NEWS RELEASE

Hologic's Multiplex COVID-19/Flu Test Now Commercially Available in North America and Europe

10/27/2021

- Aptima® SARS-CoV-2/Flu Assay Tests Simultaneously for SARS-CoV-2, Influenza A and B on Fully Automated Panther® Molecular Diagnostics System -

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that its Aptima® SARS-CoV-2/Flu Assay is now available for the simultaneous detection and differentiation of three respiratory viruses that can present with overlapping clinical symptoms.

The three viruses – SARS-CoV-2, influenza A and influenza B – typically cause similar symptoms including fever, cough, headache and fatigue1. With the potential for seasonal flu in addition to the ongoing COVID-19 pandemic, physicians may want to test patients presenting with these shared symptoms for all three viruses.

Hologic's new multiplex test is CE-Marked for diagnostic use in Europe, authorized under Interim Order by Health Canada, and has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The assay runs on Hologic's fully automated Panther® system, which provides initial results in approximately three hours and can process more than 1,000 tests in 24 hours.

"Our new assay will provide greater flexibility and testing options for labs and healthcare providers as we head into what is typically flu season in the United States," said Kevin Thornal, president of the Diagnostic Solutions Division at Hologic. "Because our Panther instruments are so widely placed in clinical labs across the country, the launch of this test will help deliver results where and when they are needed."

To date, Hologic has provided more than 100 million SARS-CoV-2 assays to its laboratory customers, making a significant contribution to the global testing supply. More than 2,700 Panther systems are installed in clinical

diagnostic laboratories around the world.

“Our new SARS-CoV-2/Flu assay is a valuable option for healthcare systems by providing the ability to detect multiple infectious agents simultaneously,” said Jan Verstreken, group president, International at Hologic. “Hologic has been consistently at the forefront of public health needs during the current pandemic by providing fully automated testing capabilities to address the global situation.”

The Aptima® SARS-CoV-2/Flu Assay can be used with both anterior nasal swab and nasopharyngeal sample types. Multiple collection devices can be used, including Hologic’s Direct Load Collection Kits, recently launched in the U.S., which are designed to reduce risk of viral transmission and improve laboratory efficiency. A buffer within the collection tube inactivates SARS-CoV-2 and other common respiratory viruses. Then the tubes are loaded directly onto the Panther instrument without any manual steps, reducing human error and repetitive motion injuries.

Development of the Aptima® SARS-CoV-2/Flu Assay was funded in part with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract no. 75A50120P00100.

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/Flu assay and Panther system. There can be no assurance the Aptima® SARS-CoV-2/Flu assay and Panther system will receive full market authorization or achieve the benefits described herein, as applicable. In addition, there can be no assurance that the products 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.

References:

1. **https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html**. Accessed October 26, 2021.

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