Abbott Receives FDA EUA For Laboratory PCR Assay That Detects And Differentiates SARS-CoV-2, Flu A, Flu B And RSV In One Test - And FDA EUA For Asymptomatic Usage Of Alinity M COVID-19 Test

-- Abbott's Alinity™ m Resp-4-Plex assay will allow healthcare workers to test for four viruses in one test, a critically important tool as flu presents with similar symptoms

-- The test helps save on much-needed testing supplies since it allows for testing for all four viruses with one swab

-- Assay will run on Abbott's most advanced molecular PCR platform, the Alinity m system, which provides fast results in high volumes

-- Abbott also received updated EUA for asymptomatic usage of its Alinity m SARS-CoV-2 assay

ABBOTT PARK, Ill., March 5, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the company's Alinity™ m Resp-4-Plex molecular assay to detect and differentiate SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus (RSV) in one test. This is an important tool because these viruses have similar symptoms but require different treatment approaches. This test is CE Marked and available in countries outside the U.S.

The Alinity m Resp-4-Plex test can be conducted with one swab specimen (anterior nasal or nasopharyngeal) collected by a healthcare provider or an anterior nasal swab specimen self-collected at a healthcare location from individuals suspected by their provider of respiratory viral infection consistent with COVID-19. Test will run on Abbott's Alinity m system — the company's most advanced high-volume laboratory molecular instrument. Alinity m uses Polymerase Chain Reaction (PCR) technology, which is known for its high sensitivity in detecting infectious diseases. To help fight the pandemic, Abbott has accelerated placements of the Alinity m system in hospital labs, academic centers and labs that are critical to patient care.

"Abbott has been developing and introducing tests that have been playing a critical role in fighting the pandemic. The need for a combination of testing methods in different settings has never been more clear," said Andrea Wainer, executive vice president, Rapid and Molecular Diagnostics, Abbott. "This newest test will allow for fast and efficient diagnosis and triage of patients who present with respiratory symptoms so they can be given the right care."

Advanced technology's role in the fight

The Alinity m Resp-4-Plex assay will be a critical tool in detecting these four prevalent respiratory viruses. The advanced technology of the Alinity m system provides automation and on-demand access, meaning an urgent test can be run at any time. This flexibility and efficiency allow for the testing of multiple diseases while still producing fast results in high volumes. This assay's ability to detect and differentiate these viruses simultaneously with only one swab will also ease the resource strain on collection devices, which have been in high demand throughout the COVID-19 pandemic.

Expanding Alinity m SARS-CoV-2 to asymptomatic cases

Abbott is also announcing that the EUA for the company's Alinity m SARS-CoV-2 test has been updated to include an asymptomatic claim – detecting COVID-19 in individuals who do not have symptoms. A recent study found that more than 60% of COVID-19 infections present as asymptomatic cases, which is why it's critical to catch those cases before they spread.[1] With the recent update to the Alinity m SARS-CoV-2 test EUA, the assay can now be used to detect individuals who are infected with SARS-CoV-2, but do not have symptoms or other reason to suspect COVID-19 infection. The Alinity m SARS-CoV-2 test EUA was also updated to include a pooling claim, which allows up to five samples to be tested at the same time. The updated Alinity m SARS-CoV-2 test, Alinity m Resp-4-Plex assay, and Abbott's existing testing technologies will now all be available to support front-line healthcare workers.

About Alinity m

Assays available for use on the Alinity m system worldwide include: SARS-CoV-2, HCV (hepatitis C), HBV (hepatitis B), HIV-1 (human immunodeficiency virus type 1), STI (CT/NG/TV/MG) and HR HPV. The easy-to-use system will help to improve laboratory workflow and efficiency with its large capacity and fast turnaround time, being able to run up to 1,080 tests in a 24-hour period based on laboratory practice and workflow. Alinity m systems are designed to be more efficient – running more tests in less time and minimizing human errors – while continuing to provide quality results. The availability of the Alinity m system and tests varies by geography. More information is available at molecular.abbott.

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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Alinity m assays: STI (CT/NG/TV/MG) and HR HPV are not commercially available in the United States.

The Abbott Alinity m Resp-4-Plex product has not been FDA cleared or approved, but been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and/or Respiratory Syncytial Virus, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

1. Zachary J. Madewell, PhD., Yang Yang, PhD., Ira M. Longini Jr, PhD., M. Elizabeth Halloran, MD, DSc., & Natalie E. Dean, PhD. (2020). "Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis". *JAMA Network.* doi:10.1001/jamanetworkopen.2020.31756

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