

Roche launches new diagnostic test for the better understanding of immune response to SARS-CoV-2

- **Elecsys IGRA SARS-CoV-2 test supports the better understanding of immune response to SARS-CoV-2 infection or vaccination**
- **The test detects T-cell response, which may play an important role in determining if immune protection has been achieved**
- **The new diagnostic test may provide clinical care guidance, particularly for immunocompromised and high-risk patient groups**

Basel, 15 August 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of the Elecsys® IGRA SARS-CoV-2 test in countries that accept the CE Mark¹. The Elecsys IGRA SARS-CoV-2 test supports the better understanding of immune response to SARS-CoV-2 infection and vaccination. The test will be an additional tool to make better-informed decisions around care, sanitary measures and treatment options. This will be particularly important for at-risk patient groups.

With the transition from a pandemic to an endemic state of COVID-19, there is an increasing need to better understand the adaptive response of the human immune system to SARS-CoV-2. An effective antiviral immune response requires coordinated T- and B-cell activities. While B-cells produce antibodies that can potentially neutralise viruses, T-cells can target infected cells to prevent further viral replication and spread. SARS-CoV-2 infection, as well as COVID-19 vaccination, induce both T- and B-cell responses, in people with a normally functioning immune system, and a timely and well-coordinated T- and B-cell response is likely the key in infection control.

While antibody testing has been adopted to measure antibody-mediated immunity, there is increasing evidence that measuring the complementary T-cell response may play an important role in determining the overall protection level achieved^{2,3}. The Elecsys IGRA SARS-CoV-2 test is intended as an aid in identifying individuals with an adaptive T-cell response to SARS-CoV-2, which is indicative of past exposure to the virus or COVID-19 vaccination.

“The Elecsys IGRA SARS-CoV-2 test can provide a deeper understanding into immune response,” said Thomas Schinecker, CEO of Roche Diagnostics. “This in turn may help to understand and identify those at higher risk of progressing to severe disease during an existing or future infection. This is particularly important in immunocompromised and high-risk patient groups that represent up to 20% in a given population⁴. The test results can help healthcare professionals to provide them with long-term guidance like appropriate treatment.”

With the launch of Elecsys IGRA SARS-CoV-2 test, Roche adds another important diagnostic solution to its COVID-19 portfolio to help health care providers, public health authorities, and patients in the fight against the COVID-19 pandemic. This further highlights Roche's commitment to support clinicians and their patients in reducing the impact of infectious diseases.

About the Elecsys IGRA SARS-CoV-2 test

The Elecsys® IGRA SARS-CoV-2 test is intended as an aid in identifying individuals with an adaptive T-cell response to SARS-CoV-2, indicative of past exposure to the virus or COVID-19 vaccination. The Elecsys IGRA SARS-CoV-2 test combines in vitro T-cell stimulation, using SARS-CoV-2 antigens in the cobas IGRA SARS-CoV-2 Tubes developed in cooperation with LG Chem Life Sciences and an automated electrochemiluminescence immunoassay ("ECLIA") for interferon gamma to qualitatively detect T cell-mediated immune response to SARS-CoV-2 in human whole blood.

Using SARS-CoV-2 antigens with a broad viral genome and HLA coverage the assay is designed for robustness against viral variants and population variability. The product runs on the cobas e 411, e 601/602, e 402 and e 801 analysers providing a fully automated random access workflow.

About Roche's response to the COVID-19 pandemic

As a leading healthcare company, we are doing all we can to support countries in their fight against COVID-19 and minimising its impact. That is why we are working with governments, policy makers, healthcare professionals and others to help contain the COVID-19 pandemic and make sure patients continue to receive the tests, treatment and care they need.

The pandemic has profoundly raised awareness of the role diagnostics play in COVID-19 diagnosis, treatment development and disease management. Roche has developed and launched more than 20 COVID-19 diagnostics solutions, including polymerase chain reaction (PCR) and rapid antigen and antibody tests. Our solutions serve the entire diagnostic continuum, from high-throughput laboratories to point-of-care and home self-testing, and cover all currently known variants. To help meet global demand, we have supplied more than 1.5 billion tests for COVID-19 since March 2020.

Roche continues to evaluate its existing therapeutic portfolio and is researching future options to help benefit patients with Covid-19. Our IL-6 inhibitor Actemra®/RoActemra® (tocilizumab) has been approved for patients hospitalised with severe COVID-19 in more than 30 countries including the European Union and is authorised for emergency use in the United States. The World Health Organization has prequalified Actemra for use in patients with severe COVID-19, facilitating its availability in low- and middle-income countries. In addition, we have been improving access to Actemra by introducing an international differentiated

pricing strategy, providing the medicine at cost for use in low- and middle-income countries and non asserting patents in these regions during the pandemic.

We have also been partnering with Regeneron to jointly develop the antibody combination Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the US). It has been approved in multiple territories including the European Union, Japan, and Switzerland and authorised for emergency or temporary pandemic use in many countries including the US. The antibody combination has been made available to patients in more than 60 countries, across many geographies including low and middle income countries. As the virus continues to evolve, we are constantly monitoring Ronapreve's activity against emerging variants of concern, and will share results with health authorities as soon as possible.

Our utmost goal remains to be a trusted partner who acts with urgency to save and improve the lives of patients with COVID-19 and to reduce its burden on society. For more information please visit our [COVID-19 response page](#).

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

About LG Chem Life Sciences

LG Chem Life Sciences is a business division within LG Chem, engaged in development, manufacturing, and global commercialization of pharmaceutical products. LG Chem Life Sciences seeks to expand and make global presence by focusing on key core therapeutic areas of Immunology, Oncology, and Metabolic Diseases. LG Chem's Diagnostic business has

strong market leadership in allergy screening and molecular diagnostics of infectious diseases.

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References

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