Abbott Receives FDA Emergency Use Authorization For COVID-19 Antibody Blood Test On Alinity™ I System

- Data shows reliable results with 99.6% specificity and 100% sensitivity for patients tested 14 days after symptoms began

- Abbott plans to ship nearly 30 million antibody tests globally in May across its ARCHITECT and Alinity i platforms and will have capacity for 60 million in June

- Abbott expects to submit for CE Mark for its Alinity i SARS-CoV-2 IgG test this week and will initiate global shipments immediately

- This is Abbott's fourth COVID-19 test to receive FDA EUA, helping to provide hospitals and labs across the U.S. with broad, reliable molecular and antibody testing during this pandemic

ABBOTT PARK, Ill., May 11, 2020 /PRNewswire/ -- Abbott announced today that the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the company's SARS-CoV-2 IgG lab-based serology blood test on the Alinity™ i system. Abbott plans to ship nearly 30 million antibody tests globally in May across its ARCHITECT® and Alinity i™ platforms and will have capacity for 60 million tests in June.

Antibody testing will help provide a greater understanding of the virus, including how long antibodies stay in the body and how much of the population has been infected. Last month, Abbott received FDA EUA and CE Mark for its SARS-CoV-2 IgG antibody blood test on the ARCHITECT system.* Abbott has already begun shipping antibody tests for use on the ARCHITECT systems globally including in the U.S., UK, Italy, Spain and India.

"Having more options of highly reliable tests across our platforms will help healthcare workers and health officials as they conduct broad scale testing for COVID-19," said Robert B. Ford, president and chief executive officer, Abbott. "Abbott is a leader in providing antibody testing at large scale on multiple systems, which is helping meet the needs of laboratories as they look to build testing capacity."

The Alinity i system is Abbott's next-generation immunoassay instrument, which was designed to offer greater efficiencies to lab clinicians running tests. Alinity i systems are in use around the world in hospital and academic centers as well as reference laboratories. Abbott also expects to submit this week for CE Mark to the IVD Directive (98/79/EC) in the European Union for the Alinity i SARS-CoV-2 IgG test.

Our contributions to bring broad scale access to reliable testing
As a leader in infectious disease testing, Abbott's goal is to bring highly reliable tests for customers and patients around the world. A study to determine the clinical performance of Abbott's SARS-CoV-2 IgG assay found it had greater than 99.6% specificity (ability to exclude false positives) and 100% sensitivity (ability to exclude false negatives) in patients tested 14 days after symptoms began.

Abbott is collaborating with leading virology labs to validate test results and is working to quickly install additional instruments to help contribute to large scale testing.

This is Abbott's fourth COVID-19 test to receive FDA EUA, helping to provide hospitals and labs across the U.S. with broad, reliable molecular and antibody testing during this pandemic.

About Alinity™
Abbott's Alinity family of harmonized solutions is unprecedented in the diagnostics industry, working together to address the challenges of using multiple diagnostic platforms and simplifying diagnostic testing. Alinity systems are designed to be more efficient – running more tests in less space and minimizing human errors – while continuing to provide quality results. The availability of the Alinity systems and tests varies by geography. More information is available at abbott.com/alinity.

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.

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 and @AbbottGlobal.

The SARS-CoV-2 IgG assay has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of the IgG antibody against 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

*All ARCHITECT analyzers are Class 1 laser products.

SOURCE Abbott

For further information: Abbott Media: Kim Modory, 224-668-4696; Darcy Ross, 224-667-3655; Abbott Investor Relations: Laura Dauer, 224-667-2299

Additional assets available online: Photos