NEWS RELEASE

FDA Amends Emergency Use Authorization for Hologic's Aptima SARS-CoV-2 Assay to Include COVID-19 Testing of Asymptomatic Individuals, Symptomatic Sample Pooling

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MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that its Aptima® SARS-CoV-2 assay, which initially received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) in May, is now authorized for testing of individuals without symptoms or other reasons to suspect COVID-19 infection.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20201006005971/en/

Aptima® SARS-CoV-2 Assay to Include COVID-19 Testing of Asymptomatic Individuals, Symptomatic Sample Pooling (Photo: Business Wire)

This authorization follows an **announcement** last week of similar claims for Hologic's Panther Fusion® SARS-CoV-2 assay. The U.S. Centers for Disease Control and Prevention (CDC) recently issued guidance recommending COVID-19 tests for people who have had recent contact with infected individuals, a key strategy for limiting the spread of the virus.1

"For many years, molecular tests – tests that directly detect the genetic material of pathogens – have been recognized as the gold standard for infectious disease diagnostics," said Kevin Thornal, president of the Diagnostic Solutions Division at Hologic. "They remain the most sensitive and accurate available options, which is particularly important when screening individuals with no symptoms or known contact with infected people, and therefore no clues about their infectious state."

The asymptomatic screening claim is based on available analytical data, including results published in a recent FDA **report**, as well as Hologic's commitment to submit results from a clinical evaluation currently in progress. The FDA report showed that Hologic's assays are the most analytically sensitive of the fully automated, high-throughput molecular tests on the market.

In addition, FDA authorized the company's pooling **protocol** for symptomatic testing with the Aptima SARS-CoV-2 assay.

To date, Hologic has produced tens of millions of SARS-CoV-2 assays, thereby making a significant contribution to the global testing supply. The Aptima and Panther Fusion SARS-CoV-2 tests run on Hologic's fully automated Panther® and Panther Fusion systems, respectively, each of which can provide initial results in approximately three hours and process more than 1,000 coronavirus tests in 24 hours. More than 2,000 Panther and Panther Fusion systems have been installed in clinical diagnostic laboratories around the world.

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 and Aptima® SARS-CoV-2 assay. There can be no assurance these products will receive full market authorization or achieve the benefits described herein. In addition, there can be no assurance that these 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 September 27, 2020.

SOURCE: Hologic, Inc.

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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.