

## **Roche announces U.S. collaboration with Pfizer to help patients who test positive for COVID-19 navigate risks, symptoms, testing and treatment options**

- **Testing early for COVID-19 can help determine the proper course of treatment.**
- **This collaboration helps patients access critical resources and locate information about testing, available treatment options, high-risk factors that increase the chance of progressing to severe COVID-19, and ways to seek timely care.**
- **The Pilot<sup>®</sup> COVID-19 At-Home Test will now include a QR code that directs individuals to [covid19knowmore.com](https://covid19knowmore.com), a Pfizer website, to learn more about testing and treatment options.**

Basel, 14 December 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has entered into a U.S. focused collaboration with Pfizer to drive awareness and educate on the importance of timely COVID-19 testing, available treatment options, symptoms and the high-risk factors that can increase the chance of progressing to severe illness.

According to the Centers for Disease Control and Prevention, nearly 9 out of 10 adults struggle to understand and use personal and public health information because it contains unfamiliar or complex terms. This collaboration aims to simplify and improve access to health information related to COVID-19. On [covid19knowmore.com](https://covid19knowmore.com), a Pfizer website, individuals can learn why early testing is important at symptom onset, which health conditions increase the risk of progressing to severe COVID-19 and what treatment options are available.

Individuals who test positive, and are age 50 or older or have certain medical conditions - such as chronic lung disease, heart disease or a weakened immune system - or a sedentary lifestyle, are at high risk of progressing to severe COVID-19.

“Empowering patients to take appropriate action following a positive test result remains critical to reducing spread of the virus and lowering rates of severe infection,” said Thomas Schinecker, CEO of Roche Diagnostics. “As we face another potential winter surge, we are proud to embark on this timely collaboration with Pfizer to improve COVID-19 health literacy among patients in the United States. This exciting initiative may serve as a foundation for future collaborations in many other countries worldwide.”

The Pilot COVID-19 At-Home Test,<sup>1</sup> distributed in the United States by Roche Diagnostics and manufactured by SD Biosensor Inc., will now include a QR code that directs individuals to [covid19knowmore.com](https://covid19knowmore.com), where they can learn more about COVID-19, including CDC guidance on testing and treatment options.

“With high numbers of respiratory infections across the country, some of which put people at high-risk for severe illness, there is cause for concern that another surge in COVID-19 cases could dramatically affect the healthcare system as the winter months set in,” said Dr. Alejandro Cane, U.S. Vaccines and Antivirals Medical and Scientific Affairs Lead, Pfizer. “This collaboration provides patients who test positive for COVID-19 critical resources that can help them take action against COVID-19, if needed.”

The Pilot COVID-19 At-Home Test is an easy-to-use, accurate and reliable rapid antigen test that delivers results in as few as 20 minutes. It is authorized for the detection of COVID-19 with or without symptoms for individuals ages 14 years and older, and by an adult for children ages 2 to 13 years old.<sup>2</sup> It has been distributed to tens of millions of Americans through the U.S. government’s efforts to expand access to testing earlier this year. The Pilot COVID-19 At-Home Test is available for over-the-counter purchase through select retail channels in the U.S.

Accurate and timely diagnosis inform appropriate treatment decisions, and can help shorten the length of hospital stays and limit the spread of infections in healthcare settings.

Taking an at-home COVID-19 test is [recommended by the CDC](#) when individuals have any COVID-19 symptoms, were exposed to someone with COVID-19 or are going to an indoor event or gathering. If an individual tests negative, they are advised to conduct serial (or repeat) testing. Receiving multiple negative test results increases the confidence that an individual is not infected with the virus that causes COVID-19.

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, please visit [www.roche.com](http://www.roche.com).

### **About the Pilot COVID-19 At-Home Test**

The Pilot COVID-19 At-Home Test is a lateral flow 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%).<sup>3</sup> Overall the studies included 168 symptomatic individuals (158 evaluable samples). This test is authorized for\* individuals with symptoms of COVID-19 within the first six days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

Variants, including omicron BA.1, BA.2, BA.4 and BA.5, have been analyzed by SD Biosensor, and there is no expected impact on the performance of the test.<sup>4</sup>

### **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 its 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 artificial intelligence as well as in the areas of diagnosis, products and services. For further information, please see their official website at [www.sdbiosensor.com](http://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 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 recognising 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](http://www.roche.com).

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

## 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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