

Roche develops new serology test to detect COVID-19 antibodies

- **The new Elecsys Anti-SARS-CoV-2 serology test can support the detection of antibodies against SARS-CoV-2 in patients who have been exposed to the virus which causes COVID-19**
- **The detection of these antibodies could help indicate if a person has gained immunity against the virus and inform treatment decisions**
- **Roche aims to have this test available by early May, in countries accepting the CE mark¹ and is actively working with the US Food and Drug Administration for an Emergency Use Authorisation²**

Basel, 17 April 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the development and upcoming launch of its Elecsys® Anti-SARS-CoV-2 serology test to detect antibodies in people who have been exposed to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) that causes the COVID-19 disease.

Antibody testing is central to help identify people who have been infected by the virus, especially those who may have been infected but did not display symptoms.³ Additionally, the test can support priority screening of high risk groups, such as healthcare workers, food supply workers who might already have developed a certain level of immunity and can continue serving and/or return to work. Once we understand more about the immunity of COVID-19, it could also help society return faster to normality.

Severin Schwan, CEO Roche Group: “Following the launch of our high-volume PCR test in mid-March to detect active infection of the disease, we are now going to launch a new antibody test in early May. Every reliable test on the market serves its purpose for healthcare systems to help us overcome this pandemic. Roche is collaborating closely with health authorities and ramping up production to ensure fast availability of the test globally.”

“Roche is deeply committed to supporting the global response to the COVID-19 pandemic,” said Thomas Schinecker, CEO Roche Diagnostics. “Timely availability and fast access to reliable, high quality tests are essential for healthcare systems. The antibody test is an important next step in the fight against COVID-19. Roche’s antibody test can be quickly scaled and made broadly available around the world as our instrument infrastructure is already in place.”

The Elecsys Anti-SARS-CoV-2 immunoassay is an in vitro test, using human serum and plasma drawn from a blood sample, to detect antibodies and determine the body’s immune reaction to SARS-CoV-2. The test may be used in epidemiological research to help better understand the spread of the disease and may also be used together with molecular tests to aid in the diagnosis of suspected COVID-19 patients. Hospitals and reference laboratories can run the test on Roche’s cobas e analysers, which are widely available in laboratories around the world.

Roche aims to have the antibody test available by early May in countries accepting the CE mark and is actively working with the FDA for an Emergency Use Authorisation. Roche is planning on an accelerated ramp up of monthly production to high double-digit million tests by June and will further scale up production as fast as possible.

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 a new strain which has not previously been identified in humans.

Signs of infection 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, the World Health Organisation (WHO) recommends regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs and avoiding close contact with anyone showing symptoms of respiratory illness.

About Elecsys Anti-SARS-CoV-2 serology test

Elecsys[®] Anti-SARS-CoV-2 is an immunoassay for the in vitro 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 can detect antibodies to the coronavirus, which could signal whether a person has been already infected and potentially developed immunity to the virus. 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, with a test throughput of up to 300 tests/hour, depending on the analyser.⁴

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.

All trademarks used or mentioned in this release are protected by law.

References

[1] 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.

[2] 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>

[3] Thus, 29 of the 33 patients who were positive for SARS-CoV-2 at admission (87.9%) had no symptoms of Covid-19 at presentation - <https://www.nejm.org/doi/full/10.1056/NEJMc2009316>

[4] Full specifications of the Roche immunoassay systems, including throughput, can be found on our diagnostics.roche website

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

- Nicolas Dunant (Head)
- Patrick Barth
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein