# *Media Release*

## Roche's COVID-19 antibody test receives FDA Emergency Use Authorization and is available in markets accepting the CE mark

- **The serology test has a specificity greater than 99.8% and sensitivity of 100% (14 Days post-PCR confirmation)**
- **The high specificity of the test is crucial to determine reliably if a person has been exposed to the virus and if the patient has developed antibodies**
- **Roche will provide high double-digit millions of tests already in May for countries accepting the CE mark and in the U.S. under Emergency Use Authorization, further ramping up capacities thereafter**
- **The test is available on Roche's cobas e analysers which are widely available around the world**

Basel, 03 May 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA)[1] for its new Elecsys® Anti-SARS-CoV-2 antibody test. The test is designed to help determine if a patient has been exposed to the SARS-CoV-2 virus and if the patient has developed antibodies against SARS-CoV-2. Roche has already started shipping the new antibody test to leading laboratories globally and will ramp up production capacity to high double-digit millions per month to serve healthcare systems in countries accepting the CE mark[2] as well as the U.S.

"Thanks to the enormous efforts of our dedicated colleagues we are now able to deliver a high-quality antibody test in high quantities, so we can support healthcare systems around the world with an important tool to better manage the COVID-19 health crisis," said Severin Schwan, CEO Roche Group. "I am in particular pleased about the high specificity and sensitivity of our test, which is crucial to support health care systems around the world with a reliable tool to better manage the COVID-19 health crisis."

"Our best scientists have worked 24/7 over the last few weeks and months to develop a highly reliable antibody test to help fight this pandemic," said Thomas Schinecker, CEO Roche Diagnostics. "Roche is committed to helping laboratories deliver fast, accurate, and reliable results to healthcare professionals and their patients."

Roche's SARS-CoV2 antibody test, which has a specificity greater than 99.8% and 100% sensitivity[3] (14 Days post-PCR confirmation), can help assess patients' immune response to the virus. As more is understood about immunity to SARS-CoV-2, the test may help to assess who has built up immunity to the virus.

With extensive global manufacturing capabilities, Roche will be able to deliver high double-digit millions of tests per month. Hospitals and reference laboratories can run the test on Roche's cobas e analysers, which are widely available around the world.

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For countries with specific regulatory requirements, local approval timelines apply. In addition there may be other country-specific regulations, such as import requirements, which will determine when the test becomes available locally. Roche will work closely with the respective regional representatives to ensure we appropriately support local registration efforts.

**About antibody testing**
An antibody test, also called a serology test, is used to determine whether a person might have gained immunity against a pathogen or not. The human body makes antibodies in response to many illnesses. In the current situation of the COVID-19 pandemic, antibody tests need to be able to specifically detect antibodies against SARS-CoV-2 with no cross-reactivity to other similar coronaviruses, which could generate a false positive result and thus wrongly indicate potential immunity. A false positive result happens when a person receives a positive test result, when they should have received a negative result. False positives are particularly critical when we do not know how many people in a given population have had COVID-19. 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[4].

**About Elecsys Anti-SARS-CoV-2 serology test**
Elecsys® Anti-SARS-CoV-2 is an immunoassay for the in-vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. Through a blood sample, the 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 99.81% specificity and shows no cross-reactivity to the four human coronaviruses causing common cold. This means it can lower the chance of false positives due to the detection of similar antibodies that may be present in an individual, but are specific for coronaviruses other than SARS-CoV-2. Elecsys® Anti-SARS-CoV-2 detected antibodies with 100% sensitivity in samples taken 14 days after a PCR-confirmed infection. The importance of specificity and sensitivity of a particular test will be dependent on its purpose and disease prevalence within a given population.

Hospitals and reference laboratories can run the test on Roche's cobas e analysers, which are widely available around the world. These fully automated systems can provide SARS-CoV-2 test results in approximately 18 minutes for one single test, with a test throughput of up to 300 tests/hour, depending on the analyser.

**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.



**References**

[1] The Emergency Use Authorisation (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of medical countermeasures needed during public health emergencies https://www.fda.gov/home
[2] CE-IVD marking is granted through completion of a comprehensive technical validation and self declaration under the European Directive for In Vitro Diagnostic Medical Devices.
[3] Full specifications of Roche's Elecsys® Anti-SARS-CoV-2 antibody test and immunoassay systems, including throughput, can be found on our diagnostics.roche website
[4] https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19

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