Media & Investor Release

Roche to introduce its next-generation portfolio of SARS-CoV-2 rapid antigen tests ("2.0") under CE Mark for self-test and professional use

- **Broad and trusted portfolio of COVID-19 rapid tests feature innovative updates and enhanced performance, building on insights gained throughout the pandemic**
- **All tests now work seamlessly with navify® Pass, Roche's digital solution that allows individuals and healthcare professionals to immediately store, display, and share COVID-19 vaccination status and test results through a unique data matrix**
- **Roche maintains the capacity to provide tens of millions tests each month to meet sustained high worldwide demand from individuals and healthcare professionals**

Basel, 12 October 2022- Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of its next-generation portfolio SARS-CoV-2 rapid antigen tests ("2.0") for self-testing and professional use in countries accepting the CE Mark. Distribution of the new rapid test portfolio is projected to begin in the coming weeks.

In doing so, Roche builds upon one of the broadest portfolios of COVID-19 rapid testing solutions with three new test configurations that feature enhanced performance through the use of an improved capture antibody and the addition of new digital data sharing capabilities to all tests. Using nasopharyngeal and nasal swab samples, respectively, the tests deliver reliable results in as few as 15 minutes, aiding in the diagnosis of SARS-CoV-2 infection in individuals with or without symptoms consistent with COVID-19.

"The continued evolution of the SARS-CoV-2 virus and COVID-19 pandemic reinforce the need for individuals and healthcare systems to have access to the most reliable rapid testing solutions possible," said Thomas Schinecker, CEO, Roche Diagnostics. "As a leader in diagnostic innovation, we are proud to be one of the first among our industry to apply insights gained from the past two years toward a next-generation rapid test portfolio. These tests are ready to support global society as we navigate this next phase of the pandemic."

The three tests set to launch are the following:

Professional use:

- **SARS-CoV-2 Rapid Antigen Test 2.0** *(nasopharyngeal sampling)*
- **SARS-CoV-2 Rapid Antigen Test 2.0 Nasal** *(nasal sampling)*

Self-Test:

- **SARS-CoV-2 Antigen Self Test Nasal** *(nasal sampling)*

Roche maintains the capacity to provide several tens of millions of each of the tests per month, with the option to quickly build up additional capacity if needed, to address sustained high worldwide demand for rapid testing from governments, healthcare systems and individuals. The next-generation test portfolio will be introduced in partnership with SD Biosensor Inc., with whom Roche has a global distribution agreement and previously launched a range of rapid antigen and antibody tests in more than 50 countries worldwide.

The tests join Roche Diagnostics's broader COVID-19 portfolio, which includes a wide range of molecular, serological and digital solutions that help diagnose and manage COVID-19 during the initial stages of infection, during the recovery phase, and following the resolution of infection.

About the next-generation portfolio of SARS-CoV-2 rapid antigen tests ("2.0")

Lab testing showed that all three tests can qualitatively detect major variants of concern including Delta and Omicron variants. Emerging variants are continuously monitored.

SARS-CoV-2 Rapid Antigen Test 2.0[1] *(nasopharyngeal sampling)*
The SARS-CoV-2 Rapid Antigen Test 2.0 is a rapid chromatographic immunoassay for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 present in human nasopharyngeal swab samples. In a prospective clinical study[A], the SARS-CoV-2 Rapid Antigen 2.0 showed a relative sensitivity of 99.00% (95% CI: 94.55 - 99.97%) and a relative specificity of 99.75% (95% CI: 98.62 - 99.99%). In total, 100 PCR-positive and 402 PCR-negative subjects participated in this study. This included 320 asymptomatic subjects, among whom 34 were positive and 286 were negative; and 182 symptomatic individuals, among whom 66 were positive and 116 were negative. This test is intended as an aid in the diagnosis of SARS- CoV- 2 infection in individuals with or without symptoms consistent with COVID- 19. This product is intended for professional use in laboratory and near- patient testing environments. This product is not intended for self- testing.

SARS-CoV-2 Rapid Antigen Test 2.0 Nasal[2] *(nasal sampling)*
The SARS-CoV-2 Rapid Antigen Test 2.0 Nasal is a rapid chromatographic immunoassay for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 present in human nasal swab samples. In prospective clinical studies[A,B], the SARS-CoV-2 Rapid Antigen 2.0 Nasal showed a relative sensitivity of 95.80% (95% CI: 91.09 - 98.44%) and a relative specificity of 100% (95% CI: 99.25 - 100%). In total, 143 PCR-positive and 487 PCR-negative subjects participated in these studies. This included 320 asymptomatic subjects, among whom 34 were positive and 286 were negative; and 310 symptomatic individuals, among whom 109 were positive and 201 were negative. This test is intended as an aid in the diagnosis of SARS- CoV- 2 infection in individuals with or without symptoms consistent with COVID- 19.

This product is intended for professional use in laboratory and near- patient testing environments. This product is not intended for self- testing.

SARS-CoV-2 Antigen Self Test Nasal[3]
The enhanced SARS-CoV-2 Antigen Self Test Nasal is a so-called lateral flow test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal samples. This test is used to detect antigens of the SARS-CoV-2 virus in individuals suspected of having COVID-19. It is designed as a self-test for patients. In prospective clinical studies[A, B], the SARS-CoV-2 Antigen Self Test Nasal showed a relative sensitivity of 95.8% (95% CI: 91.09 - 98.44%) and a relative specificity of 100% (95% CI: 99.25 - 100%). In total, 143 PCR-positive and 487 PCR-negative subjects participated in these studies. This included 320 asymptomatic subjects, among whom 34 were positive and 286 were negative; and 310 symptomatic individuals, among whom 109 were positive and 201 were negative. 128 of the subjects were lay-users, sampling and testing themselves or another lay-user, for example their underaged children[B].

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 or by individuals at home. 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 minutes.[2] 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 DNA or RNA sequence in order to generate a (semi-)quantifiable signal to indicate the presence of the pathogen 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 information, such as the individual's exposure history, clinical symptoms, and 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. 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 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 http://www.sdbiosensor.com.

About Roche

Founded in1896 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 recognizing 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.

References

[1] SD Biosensor. (2022). SARS-CoV-2 Rapid Antigen Test 2.0 package insert.
[2] SD Biosensor. (2022). SARS-CoV-2 Rapid Antigen Test 2.0 Nasal package insert.
[3] SD Biosensor. (2022). SARS-CoV-2 Antigen Self Test Nasal package insert.

A) A prospective study in South Korea, where each study participant donated three swab samples - one nasal swab and one nasopharyngeal swab for evaluation on the SARS-CoV-2 Rapid Antigen Test 2.0 Nasal and SARS-CoV-2 Rapid Antigen Test 2.0 tests, and another nasopharyngeal swab for evaluation on the RT-PCR comparator method.

B) A prospective, lay-use study in the United States, where study participants collected a nasal swab sample and tested themselves or for another lay-user. Results of the rapid antigen tests were compared to an RT-PCR comparator method performed on a mid-turbinate nasal swab sample collected by a healthcare personnel.

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

Roche Group Media Relations

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

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

Sileia Urech
Phone: +41 79 935 81 48

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

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Altermatt
Phone: +41 61 687 43 05

Roche Investor Relations

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

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

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