Abbott Begins Shipping BinaxNOW™ COVID-19 Ag Self Test To Retailers Today

- BinaxNOW is the most studied and widely available rapid antigen test in the U.S. and initially will be available at CVS Pharmacy, Walgreens and Walmart without a prescription

- Abbott to manufacture tens of millions of BinaxNOW Self Tests per month and can scale capacity upward based on demand

- The BinaxNOW Self Test will be sold in 2-count packs for an MSRP of $23.99, making it the most affordable over-the-counter (OTC) COVID-19 rapid test available in the U.S.

ABBOTT PARK, Ill., April 19, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) announced today it began shipping its BinaxNOW™ COVID-19 Ag Self Test to retailers across the country. Consumers can expect the test to be available in the next few days online and in some stores. Broader nationwide availability is expected in the next two weeks as tests work their way through distribution channels.

The BinaxNOW Self Test initially will be available at CVS Pharmacy, Walgreens and Walmart as part of Abbott's commitment to get the country's most studied COVID-19 rapid test to as many Americans as possible. The test, which can be purchased over the counter without a prescription, will then roll out to other major food, drug and mass merchandisers in the weeks ahead.

"Over the past year, Abbott has developed high-quality rapid testing and invested in U.S. facilities to scale up manufacturing so we could bring affordable testing to Americans on a mass scale," said Robert B. Ford, president and chief executive officer, Abbott. "We're pleased to be working with the country's leading retailers to provide broad access to this affordable test so that it gets out into the communities that need it most."

Abbott will manufacture tens of millions of BinaxNOW Self Tests per month and can further scale capacity based on demand. Abbott can also work with retailers to prioritize distribution to areas of the country where the virus is surging as additional supply comes online.

The BinaxNOW Self Test will be sold in 2-count packs for an MSRP of $23.99, making it the most affordable OTC COVID-19 rapid test available in the U.S. Abbott is the only manufacturer in the U.S. that has Emergency Use Authorization (EUA) for a COVID-19 self test that can provide tests immediately at this scale.

"Let's not back down on testing, let's double down on it," said Thomas Quinn, M.D., professor of medicine and pathology at the Johns Hopkins School of Medicine. "As long as COVID remains unpredictable, there's an important role for the corner pharmacy and the central lab to tackle this virus in tandem, which gives this country the best chance to detect and screen for COVID-19."

The CDC advises that "a robust and responsive testing infrastructure is essential to our success in stopping the spread of SARS-CoV-2" and provides guidance on the important role both PCR tests and rapid antigen tests play in detecting infections and screening individuals. Abbott will continue bringing accessible testing options and lead the U.S. in supplying COVID-19 tests for use in labs, at the point of care, and now over the counter.

Proven testing technology now broadly available

On March 31, Abbott announced that it received FDA EUA for over-the-counter, non-prescription, symptomatic and asymptomatic use of its BinaxNOW™ COVID-19 Ag Self Test for detection of COVID-19 infection. This new indication allows individuals with or without symptoms to have access to this test without a prescription, bringing the country's most extensively studied and widely used rapid antigen test to nearly everyone in the U.S. The test will come in a two-count pack to meet serial (frequent) testing requirements.

The BinaxNOW Self Test uses the same technology as the existing BinaxNOW test that has been available since August 2020 but is now indicated by the FDA for serial symptomatic and asymptomatic testing, meaning that people should test themselves frequently. The test can be used on children as young as two years old when samples are collected by an adult and for all people aged 15 years or older.

Using the BinaxNOW Self Test will be simple, even for people who have never tested themselves. People will only need to perform a minimally invasive nasal swab (not the deep nasopharyngeal swab) and all materials required to perform the test (swab, test card, and reagent solution) will come in the box. With results in just 15 minutes, the BinaxNOW Self Test lets people who test positive immediately isolate so that they do not infect others, rather than waiting days for results from a lab or send-away at-home tests.

Abbott launched the BinaxNOW professional test nationwide in August 2020 and scaled up production at its new U.S. manufacturing facilities to produce 50 million tests per month. The U.S. Department of Health and Human Services (HHS) purchased the company's first 150 million tests, sending them to K-12 schools, nursing homes, historically black colleges and universities, and underserved communities, where they remain in use today and serve as a powerful tool to help prevent the virus from spreading.

Since its original authorization in August 2020, the BinaxNOW COVID-19 professional use test has gone on to be used by workplaces, additional universities and other organizations throughout the country.

BinaxNOW performance in the field

Today, BinaxNOW demonstrates overall performance of 84.6% positive agreement (sensitivity) and 98.5% negative agreement (specificity) in people seven days or less post-symptom onset at all Ct counts. In our studies, it further shows performance of 95.6% positive agreement (sensitivity) in people seven days or less post-symptom onset with Ct counts of 33 or below. Ct counts are the number of times a PCR instrument must cycle through to amplify enough genetic material of the SARS CoV-2 virus for it to be detectable. The greater the amount of virus present (viral load), the fewer cycles required to detect the virus.

In a recent study published by Pilarowski et al. in the peer-reviewed journal *Clinical Infectious Diseases*, researchers in California assessed BinaxNOW in a community-based setting in people of all ages with and without symptoms. They demonstrated high sensitivity and specificity for BinaxNOW, including in asymptomatic people and in children. Among 102 people who were asymptomatic or whose symptom onset was greater than 7 days before testing, sensitivity for a Ct cutoff of 30 was 100% and specificity was 98.9%. As Ct counts increased to 35 (therefore reflecting less viral load) performance remained high in asymptomatic people of all ages, showing 97.5% sensitivity and 99.7% specificity.

As part of its Emergency Use Authorization for self-testing, Abbott has committed to complete a post-authorization study to determine serial testing performance in people without symptoms.

About BinaxNOW™ COVID-19 Ag Card Self Test
The BinaxNOW COVID-19 Ag Card Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected nasal swab samples from individuals aged two years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over three days with at least 36 hours between tests.

Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider. Individuals who test positive should take precautions, isolate and seek follow-up care from their healthcare provider. BinaxNOW COVID-19 Ag Card Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 109,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com, on LinkedIn at www.linkedin.com/company/abbott-/, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews.

The BinaxNOW™ COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Ag 2 Card is authorized for use with direct anterior nasal (nares) swab samples from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The BinaxNOW COVID-19 Ag tests have not been FDA cleared or approved. They have been authorized by the FDA under an emergency use authorization. The tests have been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and are 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.

SOURCE Abbott

For further information: Abbott U.S. Media: John Koval, 224-668-5355, Darcy Ross, 224-667-3655; or Abbott Investor Relations: Laura Dauer, 224-667-2299