

## **Roche launches new quantitative antibody test to measure SARS-CoV-2 antibodies, to support the evaluation of vaccines**

- **The new Elecsys Anti-SARS-CoV-2 S test can quantitatively measure the level of antibodies against SARS-CoV-2 in patients who have been exposed to the virus.**
- **The test targets antibodies against the spike protein. This is the focus of vaccines in development and convalescent plasma therapy.<sup>1</sup>**
- **Using the Elecsys Anti-SARS-CoV-2 S antibody test, together with the Elecsys Anti-SARS-CoV-2\* test launched in May, can help to more effectively determine the percentage of a population who already have antibodies against SARS-CoV-2.**

Basel, 18 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of its Elecsys® Anti-SARS-CoV-2 S antibody test for markets accepting the CE Mark. Roche has filed for Emergency Use Authorisation (EUA) from the U.S. Food and Drug Administration (FDA).

The Elecsys Anti-SARS-CoV-2 serology test can be used to quantitatively measure antibodies in people who have been exposed to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and can play an important part in characterising a vaccine-induced immune response.<sup>1</sup> Specifically, the test targets antibodies which are directed against the particular region of the viral spike protein responsible for binding to the host cell receptor, which is required for the virus to enter the host cell. The majority of current candidate vaccines aim to induce an antibody response against the spike protein.

“As the possibility of an effective SARS-CoV-2 vaccine becomes a reality, quantitative measurement of antibodies will be crucial in the evaluation of any potential vaccine. The new quantitative Elecsys antibody test can play a pivotal role in vaccine clinical trials as well as helping clinicians assess patients immune response. This will be instrumental in protecting people most vulnerable to the virus, as well as in overcoming COVID-19 for society in general.” said Thomas Schinecker, CEO Roche Diagnostics. “This new test, the twelfth in the Roche SARS-CoV-2 testing portfolio, is another essential addition to support healthcare systems and patients as we jointly fight COVID-19.”

Before a vaccine is administered it is important to know the starting level of antibodies a person has, in order to evaluate any change in antibody levels that the vaccine induces, especially the development of antibodies directed against the SARS-CoV-2 spike protein. These antibodies have been shown to have potent antiviral activity and correlate to potential immunity.<sup>2</sup> Measuring antibody levels could also be vital in establishing vaccine efficacy in the prevention of infection and/or the development of severe COVID-19.<sup>1</sup>

Alongside its importance to vaccine design and efficacy evaluations, the Elecsys Anti-SARS-CoV-2 S serology test can be used to determine antibody levels in plasmapheresis donations. Performing a combination of the Elecsys Anti-SARS-CoV-2 S and Elecsys Anti-SARS-CoV-2 tests can also help to more effectively define what percentage of a given population has developed antibodies (seroprevalence) against SARS-CoV-2, especially

in low to moderate seroprevalence settings.<sup>3</sup> Knowing a given population's seroprevalence is important in understanding how to contain the spread of the virus, as well as how to safely ease lockdown restrictions.

The test is the latest addition to the comprehensive Roche diagnostic portfolio to help healthcare systems combat COVID-19 through testing in the laboratory and at the point of care. Currently, this portfolio includes molecular, serology and digital solutions which help diagnose and manage COVID-19 during the initial stages of infection, during the recovery phase, as well as following the resolution of infection.

### **About SARS-CoV-2**

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.<sup>4</sup>

### **About potential SARS-COV-2 vaccines**

As of 3 September 2020, 47 candidate vaccines are in clinical evaluation and 3 vaccines have been approved for early or limited use, while at least 91 preclinical vaccines are under active investigation.<sup>1,5</sup> All candidate vaccines in Phase III or approved for limited / early use aim to induce an antibody response against the SARS-CoV-2 spike protein. Any potential vaccine for SARS-CoV-2 would work (amongst other mechanisms) by triggering the immune response to develop neutralising antibodies, in the person receiving the vaccine. In doing so, the vaccine trains the body's immune system to recognize and fight an exposure to SARS-CoV-2, in a controlled way, without being exposed to the actual virus.<sup>1</sup>

### **About Elecsys Anti-SARS-CoV-2 S and Elecsys Anti-SARS-CoV-2 serology tests**

The Elecsys® Anti-SARS-CoV-2 S is an immunoassay for the quantitative, in vitro determination of antibodies to SARS-CoV-2 in human serum and plasma. Through a blood sample, the test can measure the quantity of antibodies to the spike protein of the coronavirus, which could signal whether a person has been already infected and potentially developed immunity to the virus. This can also be used to determine antibody levels in plasmapheresis donations. Plasmapheresis is a procedure which separates and removes the plasma from a patient's blood. This plasma is then replaced with plasma from a donor. It is assumed that plasma from a donor who has already had SARS-CoV-2 will have direct antiviral properties for the donor recipient.<sup>6</sup> This is being explored as an adjunctive treatment for the management of COVID-19.<sup>6</sup> The test has both a high clinical specificity of 99.98% (N=5991) and sensitivity of 98.8% (N=1423), 14 days or later after diagnosis with PCR. Additionally, across panels of potentially cross-reactive samples (N=1100) from endemic human coronaviruses, infectious respiratory diseases, other infectious diseases, auto-immune and liver related diseases, the test demonstrated zero cross-reactivity.

Hospitals and reference laboratories can run the test on Roche's cobas e analyzers 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 analyzer.<sup>3</sup>

\*The Elecsys Anti-SARS-CoV-2 is an immunoassay for the qualitative, in vitro detection of antibodies (including IgG) to SARS-CoV-2. 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. This test can also help in the determination of seroprevalence (i.e. the frequency of individuals with antibody to the virus), in a given population, as well as a complement test to Nucleic Acid Amplification Tests (NAAT) for the diagnosis of SARS-CoV-2 infection. The test runs on Roche's cobas e analyzers which are widely available around the world.<sup>3</sup>

#### **About Roche response to COVID-19 section**

The COVID-19 pandemic continues to evolve globally with varying developments from country to country and we are partnering with healthcare providers, laboratories, authorities and organisations to help make sure that patients receive the tests, treatment and care they need. This new test is an additional step in Roche's fight against the COVID-19 pandemic, which has already included:

- Launching COVID-19 diagnostic tests for active infection and the detection of antibodies in patients who have been exposed to the virus,
- Investigating treatments from our existing portfolio to better understand their potential to treat patients with COVID-19,
- Increasing manufacturing and supply chain capacity to meet product demand across our portfolio within the wider context of COVID-19 treatment,
- Ensuring the supply of our existing medicines and diagnostics to patients around the world under exceptional conditions.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March we received FDA Emergency Use Authorisation for a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, which is also available in countries accepting the CE Mark. On 3 May, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorisation and is available in markets accepting the CE mark. Also in June we received an FDA EUA for the Elecsys® IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19, as well as launching Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic. In July, we added a Rapid Antibody Test, with SD Biosensor as distribution partner, to our portfolio, that allows the detection of antibodies against Covid-19 at the point of care. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

We are actively involved in understanding the potential of our existing portfolio and are researching options for the future. Roche has an ongoing clinical trial program evaluating the role of Actemra®/RoActemra® (tocilizumab) in COVID-19 pneumonia. On 29 July we announced that the COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality. The study was the first global, randomised, double-blind, placebo-controlled phase III trial investigating Actemra/RoActemra in this setting. Roche remains committed to continuing the Actemra/RoActemra clinical trial programme in COVID-19 to further explore Actemra/RoActemra in other treatment settings, including in combination with an antiviral. In addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations. On 19 August, we announced a partnership with Regeneron to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to people around the globe.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

### **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).

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## References

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