Abbott Receives FDA Emergency Use Authorization For Its COVID-19 IgM Antibody Blood Test

- Data demonstrates highly reliable test results with 99.56% specificity and 95.00% sensitivity for patients tested 15 days after symptom onset

- Availability of the new IgM blood test on the ARCHITECT® and Alinity™ platforms is part of Abbott's effort to offer tests across the disease progression of COVID-19

- Abbott's IgM test will give a more complete picture of where patients are in their recovery

ABBOTT PARK, Ill., Oct. 12, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the company's AdviseDx SARS-CoV-2 IgM (Immunoglobulin M) lab-based serology test for use on the ARCHITECT® and Alinity™ platforms. IgM antibody testing can play an important role in understanding if someone has developed antibodies in response to the virus, indicating a recent or prior infection.

The new IgM antibody test is Abbott's latest test to support in the fight against COVID-19. Since the start of the pandemic, Abbott has received emergency use authorization for seven tests, including molecular tests, a rapid antigen test and an IgG antibody test.

"Abbott has developed tests to detect the virus at each stage of infection so doctors and their patients are equipped with knowledge of how they are responding to the virus and progressing through recovery," said Robert B. Ford, president and chief executive officer, Abbott. "Antibody tests will continue to play an important role to better understand the virus, the prevalence of COVID-19 in an area and where a patient may be in their recovery."

Understanding a person's immune response with antibody tests

While molecular tests detect whether someone has the virus, antibody tests determine if someone had a previous infection by detecting antibodies, such as IgM and IgG.

Abbott first developed an IgG blood test, which often is the antibody that is longer-lasting in the body after infection. This test has been widely adopted and continues to play a key role in understanding if someone has recovered from the virus, as well as contact tracing and epidemiological studies.[1]

The IgM antibody, in comparison, is most useful for determining a recent infection as these antibodies become undetectable weeks to months following infection.[2] Having this more complete picture of where a patient is in their recovery can help healthcare providers determine if treatment, isolation or follow-up visits are needed.

Similar to Abbott's IgG blood test, the IgM test has demonstrated high reliability in both Abbott's research and external virology laboratory studies. Abbott's data demonstrated 99.56% specificity and 95.00% sensitivity for patients tested 15 days after symptom onset.

The IgM test is now available on Abbott's ARCHITECT and Alinity platforms.

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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* All ARCHITECT analyzers are Class 1 laser products.

References:

1. Chew KL et al., Clinical Microbiology and Infection. 2020. (26): 9.doi.org/10.1016/j.cmi.2020.05.036
2. Liu, X et al. Aging 2020. (12): 13. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377873/pdf/aging-12-103417.pdf

The AdviseDx SARS-CoV-2 IgM 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 IgM 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.

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