Abbott's Panbio Rapid Antigen Test Receives CE Mark For Asymptomatic Screening And Self-Administered Sample Collection With Nasal Swab

- Panbio™ COVID-19 Ag Rapid Test Device supports mass testing in congregate populations of people (mass screening) who are asymptomatic

- Frequent screening of asymptomatic and symptomatic people helps restore a sense of safety at workplaces, schools, travel and recreational settings, and other places where people gather in large numbers

- Test is approved for use with a patient-friendly and minimally invasive nasal swab; patients can self-administer sample collection under a healthcare professional's supervision

- Panbio COVID-19 Ag delivers results in as early as 15 minutes with no instrumentation, using proven Abbott lateral flow technology

- Test performance in clinical study demonstrated 93.8% sensitivity and 100.0% specificity in asymptomatic people with high viral loads

- Along with the test, Abbott will offer complementary digital solutions: the NAVICA™ mobile app to allow people to display negative results for proof of testing and Sympheos™ for surveillance management to understand epidemiological trends

- Since August 2020 to date, Abbott has shipped 200 million Panbio rapid antigen tests to 120 countries worldwide

ABBOTT PARK, Ill., Jan. 26, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) announced today it has received CE Mark for two new uses of its Panbio™ COVID-19 Ag Rapid Test Device for the detection of the SARS-CoV-2 virus: asymptomatic testing and self-swabbing.

Panbio COVID-19 Ag's label has been updated with clinical data on asymptomatic individuals, which enables mass testing (mass screening[1]) of people who do not currently present symptoms of the disease. According to a recent study published in JAMA,[2] at least 50% of COVID-19 infections are estimated to have originated from exposure to asymptomatic individuals.

The other update to the label allows self-collection of nasal specimens under the supervision of a healthcare worker. Self-swabbing with a patient-friendly nasal swab improves patient comfort and reduces the risk of accidental exposure to the virus for healthcare workers as they can maintain distance during the testing procedure.

"Rapid testing continues to be one of our most important tools for fighting this pandemic, and the ability to perform mass screening allows us to expand testing and reach more people in more places," said Robert B. Ford, president and chief executive officer, Abbott. "Now that Abbott's Panbio rapid antigen test has an asymptomatic indication, it becomes an even more valuable tool for enabling a safer return to work, school, travel and other activities of daily life."

Since last August to date, Abbott has shipped 200 million Panbio rapid antigen tests to 120 countries across Europe, the Americas, Asia and Africa. Healthcare professionals globally have seen the clinical utility of the test in detecting COVID-19 infections. In coordination with the Global Fund, the World Health Organization and the Bill & Melinda Gates Foundation, Abbott continues to make Panbio rapid antigen tests available to low- and middle-income countries.

Panbio COVID-19 Ag is not available in the U.S., where Abbott manufactures and sells the BinaxNOW™ COVID-19 Ag Card, which has received emergency use authorization (EUA) by the U.S. Food and Drug Administration (FDA). Abbott is in the process of pursuing FDA EUA of an asymptomatic indication for BinaxNOW.

Both Panbio and BinaxNOW rapid antigen tests use similar biologics and are highly portable, reliable and affordable.

Widespread, frequent and fast testing facilitates return to work
The large number of COVID-19 cases and fear of disease spread has resulted in a global economic recession, increased workplace absenteeism and the inability of employers to bring their employees back to the office. As a result, employers and governments around the world are looking for ways to ensure business continuity and restart their economies.

Frequent and fast screening of employees using rapid antigen tests such as Panbio COVID-19 Ag – along with preventative measures such as mask-wearing, social distancing, handwashing, disinfecting facilities and any other actions required by government – can support a safer return to work by quickly identifying and isolating infected and contagious individuals. Employees who test negative can be admitted to facilities and resume their work.

"Since October 2020, Abbott has used rapid antigen tests in a phased rollout of employee testing across multiple sites globally," said Mary Moreland, executive vice president, Human Resources, Abbott. "Our experience proves that testing helps our employees feel safer and more comfortable coming into the office during this time, so they can more effectively collaborate with each other and perform their duties."

Expanded rapid antigen testing plays critical role in restoring freedom of mobility
Beyond workplace screening, the ability to conduct mass screenings at ports of entry using the Panbio rapid antigen test will facilitate the resumption of global travel. A number of governments now mandate proof of a negative COVID-19 viral test before entering the country.[3,4]

Additionally, various airlines and cruise ship companies require that passengers present negative test results before boarding. The International Air Transport Association (IATA) and the Airports Council International (ACI) have publicly called for a systematic approach to testing that is fast, accurate, affordable, easy-to-use, scalable and supported by public health authorities. Mass screening can help restore freedom of mobility across borders and will allow people to travel safely and with confidence.

