NEWS RELEASE

Hologic's Molecular Test for the Novel Coronavirus, SARS-CoV-2, Receives FDA Emergency Use Authorization

3/16/2020

-- New Test Will be Widely Available on Hologic's Fully Automated Panther Fusion ® System, Significantly Adding to Testing Capacity --

-- Only High-Throughput System to Enable Simultaneous Testing for SARS-CoV-2 and Other Common Respiratory Viruses, Boosting Efficiency and Increasing Clinical Insight --

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the Company's new Panther Fusion® SARS-CoV-2 assay, a molecular diagnostic test that detects SARS-CoV-2, the virus that causes COVID-19 disease.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20200316005908/en/

Panther Fusion SARS-CoV-2 (Photo: Business Wire)

Hospital, public health and reference laboratories can perform the test on Hologic's Panther Fusion system, a fully automated, high-throughput molecular diagnostic platform that is widely used across the United States. Each Panther Fusion system can provide results in less than three hours and process up to 1,150 coronavirus tests in a 24-hour period.

Using the Panther Fusion system, healthcare providers can test for SARS-CoV-2 from the same patient sample and collection vial that they currently use to diagnose other common respiratory viruses whose symptoms overlap with

COVID-19, boosting efficiency and increasing clinical insight. With a small physical footprint and a broad menu that includes 16 FDA-cleared tests for various infectious diseases, the Panther Fusion system is already widely used in low-, medium- and high-throughput laboratories.

In addition, patient samples can be loaded onto the Panther Fusion system as they arrive in the laboratory, a capability known as “random access” that improves efficiency and workflow. Overall, the instrument’s high throughput and quick turnaround time will enable more patients to be tested, sooner.

“As one of the largest molecular diagnostic companies in the world, Hologic can make a huge difference in the coronavirus pandemic with our scientific expertise and fully automated, high-throughput testing system,” said Steve MacMillan, Chairman, President and CEO of Hologic. “As soon as the outbreak started, our diverse team of scientists and engineers began developing a new, highly accurate test, and we have brought it to market quickly through the FDA’s emergency use process and with assistance from BARDA. Just as we answered calls to help during the H1N1 and Zika virus outbreaks, we are proud to help our laboratory customers and clinicians respond to the urgent public health need for more coronavirus testing.”

As previously announced, Hologic was the first company to receive support for coronavirus test development from the U.S. Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA).

"Making rapid and accurate diagnostic tools available to healthcare providers is critical for early detection and control of COVID-19," said BARDA Director Rick A. Bright, Ph.D. “The speed at which this assay was developed, validated, and issued EUA -- less than two months -- is a testament to Hologic’s commitment to helping reduce the global COVID-19 burden.”

Hologic expects to provide its laboratory customers with tens of thousands of SARS-CoV-2 tests this month as it ramps up production capacity. Starting in April, Hologic expects to produce nearly 600,000 SARS-CoV-2 tests a month, representing a 12-fold increase in the Company’s prior manufacturing capacity for similar tests that run on the Panther Fusion system. The Company is also making additional investments to further increase production capacity.

“Early diagnosis of the coronavirus is critical both to managing infected patients, and to mitigating the spread of the disease,” said Maurice Exner, Vice President of Research and Development and Clinical Affairs at Hologic. “The EUA for our SARS-CoV-2 assay on the Panther Fusion system allows laboratories to run many more tests per day than they can on manual systems, enhancing the public health fight.”

About the Panther Fusion® SARS-CoV-2 Assay

The Panther Fusion SARS-CoV-2 assay is a real-time RT-PCR in vitro diagnostic test intended for the qualitative detection of RNA from the SARS-CoV-2 isolated and purified from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens obtained from individuals who meet COVID-19 clinical and/or epidemiological criteria. The Panther Fusion SARS-CoV-2 assay is for use only under Emergency Use Authorization (EUA) in the US laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal and oropharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Panther Fusion SARS-CoV-2 assay on the Panther Fusion system utilizes Open AccessTM reagents and functionality and is intended for use by trained clinical laboratory personnel specifically instructed and trained in the operation of the Panther Fusion system and in vitro diagnostic procedures. The Panther Fusion SARS-CoV-2 assay is only for use under the Food and Drug Administration’s Emergency Use Authorization.

About Emergency Use Authorization Status

The Panther Fusion SARS-CoV-2 assay has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. The test has been authorized only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. It is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the

emergency use of in vitro diagnostics for detection of SARS-CoV-2 virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About the Panther and Panther Fusion Systems

The Panther molecular diagnostics system is a best-in-class, fully automated, sample-to-result platform that can be used in low, medium or high-throughput laboratories. With a small footprint, adaptable workflow options and consolidated testing menu, it combines women's health, sexually transmitted infection and viral load testing, which can all be done simultaneously. The Panther Fusion system provides an expanded in vitro diagnostics menu, as well as Open AccessTM functionality to run laboratory developed tests. Hologic's Panther and Panther Fusion systems now offer 16 FDA-cleared assays and 20 CE-marked assays that detect more than 20 pathogens. More than 1,800 Panther systems have been installed in clinical diagnostic laboratories around the world, including about 200 Panther Fusion systems.

About COVID-19

For more information about the novel coronavirus, visit: **https://www.cdc.gov/coronavirus/2019-ncov/summary.html**.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit **www.hologic.com**.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's Panther Fusion® SARS-CoV-2 assay. There can be no assurance this product will receive full regulatory clearance, or achieve the benefits described herein. In addition, there can be no assurance that this product will be manufactured in adequate quantities to meet demand, be commercially successful, or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

SOURCE: Hologic, Inc.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20200316005908/en/**

Investor Contact

Michael Watts
Vice President, Investor Relations and Corporate Communications
(858) 410-8588
michael.watts@hologic.com

Media Contact

Jane Mazur
Vice President, Divisional Communications
(585) 355-5978
jane.mazur@hologic.com

Source: Hologic, Inc.