Roche to launch SARS-CoV-2 & Flu A/B Rapid Antigen Test in countries accepting the CE Mark to enable rapid differentiation of viral respiratory infections

- **The combination rapid antigen test quickly differentiates between SARS-CoV-2 and influenza viruses A and B infections, with results ready in less than 30 minutes, allowing informed decisions on patient and pandemic management decisions**
- **Affordable and small, instrument-free testing kit enables convenient use for healthcare professionals at different point of care locations and in resource-limited settings**
- **The test works seamlessly with NAVIFY® Pass, Roche's digital solution that allows individuals and healthcare professionals to immediately store, display, and share their COVID-19 test results and vaccine status through a unique data matrix**

Basel, 6 December 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced its plans to launch the SARS-CoV-2 & Flu A/B Rapid Antigen Test for professional use in markets accepting the CE Mark by the beginning of January. Roche also intends to file for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) in early 2022.

The SARS-CoV-2 & Flu A/B Rapid Antigen Test is intended for use by healthcare professionals to rapidly differentiate between SARS-CoV-2 and influenza viruses A and B infections in individuals with symptoms consistent with COVID-19 or influenza. The single integrated combination test uses a nasopharyngeal swab specimen to produce qualitative results ("yes/no" answer) on the presence of SARS-CoV-2 and/or influenza A and/or B antigens in 15-30 minutes. The test has a relative sensitivity of 84.85% and specificity of 98.59% for SARS-CoV-2. For the flu, the test has a positive percent agreement of 81.16% (influenza virus A) and 100% (influenza virus B) against a molecular test, and relative specificity of 100% (influenza virus A) and 99.04% (influenza virus B).[1] The currently available sequences of the Omicron variant SARS-CoV-2 (B.1.1.529) have been analyzed, and based on the initial *in silico* investigations, an impact on the performance of the test is not expected.

Equipping healthcare professionals with a single integrated combination test is beneficial in settings where timely clinical decisions are needed or where central laboratory testing is difficult to access. The SARS-CoV-2 & Flu A/B Rapid Antigen Test helps healthcare professionals at the point of care to quickly diagnose and differentiate infections with any of the three respiratory viruses and aid in pursuing appropriate courses of action, including patient and pandemic management decisions.

Thomas Schinecker, CEO of Roche Diagnostics, stated, "It is critical that healthcare professionals have the ability to quickly know whether a patient has an infection with either SARS-CoV-2 or the flu, especially as the COVID-19 pandemic extends into our flu season. The combination rapid antigen test will help ensure the right decisions are taken by healthcare providers to treat patients and ultimately prevent community spread. The test adds a solution that will be critical to healthcare systems' long-term management of SARS-CoV-2 and seasonal flu, as we transition from today's global health emergency to the endemic phase of tomorrow."

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Together with the SARS-CoV-2 & Flu A/B Rapid Antigen Test, 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. With a unique and personalised data matrix placed on the test, NAVIFY® Pass can automatically read out all details about the test and establish a connection between patients and their individual test results.

The launch will be in partnership with SD Biosensor Inc., with whom Roche has a global distribution agreement and previously launched the SARS-CoV-2 Rapid Antigen Tests (Nasopharyngeal/Nasal), SARS-CoV-2 Antigen Self Test Nasal, and SARS-CoV-2 Rapid Antibody Test in countries accepting the CE Mark throughout 2020 and 2021. The test will become the fifth rapid test and twenty-second addition to 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, 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 SARS-CoV-2 & Flu A/B Rapid Antigen Test

The SARS-CoV-2 & Flu A/B Rapid Antigen Test is a rapid chromatographic immunoassay for the simultaneous detection and differentiation of the nucleocapsid protein antigens of SARS-CoV-2, influenza virus A, and influenza virus B in human nasopharyngeal swab samples. This test is intended as an aid in the differential diagnosis of SARS-CoV-2, influenza virus A, and influenza virus B infections, in individuals suspected of respiratory viral infections consistent with COVID-19 or influenza, by healthcare providers within the first five days since the onset of symptoms.

The test has a relative specificity of 98.59% for SARS-CoV-2, 100% for influenza viruses A and 99.04% for influenza viruses B. The relative sensitivity for SARS-CoV-2 was 84.85%. These performance characteristics are based on a prospective study of 104 participants where two nasopharyngeal swab samples were collected per participant and results of the rapid antigen test were compared with those from a highly-sensitive, FDA-cleared RT-PCR method. The sensitivity for influenza viruses A and B was evaluated separately using banked human nasopharyngeal swab samples, due to the limited circulation of influenza viruses in the past season. The rapid antigen test results were compared to highly sensitive RT-PCR method results, and the positive percent agreement for influenza viruses A and B were 81.16% and 100%, respectively. A prospective clinical study is ongoing to evaluate the influenza performance using fresh clinical samples. This test is not for self-testing. It is intended for professional use in laboratory and near-patient testing environments.

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 to 30 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.

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 COVID-19 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 21 diagnostics solutions to help minimise the impact of COVID-19. 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 United States [US]). 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 US 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] SD Biosensor. (2021). SARS-CoV-2 & Flu A/B Rapid Antigen Test package insert.

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