

## **Roche to launch SARS-CoV-2 Rapid Antigen Test in countries accepting CE mark, allowing fast triage decisions at point of care**

- **Antigen test reliably and quickly triages people suspected of SARS-CoV-2, with results ready in 15 minutes, allowing informed treatment decisions**
- **Antigen test accurately screens individuals with known exposure to infected SARS-CoV-2 patients, providing fast answers regarding their infection status**
- **Affordable and small, instrument-free testing kit enables convenient use for healthcare professionals at different point of care locations, or in resource-limited settings**
- **Point of care testing increases access to high quality diagnostics solutions for the detection of a current SARS-CoV-2 infection, regardless of laboratory testing infrastructure or patient mobility**

Basel, 1 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it will launch a SARS-CoV-2 Rapid Antigen Test, in late September, for markets accepting the CE Mark. Roche also intends to file for Emergency Use Authorisation (EUA) to the U.S. Food and Drug Administration (FDA).

The SARS-CoV-2 Rapid Antigen Test is for use in point of care settings for both symptomatic and asymptomatic people. This can help healthcare professionals identify a SARS-CoV-2 infection in people suspected to carry the virus with results typically ready in 15 minutes.<sup>1</sup> In addition, it serves as a valuable initial screening test for individuals that have been exposed to SARS-CoV-2 infected patients or a high risk environment. The test has a sensitivity of 96.52% and a specificity of 99.68%, based on 426 samples from two independent study centers.\* At launch, there will be 40 million SARS-CoV-2 Rapid Tests available, per month. This capacity will increase more than two-fold at the end of this year to help with testing demands of healthcare systems globally.

The launch is a partnership with SD Biosensor Inc., with whom Roche has a global distribution agreement and had also launched a Rapid Antibody Test in July.

The test is the tenth 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.

The SARS-CoV-2 Rapid Antigen Test is performed by healthcare professionals in a number of different settings close to the patient. This is highly beneficial where timely decisions are needed or laboratory testing is inaccessible. The test will help to quickly identify people who are infected and allows better patient management as well as more effective use of healthcare resources.

Thomas Schinecker, CEO of Roche Diagnostics, stated, “As the COVID-19 pandemic persists, healthcare systems remain challenged. Testing continues to be an important focus for many countries. Especially in the

upcoming flu season, it is important to know whether a person has SARS-CoV-2 or the flu to ensure the right course of treatment. COVID-19 testing solutions that provide healthcare professionals and patients with a quick answer regarding their infection status are critical to contain the community-spread of the COVID-19 virus. We are working relentlessly to deliver solutions that help alleviate some of the healthcare burden with reliable SARS-CoV-2 testing solutions as we learn more about the disease and how it affects people around the world.”

### **About the SARS-CoV-2 Rapid Antigen Test**

Roche’s SARS-CoV-2 Rapid Antigen Test is a rapid chromatographic immunoassay intended for the qualitative detection of a specific antigen of SARS-CoV-2 present in human nasopharynx. This test is performed by healthcare professionals using a nasopharyngeal swab collected from a patient.<sup>1</sup> The results are intended to aid in the early diagnosis of SARS-CoV-2 infection in patients showing clinical symptoms of SARS-CoV-2 and assist in the initial screening of patients. The test has a sensitivity of 96.52% and a specificity of 99.68%, based on 426 samples from two independent study centers. Results are ready in only 15 minutes.<sup>1</sup> This test is another important addition to the testing options for SARS-CoV-2 at the point of care, following the launch of the SARS-CoV-2 Rapid Antibody Test, in July 2020, that is helping healthcare professionals identify patients that have developed antibodies against SARS-CoV-2, indicating prior infection.

### **About antigen testing**

An antigen test detects proteins which are structural or functional components of a pathogen and are thus very specific to that pathogen.<sup>2</sup> In this case, the test would provide a qualitative “yes/no” answer on the presence of the pathogen in the patient sample and can be offered as a rapid strip test that is performed at the point of care. If the target antigen is present in sufficient concentrations in the sample, it will bind to specific antibodies and generate a visually detectable signal on the test strip, typically with results ready in 15 minutes.<sup>1,3</sup>

In general, antigen tests have a high specificity, though are not as sensitive as molecular tests that amplify the target viral DNA or RNA sequence in order to generate a quantifiable signal to indicate the presence of the virus in a sample. Therefore, to make up for the potential decrease in sensitivity of an antigen test, negative results should be analysed together with additional patient factors, such as COVID-19 exposure history, clinical symptoms, additional test results to help guide the diagnosis and subsequent treatment of the patient.

### **About Roche’s response to the COVID-19 pandemic**

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, and
- 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 SD Biosensor**

SD Biosensor is a global bio-diagnostic company that provides in vitro products engrafted with innovative technologies. Established in 2010, SD Biosensor has successfully launched diagnostics of blood glucose, glycated hemoglobin, and cholesterols globally, and with innovative products, are striving to become a leading global in vitro diagnostic company.

## 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

- [1] Roche Diagnostics Ltd. (2020). SARS-CoV-2 Rapid Antigen Test package insert
- [2] European Centre for Disease Prevention and Control. Diagnostic testing and screening for SARS-CoV-2. 2020. <https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing>. Accessed July 2020.
- [3] <https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19>

\* Evaluation was carried out in study centers in India and Brazil.

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