Abbott's BinaxNOW COVID-19 Rapid Test Receives FDA Emergency Use Authorization For First Virtually Guided, At-Home Rapid Test Using EMed's Digital Health Platform

- First at-home, virtually guided service to bring rapid, reliable and affordable testing into the home where the result is delivered in minutes

- Abbott and eMed™ expect to deliver and administer 30 million BinaxNOW™ tests in the first quarter of 2021, with an additional 90 million in the second quarter

- $25 cost for the test and service is the lowest available for at-home testing, which supports the home user to ensure a successful testing process

- BinaxNOW is a highly portable, easy-to-use, 15-minute antigen test with no instrument that detects the virus when people are most infectious, which is critically important in slowing the spread of the virus

- Service uses Abbott's complementary NAVICA™ app to enable the testing process and display authenticated BinaxNOW test results verified by a trained guide - and supports consumer confidence in testing at home

ABBOTT PARK, Ill.,, Dec. 16, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for virtually guided at-home use of its BinaxNOW™ COVID-19 Ag Card rapid test for detection of COVID-19 infection. Abbott is bringing BinaxNOW, the most affordable and widely distributed rapid test into the home, where the result is delivered in minutes without the need to send it out for processing. The $25 cost for the test and service is the lowest currently available for at-home testing.

To facilitate the delivery of the BinaxNOW test to the home and the guided collection and testing process, Abbott has partnered with digital health solutions provider eMed™. This agreement furthers Abbott's vision of making as many tests as possible available in a variety of different settings to improve accessibility, support consumer confidence in testing at home, and help people start returning to living their daily lives with more normalcy.

Abbott and eMed expect to deliver and administer 30 million BinaxNOW at-home tests in the first quarter of 2021, with an additional 90 million in the second quarter. Scale is critical to provide broad access to people who need testing and Abbott has scale for all its eight COVID-19 lab and rapid tests. In fact, since launching BinaxNOW in August, Abbott has ramped up capacity to 50 million tests a month in its U.S. facilities that are currently being distributed through the federal government and is expanding further so even more people have access to the tests.

"As the pandemic has evolved, the need for rapid testing has only grown. Unfortunately, we're still hearing that many people can't access testing as quickly as they need it," said Robert B. Ford, Abbott's president and chief executive officer. "That's why Abbott is bringing our rapid BinaxNOW test and NAVICA platform into homes through this partnership with eMed, which allows us to maintain the integrity of the testing process, get even closer to people who need testing and help provide the confidence we need to help get back to living with a bit more normalcy."

The eMed service offering costs $25 a test, and eMed takes care of determining eligibility, the guided self-collection process, public health reporting requirements and gets people their results through their NAVICA app in a matter of minutes.

The eMed offering could also remove some of the obstacles that individuals, governments and organizations face when seeking to provide or perform testing. These include mobility issues for people with disabilities or who may not have a reliable form of transportation, inconvenient testing windows for people who work non-traditional hours or have childcare or eldercare responsibilities, and discouragingly long lines at testing centers.

"COVID-19 is the greatest public health threat our nation has experienced in a century," said Dr.Patrice Harris, CEO of eMed. "This pandemic has had devastating effects in every region of our country but particularly on seniors, essential workers and communities of color. FDA's authorization of Abbott's BinaxNOW test for home use is a breakthrough in the battle against COVID-19. I am proud to lead eMed's partnership with Abbott to democratize access to frequent, affordable, at-home testing with results in 15 minutes. Together we can help to mitigate the spread, save lives and support our return to school, work and play."

Through eMed and the NAVICA app, people can use authenticated BinaxNOW results to enter into venues that accept the NAVICA digital certificate. The virtually guided process preserves the integrity of the testing process and state-mandated reporting obligations, while ensuring equitable access to people who need tests through the prescription process. Real-time data generated from at-home testing can also help federal and state public health authorities to better understand the extent of an outbreak and take appropriate steps to control its spread.

How the at-home digital health service works

A person can access the eMed service through Abbott's NAVICA app, which can be downloaded from the Apple and Android app stores. Once eligibility requirements are met, the test kit is shipped directly to the home user or a pick-up location, allowing a person to remain isolated until their status is known.

Once a BinaxNOW test kit arrives at the home, the home user logs into the eMed portal for their guided testing session and can

expect results in approximately 20 minutes. The eMed certified guide is available to answer questions throughout the testing process.

