Media Release

Roche launches Pilot brand, expands retail channels for COVID-19 At-Home Test

- **The COVID-19 At-Home Test that tens of millions of Americans received via the U.S. government is now available over-the-counter nationwide under the new Pilot name and brand.**
- **Accurate, fast and easy to use, the Pilot COVID-19 At-Home Test is the first over-the-counter test launched by Roche Diagnostics in the U.S.**
- **Following Centers for Disease Control and Prevention (CDC) guidance for at-home testing and appropriate next steps can help reduce the spread of COVID-19.**

INDIANAPOLIS, November 10, 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced a new name and brand for the COVID-19 At-Home Test – **Pilot® COVID-19 At-Home Test**, which debuts this week nationwide.

The Pilot COVID-19 At-Home Test, the first over-the-counter test distributed in the U.S. by Roche Diagnostics, received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) on December 24, 2021[1], and is manufactured by SD Biosensor Inc. The test has been distributed to tens of millions of Americans via the U.S. government's efforts to expand access to testing earlier this year. It uses a simple anterior nasal swab sample that can be conveniently self-collected and self-tested by individuals ages 14 years and older, and by an adult for children ages 2 to 13 years old.[2] The Pilot COVID-19 At-Home Test is able to produce accurate, reliable and quick results in as few as 20 minutes for SARS-CoV-2.

"Great progress has been made to make COVID-19 testing easy and universal," said Matt Sause, president and CEO of Roche Diagnostics North America. "We are excited that the Pilot test offers convenience and broad accessibility for frequent testing needs, whether for a known exposure or safety for group settings."

With a relative sensitivity of 93.2% and a relative specificity of 100%[3], the Pilot COVID-19 At-Home Test can help you determine your next step, such as self-isolation for COVID-19, seeking further testing, and pursuing advice from a healthcare professional about treatment options, or ending isolation with two confirmed negative results.

Taking an at-home COVID-19 test is recommended by the CDC when: you have any COVID-19 symptoms; were exposed to someone with COVID-19; or are going to an indoor event or gathering. If you test negative, consider repeating the test 48 hours later. Receiving multiple negative test results increases the confidence that you are not infected with the virus that causes COVID-19. If you have symptoms, although serial testing may be useful, seeing a healthcare provider should be considered because multiple viruses including the flu are currently circulating.

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The Pilot COVID-19 At-Home Test is available at CVS Pharmacy and cvs.com, Amazon and in the Optum Store.

In March 2020, Roche became the first company to launch a commercial COVID-19 PCR test running on high-throughput laboratory instruments. The company has developed more than 20 COVID-19 tests and solutions globally, and sold more than 1.8 billion COVID-19 tests worldwide since the beginning of the pandemic. Roche offers high-quality solutions for every setting, from large reference laboratories to at-home testing. For more information about the Pilot COVID-19 At-Home Test, visit go.roche.com/COVID-Home-Test.

About Pilot COVID-19 At-Home Test

The Pilot 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 Pilot COVID-19 At-Home Test showed a relative sensitivity of 93.2% (95% CI: 81.8 to 97.7 %) and a relative specificity of 100% (95% CI: 96.7 to 100%). Overall the studies included 168 symptomatic individuals (158 evaluable samples).[2] This test is intended for*: 1) non-prescription home use (OTC) within the first 6 days of symptom onset, and 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 ages 14 years or older can sample and test themselves. Children ages 2 to 13 must be sampled and tested by an adult.

Variants, including omicron BA.1, BA.2 , BA.4 & BA.5, have been analyzed by SD Biosensor, and there is no expected impact on the performance of the test.[4]

About SD Biosensor

SD Biosensor, Inc., with its slogan 'Beginning of all things that protect lives,' is a global in-vitro diagnostic company that contributes to improving everyone's quality of life by diagnosing diseases quickly and accurately. SD Biosensor is a Total Solution Provider in the IVD industry that develops and researches innovative diagnostic platforms. In 2020, SD Biosensor, Inc. began supplying numerous WHO prequalified for global public health diagnostic products, especially those for malaria, HIV and HCV.

Based on our R&D know-how, Mass Production Capacity, and Global Sales Network, SD Biosensor, Inc. will continue to grow as a global biotech company by creating new value through accumulating data using AI as well as in the areas of diagnosis, products, and services. For further information, please see our official website at https://www.sdbiosensor.com/.

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 personalized 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] 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] Study data on file with National Institutes of Health, dated December 21, 2021. Sensitivity is the test's ability to correctly identify a positive result, and specificity is the test's ability to correctly identify a negative result.
[4] Data on file with Roche Diagnostics.

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