global production rapidly in an effort to expand broader access as quickly as possible.

Healthcare providers can order the test for patients through their normal clinical laboratory process.

#### **About the Elecsys® Anti-SARS-CoV-2 test**

The Elecsys® Anti-SARS-CoV-2 test, which is based on an in-solution double-antigen sandwich format, can detect antibodies to the new coronavirus causing COVID-19, which could signal whether a person has already been infected and potentially developed immunity to the virus. Based on the measurement of a total of 5272 samples, the Elecsys® Anti-SARS-CoV-2 assay has 99.8% specificity and shows no cross-reactivity to the common cold, HIV and other coronaviruses. This means it can lower the chance of false positives due to the detection of similar antibodies that may be present in an individual. Elecsys® Anti-SARS-CoV-2 detected antibodies with 100% sensitivity in samples taken 14 days after a PCR-confirmed infection. As of 24 April 2020, no study has evaluated whether the presence of antibodies to SARS-CoV-2 confers immunity to subsequent infection by this virus in humans.

More information for healthcare providers, patients and the general public is available at [diagnostics.roche.com](https://diagnostics.roche.com). Technical information about the test is available at [Elecsys® Anti-SARS-CoV-2 test](#).

#### **About Emergency Use Authorization Status**

The Elecsys Anti-SARS-CoV-2 test has not been FDA cleared or approved. It has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. It is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 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](http://www.roche.com) or [diagnostics.roche.com](http://diagnostics.roche.com).

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