BinaxNOW at-home performance data

In an interim, ongoing analysis of data collected in the U.S. from four investigational sites – where people tested themselves or a child – on a total of 52 people ranging from less than one-year-old to 63 years of age, which included analyses of people by days post-symptom onset and Ct counts, results showed that BinaxNOW for at-home use delivered the following performance as compared to lab-based molecular PCR tests:

- Overall performance of 91.7% positive agreement (sensitivity) and 100% negative agreement (specificity) in people seven days or less post-symptom onset at all Ct counts.
- Performance of 100% positive agreement (sensitivity) in people seven days or less post-symptom onset with Ct counts of 33 or below. These are people who are most likely to be infectious and spread the virus to others due to their lower Ct values.
- The performance of BinaxNOW in the at-home setting is similar to performance in the larger post-authorization study (see section below in release).

There is a growing body of scientific literature[i] and experience focused on the correlation between infectiousness, Ct counts and viral load. Specifically, scientific evidence suggests that at Ct counts in the 30s, the SARS-CoV-2 virus can't be replicated, meaning people are no longer infectious. This underscores the importance of frequent antigen testing to catch people with lower Ct counts while they are most contagious and need to self-quarantine.

- A study by La Scola et. al. published in the European Journal of Microbiology & Infectious Diseases,[ii] shows the inability to culture virus at Ct counts greater than or equal to 34.
- A recent study from the University of California-San Francisco of BinaxNOW in a real-life setting, which showed performance of 93.3% sensitivity and 99.9% specificity at a Ct count of 30 and 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. A person with a higher viral load (and lower Ct count) is more likely to be infectious.

Updated BinaxNOW professional use data

As part of its submission to the FDA for at-home use, Abbott also released the latest clinical data for its BinaxNOW COVID-19 Ag Card professional use product (not inclusive of at-home data) to show real-world evidence of clinical utility and efficacy.

In data collected from ten clinical sites in 460 people ranging from 6 to more than 60 years of age, which included analyses of people by days post-symptom onset and Ct counts, results showed that BinaxNOW delivered the following performance as compared to lab-based molecular PCR tests:

- 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.
- Performance of 95.6% positive agreement (sensitivity) in people seven days or less post-symptom onset with Ct counts of 33 or below. These are people who are most likely to be infectious and spread the virus to others due to their lower Ct values.

Abbott also conducted multiple culture studies that consistently showed that Ct counts less than or equal to 28 are required to grow the virus in a lab. Other independent third-party studies have identified that higher Ct counts are correlated with a lack of infectiousness, and a rapid antigen test with high performance at a Ct count of 33 or below is able to detect the virus in people who are infectious.

Abbott continues to study the BinaxNOW COVID-19Ag Card, including in asymptomatic people.

About the BinaxNOW COVID-19 Ag Card Home Test and NAVICA App

The BinaxNOW™ COVID-19 Ag Card Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for prescription home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset or adult collected nasal swab samples from individuals aged four years or older who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. The BinaxNOW COVID-19 Ag Card Home Test is to be performed only with the supervision of a telehealth proctor.

Along with BinaxNOW, Abbott is also offering a mobile app at no charge called NAVICA, which will allow people to display their results obtained through a healthcare provider or through the eMed at-home service when entering facilities requiring proof of testing. The NAVICA app is optional and an easy-to-use tool that allows people to store, access and display their results with organizations that accept the results so people can move about with greater confidence. The NAVICA app is supported by Apple and Android digital wallets and is available from public app stores in the U.S.

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 107,000 colleagues serve people in more than 160 countries.

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About eMed

eMed is democratizing healthcare with a digital point-of-care platform that provides fast, easy and affordable at-home healthcare testing, supervised and guided online by eMed Certified Guides. We utilize quantitative medicine to deliver prescribed tests and treatments directly to patients, driving better and more cost-effective results.

The BinaxNOW™ COVID-19 Ag Card Home Test has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization. The test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.

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i This article is a pre-print and has not been peer-reviewed. The article reports new medical research that has yet to be evaluated and so should *not* be used to guide medical practice.

ii La Scola et. al., Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards, European Journal of Microbiology and Infectious Diseases, April 27, 2020.

SOURCE Abbott

Additional assets available online: Photos