NEWS RELEASE

Hologic Granted FDA Emergency Use Authorization for Its Second Molecular Test for COVID-19

5/15/2020

-- Significant Test Manufacturing Capacity, Large Installed Base of Automated Instruments Yield Testing Breakthrough --

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Aptima SARS-CoV-2 assay to detect the novel coronavirus.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20200515005103/en/

Aptima SARS CoV-2 (Photo: Business Wire)

The newly authorized test runs on Hologic's fully automated Panther® system, more than 1,000 of which are already installed in clinical laboratories throughout the United States. Each Panther system can provide initial results in approximately three hours and process more than 1,000 coronavirus tests in 24 hours. Hologic has begun distributing its new coronavirus test, and expects to produce an average of one million tests per week. Combining significant manufacturing capacity for the new test with the world's largest installed base of high-throughput molecular instruments is expected to dramatically increase testing capabilities.

"Delivering test results when and where they are needed – so people can either get back to work or quarantine themselves – is key to re-opening global economies safely," said Steve MacMillan, the Company's Chairman, President and CEO. "I'm so proud of the incredible teamwork across the company that brought this test to market so quickly."

The Panther system is a fully automated, high-throughput molecular diagnostic platform that is widely used around the world, with more than 1,800 systems installed in 60 countries. In the United States, instruments are installed across all 50 states. Approximately 750 U.S. hospital, public health and reference labs use the Panther system and its suite of Aptima assays to perform tens of millions of molecular tests annually for sexually transmitted infections, cervical cancer screening and viral load monitoring in people with HIV and hepatitis.

Certain aspects of the Aptima SARS-CoV-2 assay project were conducted under a $13 million contract, initially **announced** on April 29, 2020, with the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

Hologic plans to register its Aptima SARS-CoV-2 assay for a CE Mark for diagnostic use in Europe later in May.

About the Panther System

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 infections and viral testing, which can all be done simultaneously. In addition, patient samples can be loaded onto the Panther 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 enable more patients to get results sooner.

The Panther system, launched in Europe in 2010 and the U.S. in 2012, employs a suite of proprietary Aptima technologies that are familiar to clinical laboratory customers. Notably, extraction and purification of microbial nucleic acids is done via a process called target capture, in which specific viral nucleic acids are bound to magnetic particles. Then, amplification is performed in a single tube by Transcription Mediated Amplification, or TMA, which produces billions of copies of the target genetic material. This genetic material is then detected via chemiluminescent probes.

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 Aptima® SARS-CoV-2 assay. There can be no assurance this product will receive full market authorization 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.

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