Abbott Releases Interim Clinical Study Data On ID NOW COVID-19 Rapid Test Showing Strong Agreement To Lab-Based Molecular PCR Tests

- Urgent care clinic study shows ID NOW test performance of ≥94.7% positive agreement (sensitivity) and ≥98.6% negative agreement (specificity) compared to lab-based PCR reference tests

- The Everett Clinic study shows 91.3% positive agreement and 100% negative agreement

- Ongoing study of hospitalized and nursing home patients tested with late symptom onset shows ≥83.3% positive agreement and ≥96.5% negative agreement

- Abbott's studies suggest ID NOW performs best in patients tested earlier post symptom onset

- ID NOW delivers results in minutes rather than days and is helping reduce the spread of infection by detecting more positive patients faster than would otherwise be the case

ABBOTT PARK, Ill., May 21, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) announced today an interim analysis of an ongoing multi-site clinical study in urgent care clinics that indicates its ID NOW COVID-19 rapid test is showing strong agreement to lab-based molecular polymerase chain reaction (PCR) instruments. The interim results are demonstrating ID NOW COVID-19 test performance is ≥94.7% in positive agreement (sensitivity) and ≥98.6% negative agreement (specificity) when compared to two different lab-based PCR reference methods.

Data from this, as well as two other Abbott-sponsored studies – The Everett Clinic in Washington and an ongoing study of hospitalized and nursing home patients – suggest ID NOW performs best in patients tested earlier post symptom onset, when they are most likely to go for care. In these studies, ID NOW was used as intended with variations in patient populations based on the number of days a patient was tested after first experiencing symptoms.

"We're pleased that ID NOW is delivering on what it was designed to do – quickly detect the virus in people who need to know now if they're infected," said Philip Ginsburg, M.D., senior medical director, infectious disease, Rapid Diagnostics, Abbott. "This is great news for people who are experiencing symptoms and want to take action before they infect others, reducing the spread of infection in society."

"These new interim results reflect what we're hearing from hundreds of our customers, which is that they're seeing results with positive rates from ID NOW that are at, or above, their local COVID-19 infection rates," continued Dr. Ginsburg. "This tells us that ID NOW is performing comparable to molecular laboratory tests in detecting the virus."

Urgent Care Clinic Study
In 256 subjects enrolled to date, ID NOW has identified 29 of 29 positive samples (100% positive agreement) and 226 of 227 negative samples (99.6% negative agreement) when compared to a commonly-used lab-based molecular PCR assay (the Roche cobas® SARS-CoV-2 assay).

In parallel, ID NOW has demonstrated 94.7% positive agreement and 98.6% negative agreement compared to the Centers for Disease Control (CDC) 2019-Novel Coronavirus (COVID-19) Real-Time RT-PCR Diagnostic Panel. In comparison, Roche has demonstrated 95.0% positive agreement and 98.7% negative agreement when compared to the CDC assay.

In these subjects, the mean number of days from symptom onset is 4.1 days with 90% of subjects tested within 7 days post symptom onset, when patients typically show up for care.

"This corresponds to what my colleagues and I are seeing every day when using ID NOW, which is that it combines strong sensitivity and specificity with rapid results so that we can provide immediate information and care," said Warren Wollin, D.O., senior medical director, Physicians Immediate Care, who is not affiliated with this study. "It is a powerful tool for near-patient testing and is essential to us in helping reduce the spread of this virus."

The ongoing study is examining ID NOW COVID-19 test performance at five urgent care clinics (New Jersey, Tennessee, Louisiana, Texas and South Carolina). This is one of the first studies conducted on the ID NOW COVID-19 test in a real-world setting as it is intended to be used, compared with other studies that have used banked or retained samples.

The Everett Clinic Study
These interim results are consistent with results from a 955 subject study (763 symptomatic and 192 asymptomatic) presented last week in an Association for Molecular Pathology webinar by Yuan-Po Tu, M.D., of The Everett Clinic in Washington in a similar setting, which showed 91.3% positive agreement (sensitivity) and 100% negative agreement (specificity greater than 99.5% at the lower confidence limit) for ID NOW compared to lab-based PCR assays.

Study with Hospitalized and Nursing Home Patients
Abbott is conducting another ongoing study looking at ID NOW's performance compared to two lab-based reference methods in nursing home and hospitalized settings later in post symptom onset than the populations in the urgent care and The Everett Clinic settings.

In an interim analysis, the mean number of days from symptom onset is 12.2 days with more than 68% presenting with ≥8 days post symptom onset. In comparison, the Everett study mean was 9.7 days post symptom onset and the urgent care clinic at 4.1 days post symptom onset.

In the hospitalized and nursing home analysis to date, ID NOW has shown 85.7% positive agreement and 97.6% negative agreement compared to the CDC assay, and 83.3% positive agreement and 96.5% negative agreement when compared to Hologic's Panther Fusion® SARS-CoV-2 test. In comparison, the Hologic assay has demonstrated 91.8% positive agreement and 98.2% negative agreement when compared to the CDC assay.

Data from these studies suggest ID NOW performs best in people tested earlier after they first begin experiencing symptoms. This is consistent with a recent study published in the Annals of Internal Medicine, where researchers from Johns Hopkins found that even the most sensitive lab-based molecular tests can have false negatives when viral load levels are ramping down, near the end of the infection cycle when viral load winds down and patients may no longer be infectious.

Abbott will report full results from these studies when the studies and analyses are completed.

About the ID NOW™ Point-of-Care Molecular Platform
First introduced in 2014, ID NOW is the leading molecular point-of-care platform for Influenza A & B, Strep A and RSV testing in the U.S.

ID NOW is a rapid, instrument-based, isothermal system for the qualitative detection of infectious diseases. Its unique isothermal nucleic acid amplification technology provides molecular results in just minutes, allowing clinicians to make evidence-based clinical decisions during a patient visit.

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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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.

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