Abbott's BinaxNOW™ Rapid Antigen Self Test Receives FDA Emergency Use Authorization For Asymptomatic, Over-The-Counter, Non-Prescription, Multi-Test Use

- FDA Emergency Use Authorization permits asymptomatic, non-prescription, over-the-counter self use for people with or without symptoms

- The BinaxNOW COVID-19 Self Test is identical to the professional-use test, used since August 2020, bringing the most studied and widely used rapid antigen test to retail shelves across the country

- BinaxNOW Self Test will be available nationwide and in large quantities at major food, drug and mass merchandiser retailers nationally and will be priced affordably, similar to common over-the-counter (OTC) tests

- Together with vaccines, serial testing of asymptomatic people will help restore a sense of safety in everyday settings where people gather

- Asymptomatic multi-test authorization also applies to BinaxNOW professional-use test

ABBOTT PARK, Ill., March 31, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) announced today it has received U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for over-the-counter, non-prescription, 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. Abbott will begin shipping to major food, drug and mass merchandiser retailers in the coming weeks and expect the test to be available through some of their online store websites.

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, 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 box to meet serial (frequent) testing requirements.

Using the 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.

"We've now accomplished what we set out to do when we launched BinaxNOW, which is to bring an accurate, affordable and readily available test to the American people that they can have on hand, whether they want to test frequently or in certain circumstances," said Robert B. Ford, president and chief executive officer, Abbott. "Together with vaccines, the BinaxNOW Self Test will help Americans get back to doing what they want and need to do – like going to work and school or seeing friends and family – with greater confidence."

Abbott launched the BinaxNOW professional test nationwide inAugust 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 approval, BinaxNOW has also been used by workplaces, K-12 schools and universities and other organizations throughout the country.

The BinaxNOW Self Test is the same technology as theexisting BinaxNOW test that has been available since August 2020 but is indicated by the FDA for serial asymptomatic testing, meaning that people should test themselves frequently.

The advantages of serial (frequent) testing with BinaxNOW
Serial testing makes it possible for people to know their infection status when it matters most. And because rapid antigen testing is less expensive, people can test themselves with greater regularity, which is important for those who may be concerned that they were recently exposed or may be attending a large event in close confines.

When combined with vaccines and other public health precautions, serial testing can restore a sense of safety and let Americans get back to celebrating life's big milestones or everyday moments, such as weddings, birthdays and graduation parties, traveling, dinner with friends, and countless other cherished moments that were once taken for granted.

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. BinaxNOW is proven to be high quality, with a complaint rate for the 150 million professional tests distributed to HHS of 0.0034% as of March 24. That is 1 out of every 29,511 tests, affirming Abbott's decades of leadership in infectious disease detection and commitment to studying real-world performance of its products.

Abbott to bring massive scale and experience to over-the-counter COVID-19 testing
Abbott's manufacturing scale and existing retail distribution partnerships with the nation's largest food, drug and mass merchandiser retailers are unmatched by any rapid-test maker. Abbott expects the BinaxNOW Self Test to be priced affordably – similar to common OTC tests – to make it more accessible and affordable for Americans to test themselves, whether regularly or for life's important moments.

Digitally verified results remain important in many settings

Abbott's earlier innovations in rapid testing remain as important as ever, especially for people who need to show digitally verified proof of a negative COVID-19 test before returning to work, school, travel, and congregate-care living environments.

As part of this authorization, the BinaxNOW COVID-19 Ag Card test for professional use will no longer require a prescription, meaning that states, workplaces, schools and other organizations no longer need to work through a medical provider to generate a prescription before the test can be administered. For congregate environments using the professional-use version of BinaxNOW, a CLIA certificate is still required.

Abbott continues to deploy its NAVICA system so that individuals can obtain digitally verified test results. Users can download the NAVICA app, take a BinaxNOW Home Test or BinaxNOW professional-use test at a NAVICA-enabled testing site, and display negative results through an encrypted NAVICA Pass. This solution supports organizations – such as employers, K-12 schools, universities, sports and entertainment venues, and nursing homes – to take ownership of their testing solutions and make informed decisions about who enters their facilities.

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 Card
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 observed 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 a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swab samples from COVID-19 symptomatic individuals tested twice over three days with at least 36 hours between tests within the first seven days of symptom onset.

This test 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 Card 2 Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs 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 observed 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 Card 2 Home Test is to be performed only with the supervision of a telehealth proctor.

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

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