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Hologic Launches Validated Pooling Protocol for COVID-19 Testing

In Time of Extraordinary Need, New Protocol Expected to Help Laboratories Deliver Greater Quantities of Highly Accurate Molecular Test Results and Reduce Turnaround Times

Hologic, Inc. announced today that it has validated use of its Aptima® and Panther Fusion® molecular diagnostic COVID-19 assays with pooled patient samples and completed an emergency use notification to the U.S. Food and Drug Administration (FDA) to make this workflow available to laboratory customers in the United States. By allowing samples from multiple individuals to be tested simultaneously, pooling is expected to help laboratories deliver increasing numbers of highly accurate molecular test results more quickly.

Hologic believes it is the first test manufacturer in the country to validate and launch a pooling workflow that ensures highly accurate detection of the SARS-CoV-2 virus. As described in the protocol, pooling is used most effectively in areas or populations of lower disease prevalence.

“By providing a pooling protocol, we are helping our lab customers meet the extraordinary demand for highly accurate molecular test results during this unprecedented time,” said Kevin Thornal, president, Diagnostic Solutions Division at Hologic. “Pooling will enable more samples to be tested each day, but at the same time, help test results get back to patients and their caregivers faster. I am very proud of the ingenuity and innovations that our Hologic teams continue to bring to fighting this pandemic.”

Hologic’s pooling protocol enables clinical laboratories to combine up to five patient samples into a single tube for processing. A negative result means that all five individuals have tested negative for SARS-CoV-2. In cases of a positive result, all five samples are re-tested individually to determine which patient or patients are infected.

The pooling workflow for the Aptima and Panther Fusion SARS-CoV-2 assays has not yet been reviewed by FDA. This workflow is being made available in accordance with Section IV.C. of FDA’s policy for diagnostic tests for Coronavirus disease – 2019 during the public health emergency at https://www.fda.gov/media/135659/download [fda.gov].

Hologic’s Aptima and Panther Fusion SARS-CoV-2 assays detect the genetic material of the virus and run on fully automated testing platforms that return initial results in approximately three hours. The Aptima SARS-CoV-2 test runs on Hologic’s Panther® system, and the Panther Fusion SARS-CoV-2 test runs on the Panther Fusion® system. More than 1,100 of these automated systems are installed in U.S. clinical laboratories. Each Panther and Panther Fusion system can process more than 1,000 SARS-CoV-2 tests in 24 hours. Hologic is currently producing an average of more than one and a half million COVID-19 tests per week.

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