

Roche launches laboratory SARS-CoV-2 antigen test to support high-volume testing of suspected COVID-19 patients

- **The Elecsys® SARS-CoV-2 Antigen test is an automated laboratory assay intended as an aid in the diagnosis of active SARS-CoV-2 infection**
- **Roche will be able to ramp up to a double-digit million number of tests per month, by early 2021**
- **The test is the latest addition to Roches comprehensive COVID-19 portfolio and can help in the management of patients for optimal care delivery**

Basel, 11 December 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has launched a high-throughput SARS-CoV-2 antigen test as an aid in the diagnosis of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infections, in markets accepting the CE Mark. Roche has also filed for Emergency Use Authorisation (EUA) from the U.S. Food and Drug Administration.

The Elecsys® SARS-CoV-2 Antigen test is a highly accurate laboratory immunoassay for the in vitro qualitative detection of the nucleocapsid antigen of SARS-CoV-2. In clinical studies, the Elecsys SARS-CoV-2 Antigen test showed a 94.5% sensitivity across 200 PCR confirmed symptomatic individuals* and a 99.9% specificity across 2747 PCR negative symptomatic and screening individuals. It is planned to ramp up production to have a double-digit million number of tests per month, in early 2021, depending on the demand of healthcare systems, globally. The test is performed by healthcare professionals and uses nasopharyngeal or oropharyngeal swab samples from patients with symptoms suggestive of COVID-19, or people with either known or suspected exposure to SARS-CoV-2. A widely available, laboratory-based automated antigen assay allows for cost and error reduction due to removal of manual handling as well as fast turn-around times and high test throughput.

“Healthcare systems remain under significant pressure to deliver robust testing options, with a sufficient number of tests available”, said Thomas Schinecker, CEO Roche Diagnostics. “The launch of our high-throughput antigen test will provide additional testing capacity to reliably support healthcare systems in diagnosing SARS-CoV-2 infection, as a supplement to PCR testing.”

About the Elecsys SARS-CoV-2 Antigen test

Roche’s Elecsys SARS-CoV-2 Antigen test is an immunoassay intended for the qualitative detection of SARS-CoV-2 present in the respiratory tract including nasopharynx and oropharynx. The Elecsys SARS-CoV-2 Antigen test is performed by healthcare professionals and could be used as an alternative or in conjunction with PCR testing. This is highly beneficial where reliable laboratory PCR testing is limited or not available. A positive result with the Elecsys SARS-CoV-2 Antigen test, In symptomatic individuals, a positive result with the Elecsys SARS-CoV-2 Antigen test, indicates an active SARS-CoV-2 infection with a likelihood of 94.5%. A negative result may require to be confirmed with a PCR test or repeated (antigen test) after one to two days, if other clinical indications point to a SARS-CoV-2 infection.

*The performance evaluation was performed in symptomatic individuals with a cobas® SARS-CoV-2 RT-PCR Target 2 Ct value <30.

The Elecsys SARS-CoV-2 Antigen immunoassay runs on all cobas e immunochemistry analysers which are widely available around the world and allow for these test to be run alongside other COVID-19 infectious diseases diagnostic markers available from Roche, which run on the cobas e systems. These fully automated systems can provide test results in 18 minutes for a single test (excluding time for sample collection, transport, and preparation), with a throughput of up to 300 tests per hour from a single analyser, depending on the analyser.¹

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.² In this case, the test would provide a qualitative “yes/no” answer on the presence of the pathogen in the patient sample. If the target antigen is present in sufficient concentrations in the sample, it will bind to specific antibodies and generate a positive result, indicating an active infection.³

In general, antigen tests have a high specificity, though are not as sensitive as PCR 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.

