Roche COVID-19 At-Home Test granted FDA Emergency Use Authorization to expand access to rapid self-testing solutions in the United States

- **Rapid test to support the American public's fight against the COVID-19 pandemic, with availability to purchase over-the-counter (OTC) at pharmacies and retailers nationwide**
- **The COVID-19 At-Home Test uses a simple nasal swab sample to enable individuals to self-test at home and receive accurate, reliable and quick results in as few as 20 minutes for SARS-CoV-2 and all known variants of concern, including Omicron.**
- **EUA granted through Roche's participation in the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Independent Test Assessment Program to bring rapid tests to the OTC market**

Basel, 24 December 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its COVID-19 At-Home Test.[1] The test uses a simple anterior nasal swab sample that can be conveniently self-collected and self-tested by individuals aged 14 years and older, and by an adult for children aged 2-13 years old.[2] The test is able to produce accurate, reliable and quick results in as few as 20 minutes for SARS-CoV-2 and all known variants of concern, including Omicron.

The FDA's EUA decision stems from Roche's participation in the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics' (RADx) Independent Test Assessment Program (ITAP), which aims to accelerate the regulatory review and availability of high-quality, accurate and reliable OTC tests to the American public. The COVID-19 At-Home Test was prioritised by the FDA based on Roche and SD Biosensor's ability to deliver large quantities of high-quality tests and ramp up manufacturing to meet future demands.

Starting in January, the COVID-19 At-Home Test will be available across the United States and in accordance with local guidelines and testing strategies. At the time of launch, Roche has the capacity to produce tens of millions of tests per month to help support the pandemic response. The COVID-19 At-Home Test offers a convenient frequent testing option without the need to visit a healthcare provider.

"The COVID-19 pandemic continues to shed light on the critically important role that rapid self-testing plays in empowering individuals to protect their personal health and the health of their families and communities," said Thomas Schinecker, CEO, Roche Diagnostics. "At this inflection point in the American public's fight against COVID-19, we are proud to have worked in close collaboration with the US Government to introduce and expand access to accurate, reliable and high-quality at-home tests."

"Expanding access to rapid testing solutions for all patients in the United States is essential to public health and the pandemic response," said Matt Sause, President & CEO of Roche Diagnostics North America. "As long as there remains a need for reliable testing, Roche will continue to invest in effective solutions to ensure there are testing options available to those who need them."

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland | Group Communications Roche Group Media Relations | Tel. +41 61 688 88 88 www.roche.com

Together with the COVID-19 At-Home Test, Roche will offer NAVIFY® Pass as a solution to organizations who want to allow individuals and health care professionals to remotely and securely store, display, and share results. All COVID-19 At-Home Tests are supplied with a unique data matrix, enabling NAVIFY® Pass to automatically link individuals' test results to their respective test devices.

The launch will be in partnership with SD Biosensor Inc., with whom Roche has a global distribution agreement and previously launched a range of tests throughout 2020 and 2021 in countries outside of the U.S. that accept the CE Mark, including the SARS-CoV-2 Rapid Antigen Tests (Nasopharyngeal/Nasal), SARS-CoV-2 Antigen Self Test Nasal, SARS-CoV-2 Rapid Antibody Test and SARS-CoV-2 & Flu A/B Rapid Antigen Test[3]. The test becomes the first rapid antigen test for SARS-CoV-2 from Roche to receive FDA Emergency Use Authorization, and the sixth rapid test overall to accompany Roche's comprehensive portfolio of diagnostic solutions to help healthcare systems across the globe combat the COVID-19 pandemic through laboratory testing and at the point of care. Roche Diagnostics' portfolio includes a wide range of molecular, rapid serological and digital solutions that help diagnose and manage COVID-19 during the initial stages of infections, during the recovery phase, and following the resolution of infection.

About the COVID-19 At-Home Test[2]

The COVID-19 At-Home Test is a rapid chromatographic immunoassay for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 present in anterior nasal swab samples. In a prospective clinical study, the COVID-19 At-Home Test showed a relative sensitivity of 95.3% (95% CI: 84.5 to 98.7%) and a relative specificity of 100% (95% CI: 95.7 to 100%). Overall the studies included 138 symptomatic individuals (128 evaluable samples).[2] This test is intended for*: 1) Non-prescription home use (OTC) within the first 6 days of symptom onset; 2) Non-prescription home use with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

*Individuals aged 14 years or older can sample and test themselves. Children below the age of 14 must be sampled and tested by an adult.

