Roche obtains CE mark for the SARS-CoV-2 Antigen Self Test Nasal allowing for rapid self testing of COVID-19 at home

- **The SARS-CoV-2 Antigen Self Test Nasal enables individuals to quickly and conveniently test themselves for COVID-19 at home using a simple nasal swab**
- **An early version of the test has already been available as a home-test in a number of European markets under local special approval pathways since February 2021**
- **The test will be widely available to individuals through pharmacies and other locations in accordance to local guidelines and testing strategies**
- **The test works seamlessly with NAVIFY® Pass, Roche's digital solution that allows individuals and healthcare providers to immediately store, display, and share their COVID-19 test results and vaccine status through a unique QR code**

Basel, 08 June 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has received CE mark for its SARS-CoV-2 Antigen Self Test Nasal for at-home testing. The test will be available in countries accepting the CE mark through pharmacies and other locations, in packs of five tests.

An early version of the test has already been available as a home-test in a number of European markets under local special approval pathways since February 2021. With the CE Mark, the SARS-CoV-2 Antigen Self Test Nasal for rapid self testing of COVID-19 test has received official approval following the traditional registration pathway and can now also be used in markets that have not established regulatory exemption pathways.

By following simple instructions, individuals can perform the test at home using a nasal swab without special training or the supervision of a healthcare worker. The test provides results in as little as 15 minutes and can help people to conveniently check if they are likely to be infectious from the comfort of their home. In the case of children under 18 years of age, the test must be performed by an adult or under close adult supervision.

As societies begin to reopen and in line with local health regulations, the convenient test allows individuals planning to attend an event or gathering to use the test as a tool to confirm that they are not likely to be carriers of a substantial amount of the virus thus helping them make informed decisions and reduce the risk of transmission to others.

Complementary to the SARS-CoV-2 Antigen Self Test Nasal, Roche is offering NAVIFY® Pass. This digital solution allows individuals and healthcare professionals to remotely store, display, and share their COVID-19 test results and vaccine status through a personalised QR code. Having easy digital access to test results and vaccination status could potentially be used by both individuals and companies to facilitate access to locations with COVID-19 entry protocols, such as restaurants or entertainment venues, as well as to validate

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safety to travel.

"As the world prepares to reopen, high-quality, home-based testing will play an important role in the battle against the pandemic," said Thomas Schinecker, CEO, Roche Diagnostics. "Regular self-testing at home can reduce pressure on healthcare systems. It can quickly identify people with the highest potential to be infectious so they can take immediate action to seek medical advice, manage their infection and protect others."

This test is part of a partnership with SD Biosensor Inc., with whom Roche has also launched a SARS-CoV-2 Rapid Antibody Test in July 2020 and two SARS-CoV-2 Rapid Antigen Tests for professional use in September 2020 and February 2021. These tests will continue to play an important role in fighting this pandemic and remain available for healthcare professional testing.

In addition to diagnostic testing, preventive measures remain key to protecting yourself and others against SARS-CoV-2. It is recommended to continue wearing masks, socially distance and practice good hygiene, especially if you have symptoms or known contact with others who have tested positive for the virus.

Roche continues to expand its comprehensive COVID-19 portfolio to support healthcare systems in diagnosing SARS-CoV-2 infection.

About the SARS-CoV-2 Antigen Self Test Nasal for at-home patient self-testing
The SARS-CoV-2 Rapid Antigen Self Test Nasal is a rapid chromatographic immunoassay (lateral flow assay) for the detection of the nucleocapsid protein of SARS-CoV-2 in human nasal samples. Each test contains a unique QR code to enable individuals to share their test results and vaccine status using NAVIFY Pass, Roche's digital solution. For more information on NAVIFY Pass, visit www.navifypass.com

The clinical performance of the test was measured by head to head comparison with Roche's highly sensitive reverse transcriptase polymerase chain reaction (RT-PCR) test using nasopharyngeal swab samples as a comparator, the gold standard sampling and detection method for SARS-CoV-2 detection.[1,2] Combined study results showed that the relative sensitivity of the SARS-CoV-2 Antigen Self Test Nasal was 91.1%.** The overall relative specificity was 99.6 %,[3] which represents the ability of the test to correctly identify patients without the virus. In one comparative independent self testing study where patients followed written and illustrated instructions to sample, test and read-out the results themselves, the majority of study participants considered the procedures easy to perform.[4]

About antigen testing
An antigen test detects proteins which are structural or functional components of a pathogen and are very

specific to that pathogen.[5] In this case, the test would provide a qualitative "yes/no" answer on the presence of the antigen 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 (nucleocapsid protein) 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. A rapid antigen test can reliably detect individuals with a high viral load allowing healthcare professionals to quickly identify those patients at the greatest risk of spreading the infection.[6]

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 2020 we received FDA Emergency Use Authorization 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 2020, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorization and is available in markets accepting the CE mark. Also in June of last year 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 of 2020, we added a Rapid Antibody Test, with SD Biosensor as manufacturing partner, to the portfolio that allows the detection of antibodies against COVID-19 at the point of care. In addition, we also launched a Rapid Antigen Test in September and a lab-based Antigen Test in December. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

Roche is actively involved in understanding the potential of the existing portfolio and is 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 2020 Roche 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 2020, Roche announced a partnership with Regeneron to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to people around the globe. On 18 October 2020, Roche announced a collaboration with Atea Pharmaceuticals to develop a potential oral treatment for COVID-19 patients.

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 in-vitro diagnostic company focused on the development of immunoassay and molecular diagnostic products at the POC. Founded in 2010, SD Biosensor has continued to research and develop products that can aid in the fast and accurate diagnosis of patients across the testing journey. Through these innovative products, they are striving to become a leading global in vitro diagnostics company.

For more information, please visit **www.sdbiosensor.com**.

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an

industry-leading partner for medical insights.

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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

*Production capacity for all Roche SARS-CoV-2 rapid antigen tests
** Combined study results include three cohorts: professional, self collected and self testing.

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