	Detection of acute infections (SARS-CoV-2 PCR or Antigen)	Detection of immune response (SARS-CoV-2 Antibodies)
Laboratory setting	cobas® SARS-CoV-2 Test cobas® SARS-CoV-2 & Influenza A/B Test NEW: Elecsys® SARS-CoV-2 Antigen Test	Elecsys® Anti-SARS-CoV-2 (N) ⁴ immunoassay Elecsys® Anti-SARS-CoV-2 S ⁵ Immunoassay
Point of Care setting (near patient)	SARS-CoV-2 Rapid Antigen Test** cobas® Liat® SARS-CoV-2 Test	SARS-CoV-2 Rapid Antibody Test**

**currently only available in CE markets

About Roche's response to the COVID-19 pandemic

As a leading healthcare company we are doing all we can to support countries in minimising the impact of COVID-19. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection in patients, as well as providing digital support to healthcare systems, and we continue to identify, develop and support potential therapies which can play a role in treating the disease.

We understand the impact of COVID-19 goes beyond those who contract it, which is why we are working with healthcare providers, laboratories, authorities and organisations to help make sure that patients continue to receive the tests, treatment and care they need during these challenging times. As we learn from the pandemic, we are partnering with governments and others to make healthcare stronger and more sustainable in the future.

Our diagnostics solutions:

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. Our portfolio includes:

- a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, (FDA Emergency Use Authorisation (EUA) and available in countries accepting the CE Mark)
- a SARS-CoV-2 laboratory-based antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid (FDA EUA and CE Mark)
- an IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
- Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic
- a SARS-CoV-2 rapid antibody test to help determine at the point of care whether a person has been exposed to the virus (CE Mark)
- a rapid antigen test to support in the detection of SARS-CoV-2 at the point of care within 15 minutes (CE Mark)
- a high-volume molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both (FDA EUA and CE Mark)
- a second SARS-CoV-2 antibody test, aimed at measuring the spike protein to support vaccination development and complement our existing portfolio
- a point-of-care molecular PCR test that simultaneously detects and differentiates between SARS-CoV-2 and influenza A/B infections to support urgent triage and diagnosis (FDA EUA and CE Mark)

Our research into therapies:

Roche is committed to improving the treatment of COVID-19. We are actively involved in understanding the potential of our existing portfolio and are exploring the potential of our investigational molecules.

In August we signed a collaboration agreement with Regeneron on developing and manufacturing and significantly increasing global supply of an investigational antibody combination for COVID-19 if it proves safe and effective in clinical trials and regulatory approvals are granted. We are also partnering with Atea to jointly develop AT-527, an orally administered direct-acting antiviral (DAA) currently in Phase 2 clinical trials. If approved, Atea will distribute AT-527 in the United States and Roche will be responsible for global manufacturing and distribution outside the United States.

At the beginning of the pandemic, on 19 March, we announced the initiation of COVACTA - a global Phase III randomised, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of intravenous Actemra®/RoActemra® (tocilizumab) plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care. On 29 July we announced that COVACTA did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia or the key secondary endpoint of reduced mortality.

Separately, we have studied Actemra®/RoActemra® in the EMPACTA study in COVID-19 associated hospitalised pneumonia in patients that are often underrepresented in clinical trials. On 18 September we announced that the phase III EMPACTA study showed Actemra/RoActemra plus standard of care reduced the likelihood of progression to mechanical ventilation or death in hospitalised patients with COVID-19 associated pneumonia compared to placebo plus standard of care. However, there was no statistical difference in mortality between patients who received Actemra/RoActemra or placebo.

Actemra®/RoActemra® is also being studied in combination with the investigational antiviral remdesivir in hospitalised patients with severe COVID-19 pneumonia in the REMDACTA trial in partnership with Gilead, announced 28 May. Actemra®/RoActemra® is not approved by any health authority for use in COVID-19 pneumonia. 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.

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 twelfth 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.

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References

- [1] Full specifications of the Roche immunoassay systems, including throughput, can be found on our diagnostics.roche website
- [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>
- [4] Nucleocapsid protein (qualitative)
- [5] Spike protein (quantitative)

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