The currently available sequences of variants of concern, including the Omicron variant SARS-CoV-2 (B.1.1.529), have been analysed and we can confirm that there is no impact on the performance of the test.

About antigen testing

An antigen test detects proteins which are structural or functional components of a pathogen and are very specific to that pathogen. 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 by healthcare professionals at the point of care. If the target antigen (in this case the 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 15-20 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.

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 (semi-)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 SARS-CoV-2 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

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

The impact of SARS-CoV-2 goes beyond those who contract it. That is why we are working with healthcare providers, laboratories, authorities, and organisations to help make sure patients continue to receive the tests, treatment and care they need during these challenging times. Building on a longstanding tradition of partnerships, we are working together with governments and others to make healthcare stronger and more sustainable in the future.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic and Roche has so far launched 22 diagnostics solutions to help minimise the impact of COVID-19. The acquisition of TIB Molbiol in early December 2021 has also since added another 24 SARS-CoV-2 tests to Roche's portfolio, including test kits to identify virus variants. As soon as the novel SARS-CoV-2 virus was sequenced in early 2020, we got to work. On 13 March 2020 we became the first company to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a high-volume molecular test to detect the virus. Since then, we have continued to add a range of diagnostics solutions to our global portfolio to help in the fight against COVID-19. In addition to the gold standard PCR test, we have developed antigen tests to help diagnose the virus in settings where there is limited molecular laboratory infrastructure, rapid antigen tests where the virus can be detected on the spot, tests that can test for both flu and COVID-19 at the same time, both high throughput and at the point of care, and tests that can detect virus antibodies that can help monitor the spread of the virus and can also support in vaccine development. In March 2021 the SARS-CoV-2 variant test was launched, designed to detect key spike mutations.

Aside from these tests we have also looked at how we can support care for patients who have COVID-19, receiving an U.S. 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, a digital algorithm that could help simplify the screening, diagnosis, and monitoring of respiratory-compromised patients with COVID-19. Roche is working closely with governments and health authorities around the world, and has significantly increased production to support availability of tests globally.

Roche is also actively involved in understanding the potential of the existing pharmaceuticals portfolio and is researching options for the future. In 2020, Roche entered into a number of new partnerships, including with Regeneron and Gilead to develop, manufacture and distribute molecules that can potentially both treat and prevent COVID-19.

Roche entered a partnership with Regeneron to jointly develop Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the U.S.). The antibody combination has been approved for use in the European Union and Japan, and conditionally in the United Kingdom and Australia, and is authorised for emergency or temporary pandemic use in additional territories such as the U.S. and Canada. In addition, the World Health Organization recommended the use of Ronapreve for the treatment of patients with COVID-19.

In addition, we have explored the potential of our existing medicine Actemra/RoActemra in three global phase III clinical trials investigating its safety and efficacy in COVID-19 associated pneumonia (COVACTA, EMPACTA and REMDACTA). In June 2021, Actemra/RoActemra received an EUA from the U.S. FDA for the intravenous treatment of COVID-19 in hospitalised adults and paediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. In addition, the World Health Organization recommended the use of Actemra/RoActemra for the treatment of certain patients with COVID-19.

For more information on how Roche is responding to the global COVID-19 pandemic, please visit our COVID-19 response page.

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, the company 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 thirteenth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceutical 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.

References

[1] This product has not been FDA cleared or approved, but has been authorized by the FDA under an EUA for non-prescription home use (OTC) with self- and adult-collected anterior nasal swab samples. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens;

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

[2] SD Biosensor. (2021). COVID-19 At-Home Test package insert.

[3] CE Mark obtained on 21 December 2021 for the SARS-CoV-2 & Flu A/B Rapid Antigen Test.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Nina Mählitz
Phone: +41 79 327 54 74

Sileia Urech
Phone: +41 79 935 81 48

Karsten Kleine
Phone: +41 61 682 28 31

Nathalie Meetz
Phone: +41 61 687 43 05

Roche Investor Relations
Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America
Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com