Abbott Provides Update On ID NOW™

ABBOTT PARK, Ill., May 14, 2020 /PRNewswire/ -- (NYSE: ABT) -- Abbott's ID NOW™ is the fastest molecular point-of-care rapid test available today and has been delivering reliable results when and where they're needed. The availability and ease-of-access of ID NOW, which delivers results in minutes rather than a day or more, is helping to reduce the risk of infection in society by detecting more positive results than would otherwise be found.

We're seeing studies being conducted to understand the role of ID NOW in ways that it was not designed to be used. In particular, the NYU study results are not consistent with other studies. While we've seen a few studies with sensitivity performance percentages in the 80s, we've also seen other studies with sensitivity at or above 90%, and one as high as 94%.

While we understand no test is perfect, test outcomes depend on a number of factors including patient selection, specimen type, collection, handling, storage, transport and conformity to the way the test was designed to be run. ID NOW is intended to be used near the patient with a direct swab test method.

It is our responsibility to provide healthcare professionals and the public with accurate information, and that's why we're doing the following:

- Further clarifying our product information to provide better guidance to healthcare providers that negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Negative results should be presumed negative, but if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. We are also reinforcing proper sample collection and handling instructions. We are communicating this to our customers.
- Continuing to optimize this test as the world learns more about this virus. We're working to incorporate those learnings into the test as we do with all of our diagnostics tests.

Abbott has been working in collaboration with FDA throughout the Emergency Use Authorization (EUA) process.

The world needs a variety of tests in labs and at the point of care if we are to help reduce the risk people have every day of contracting the virus. ID NOW is an important tool in that equation. Risk reduction is the goal, which is why we're developing and continually optimizing as many tests as we can across all of our diagnostics 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.

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 ID NOW COVID-19 EUA has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories and patient care settings. The test has been authorized only for the detection of nucleic acid 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

SOURCE Abbott

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