"Being able to effectively screen asymptomatic people – along with other hygienic measures already in place – is the best way to ensure the safety of our passengers and all air transport workers," said Olivier Jankovec, director general, Airports Council International Europe. "Over 100 airports across Europe are already providing COVID-19 testing facilities in close cooperation with their health authorities. Rapid screening using high-quality and affordable antigen tests is a crucial part of resuscitating global travel until the vast majority of the world's travelers and crews are vaccinated."

Digital solutions facilitate return to daily life and understanding epidemiological trends

Digital health technologies play an important role in pandemic response.[5] Integrated into testing strategies, digital technologies can support mass screening of people for safe entry into facilities and disease surveillance management to understand epidemiological trends. Abbott is offering two distinct digital solutions to support each of these functions.

Abbott's NAVICA mobile app for iPhone and Android devices allows people who test negative to display a temporary digital health certificate that is renewed each time a person is tested by a healthcare worker together with the date of the test result. Organizations using the NAVICA verifier app can scan and verify the information on a mobile device to manage safe entry into workplaces, airplanes and cruise ships, schools and universities, and other places where people come together in large numbers. NAVICA for use with Panbio Ag is soon to be available at no charge to customers outside the U.S.

In support of public health strategies, Abbott is offering Sympheos™, a web-based data collection and visualization tool, for use with Panbio Ag. Sympheos allows healthcare workers to log real-time test results on a smart phone, aggregate the collected data, and display it in a dashboard with heat maps, disease surveillance and testing trends. Sympheos data visualization may help health authorities better understand the epidemiological status of their epidemic and mobilize their COVID-19 response more effectively. Sympheos, which is available now to customers outside the U.S., can also be used to track in parallel other diseases such as malaria and HIV where there are high rates of co-infection.

Since the pandemic began, Abbott has developed the most advanced and comprehensive portfolio of COVID-19 tests across its testing platforms — from high-throughput molecular tests on its m2000™ RealTi*m*e and Alinity™ m lab-based systems; to serology tests on its Alinity™ i and ARCHITECT® i1000SR and i2000SR instruments; to rapid molecular tests on the ID NOW™ instrument; to rapid antigen test options on BinaxNOW™ (available in the U.S. only) and the Panbio™ COVID-19 Ag Rapid Test Device (available in countries outside the U.S.).

About Panbio COVID-19 Ag Rapid Test Device

Panbio COVID-19 Ag Rapid Test Device is a lateral flow assay for rapid, qualitative detection of SARS-CoV-2 virus. A nasal or nasopharyngeal swab is used for collection of specimens from individuals. Test results are delivered in as early as 15 minutes with no instrumentation.

Negative results must be combined with clinical observations, patient history and epidemiological information. Negative results do not preclude COVID-19 infection and cannot be used as the sole basis for treatment or other management decisions.

Clinical performance of Panbio COVID-19 Ag Rapid Test Device was determined by testing 483 asymptomatic people for SARS-CoV-2 antigen and comparing results against a PCR reference method.

Positive results (n=50) were stratified by cycle threshold (Ct) counts in order to understand the correlation between product performance and the amount of virus present in the clinical sample. A lower Ct value corresponds to a higher concentration of the virus.

Specificity of the test across 433 negative samples was 100.0%, which means no false positives were identified. Results for sensitivity were:

- 93.8% in 32 samples with Ct values less than or equal to 30
- 80.0% in 40 samples with Ct values less than or equal to 33
- 66.0% across all 50 positive samples (at all Ct counts)

There is a growing body of scientific literature[6] 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.

Panbio COVID-19 Ag is CE-Marked for use with a nasal swab on asymptomatic and symptomatic people. Abbott has submitted documentation to the World Health Organization for Emergency Use Listing for the two new claims for asymptomatic testing and self-swabbing. Panbio COVID-19 Ag Rapid Test device is available in countries outside of the U.S. and subject to local regulatory and commercialization requirements.

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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[1] Panbio COVID-19 Ag Rapid Test Device is not approved for screening of blood supply.

[2] JAMA, SARS-CoV-2 Transmission from People Without COVID-19 Symptoms, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707.

[3] CDC Expands Negative COVID-19 Test Requirement to All Air Passengers Entering the United States | CDC Online Newsroom | CDC

[4] The types of test accepted for travel may vary on a country by country basis.

[5] Lancet, Applications of digital technology in COVID-19 pandemic planning and response, https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30142-4/fulltext.

[6] 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.

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For further information: Abbott U.S. Media: John Koval, 224-668-5355, Jackie Lustig, 224-668-9857, Darcy Ross, 224-667-3655. For all other countries, see: https://www.abbott.com/corpnewsroom/utilities/media-contacts.html. Abbott Investor Relations: Laura Dauer, 224-667-2299

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