

# **ABBOTT RECEIVES CE MARK FOR ITS PANBIO™ RAPID ANTIGEN SELF-TEST, OPENING ACCESS THROUGHOUT EUROPE TO FAST, RELIABLE COVID-19 TESTING**

- Panbio™ COVID-19 Antigen Self-Test is approved for sale directly to consumers and for use in adults and children with or without symptoms, enabling fast, convenient coronavirus testing
- The self-test features a minimally invasive nasal swab and delivers results in as early as 15 minutes with no instrumentation, using proven Abbott lateral flow technology
- In clinical evaluations with self-test users, the Panbio Self-Test correctly identified 95.2% of positive samples and 100% of negative samples
- Abbott is the only diagnostics manufacturer to provide performance data on a rapid antigen test specific for use on children who are 15 years and younger, including infants
- Together with vaccines and health protocols, frequent, regular screening of asymptomatic and symptomatic people can restore a sense of safety and stability as more people return to work, school, family gatherings and recreational activities

ABBOTT PARK, Ill., June 28, 2021 [/PRNewswire/](#) -- Abbott (NYSE: ABT) announced today it has received CE Mark for its Panbio™ COVID-19 Antigen Self-Test for sale directly to consumers for use in the detection of the SARS-CoV-2 virus in adults and children with or without symptoms. This over-the-counter approval paves the way for critical access to fast, reliable self-testing throughout Europe to reduce the spread of infection as economies reopen and daily life activities resume.

Frequent rapid testing at work, school, home and other facilities makes it possible for people to know their infection status when it matters most – making mass screening an essential tool in the mitigation of COVID-19 as restrictions lift and vaccines roll out. According to a recent study published in JAMA, at least 50% of COVID-19 infections are estimated to have originated from exposure to asymptomatic individuals.<sup>1</sup>

Abbott's Panbio COVID-19 Antigen Self-Test arms people with timely health information to help reduce further spread of infection. The test delivers results in 15 minutes, is easy to use and features a minimally invasive nasal swab for self-collection of specimens. The test can be used on symptomatic or asymptomatic adults and children, including infants with an adult's support.

"We need to remain vigilant in identifying and slowing the spread of the virus to be successful in winning the fight against COVID-19 even as vaccines roll out," said Andrea Wainer, executive vice president, Rapid and Molecular Diagnostics, Abbott. "With CE Mark approval for the Panbio Self-Test, we are able to quickly get these critical rapid tests into the European countries and communities that need them to sustain the reopening of local economies and enable a safer return to work, school, sports, travel and other activities."

## **Restoring freedom and peace of mind through frequent, regular rapid testing**

Rapid antigen testing is less expensive than PCR testing allowing people to test more frequently. While vaccines continue to roll out, the best way to curb the spread of infection is to regularly test people as they return to work or school and attend events and sports or opt to travel.

The Panbio Self-Test is already authorized for use in Germany and France as part of national testing programs in schools, universities and workplaces to test staff and students and restore continuity of in-person classes and safety. Abbott is the only diagnostics manufacturer to provide performance data on a rapid antigen test specific for use on children who are 15 years and younger, including infants.

In the German state of Bavaria, kindergarten students and staff are provided access to Abbott Panbio self-test kits to screen at the start of the week to quickly identify any contagious individuals and reduce the spread of infection.

In France, the Ministry of Education supplied Panbio Self-Tests to schools and universities as part of an overall prevention and control strategy enabling students, teachers and staff to return to school facilities with confidence and peace of mind.

Globally, the large number of COVID-19 cases and fear of disease spread has resulted in restrictions on travel, increased workplace absenteeism and the inability of employers to bring their employees back to the office. To help ensure business continuity and safety, many governments and employers are using the Panbio™ COVID-19 Antigen Rapid Test Device, for professional use, to facilitate mass screenings in airports, for cross-border travel, sporting events and other activities where people congregate in order to reopen and sustain operations.

Since last August to date, Abbott has shipped 300 million Panbio COVID-19 Antigen Rapid tests for professional use across Europe, the Americas, Asia and Africa.

## **Panbio delivers reliable performance for adults and children**

Panbio COVID-19 Antigen is one of the mostly widely studied and used rapid antigen tests in the world.

In clinical evaluations of Panbio Covid-19 Rapid Antigen, performed by healthcare professionals, the test correctly identified 98.1% of positive specimens and 99.8% of negative specimens. All samples were confirmed negative or positive by an approved RT-PCR test.

In clinical evaluations with self-test users, the test correctly identified 95.2% of positive samples and 100% of negative samples. All samples were confirmed positive or negative by the Panbio COVID-19 Antigen Rapid Test Device (Nasopharyngeal).

### **Bringing affordable, reliable tests closer to home for more people**

With CE Mark, the availability of Panbio COVID-19 Antigen Self-Tests can be offered for sale direct-to-consumer, increasing access to fast, reliable testing for more people.

Available in packages to support a variety of testing needs, the Panbio Self-Test comes in one, four, and 10 count test kits for individual and family or friends testing; it also comes in larger quantities of 20 test kits to meet school and workplace screening needs.

Panbio COVID-19 Antigen Self-Test is available in countries outside of the U.S.

### **About Panbio COVID-19 Antigen Tests**

Panbio COVID-19 Antigen Rapid Self-Test is a lateral flow assay for rapid, qualitative detection of SARS-CoV-2 virus. A nasal 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.

The Panbio COVID-19 Antigen Rapid Test Device for professional use is CE-Marked and has received World Health Organization (WHO) Emergency Use Listing for use on asymptomatic individuals and for self-collection of samples using a nasal swab under the supervision of a healthcare professional.

The professional test has data to support use on children 15 years and younger, including infants. Abbott has updated its existing label for use to include performance data in children and has submitted the updated label to the WHO for EUL.

The Abbott Panbio COVID-19 Antigen Rapid Test Device and Panbio COVID-19 Antigen Self-Test are 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 109,000 colleagues serve people in more than 160 countries.

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<sup>1</sup> JAMA, SARS-CoV-2 Transmission from People Without COVID-19 Symptoms, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707>.

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