Aptima SARS-CoV-2 assay gets expanded EUA

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November 2020—Hologic's Aptima SARS-CoV-2 assay, which initially received FDA emergency use authorization in May, is now authorized for testing people without symptoms or other reasons to suspect COVID-19 infection.

"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," Kevin Thornal, president of the diagnostic solutions division at Hologic, said in a press statement. "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 FDA also authorized the company's pooling protocol for symptomatic testing with the Aptima SARS-CoV-2 assay.

The Aptima test runs on Hologic's fully automated Panther system, which provides initial results in about three hours and processes more than 1,000 coronavirus tests in 24 hours.

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