Abbott Receives FDA Emergency Use Authorization For COVID-19 Molecular Test On New Alinity™ M System

- Alinity m is Abbott's new molecular lab system, which was approved by the U.S. FDA in March

- The Alinity m system is highly advanced and greatly improves speed and efficiency, running up to 1,080 tests in 24 hours

- Abbott is launching Alinity m to U.S. customers and will be making the SARS-CoV-2 test available for use under an Emergency Use Authorization

- This is Abbott's fifth 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 12, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the company's molecular test for the novel coronavirus (COVID-19) for use on its new Alinity™ m molecular laboratory instrument. Abbott is in the process of launching the Alinity m system to U.S. customers.

The Alinity m system was cleared by the FDA for use with Abbott's HCV (hepatitis C) assay in late March. Abbott is working with hospitals and health systems in the U.S. to install this new instrument, which will help keep up with the growing demand for testing.

"Molecular lab tests play a critical role in detecting the virus for COVID-19. As a leader in diagnostics, we are pushing forward to develop high-performing tests across our platforms to help combat this pandemic," said Robert B. Ford, president and chief executive officer, Abbott. "As we continue to develop and improve our testing technologies, we want to ensure they are meeting the needs of our customers – and right now that means having reliable tests for COVID-19 on all of our diagnostic instruments."

The Alinity m system is Abbott's most advanced laboratory molecular instrument. It is an automated platform, which can run more tests in less time to give laboratories improved efficiency and flexibility when using the system. The Alinity m system is able to run up to 1,080 tests in 24 hours, and our *m*2000 RealTi*m*e system can run up to 480 tests in 24 hours.

With current systems, running different types of tests at the same time will slow down the time to results and/or volume throughput. Alinity m delivers true random access, allowing labs to run any test, any time for different types of infectious diseases while still providing results in less than two hours. This is especially critical during the COVID-19 pandemic when volume, speed and flexibility are needed.

Our contributions to bring broad scale access to reliable testing
As a leader in infectious disease testing, Abbott is working to bring as many tests as possible across our platforms to customers and patients around the world. This is Abbott's fifth 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.

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The Abbott RealTime SARS-CoV-2 assay and the Alinity m SARS-CoV-2 assay have not been FDA cleared or approved. These tests have been authorized by the FDA under an Emergency Use Authorization for use by authorized laboratories. These tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens, and are 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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For further information: Abbott Media: Kim Modory, 224-668-4696, or Darcy Ross, 224-667-3655; Abbott Investor Relations: Laura Dauer, 224-667-2299

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