Ortho Clinical Diagnostics

COVID-19 Antibody Test Released by Ortho Clinical Diagnostics

April 3, 2020



Aligned with its mission to improve and save lives with diagnostics, Ortho Clinical Diagnostics today announced it is launching to market its SARS-CoV-2 (COVID-19/coronavirus) antibody test—the VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack. Testing kits are expected to be available in a few weeks.

Ortho followed the guidelines established by the U.S. Food and Drug Administration's (FDA) Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency.

> ***"The unprecedented nature of this rapidly spreading virus required an immediate response from the diagnostics industry, and Ortho followed through on its commitment to help develop better ways to treat patients and provide robust data to help manage COVID-19," said Chris Smith, chief executive officer. "At Ortho Clinical Diagnostics, the patient is at the heart of everything we do—because we believe behind every test is a life."***

The VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack detects antibodies (including IgG and IgM) to SARS-CoV-2 that can be used to detect immune response to the virus. The test may be used in epidemiological research to help better understand the spread of the disease and may also be used to aid in the diagnosis of suspected COVID-19 patients in conjunction with molecular tests.

> ***"Ortho leveraged its history of innovation and history of advancing through science to quickly develop these solutions," said Chockalingam Palaniappan, PhD, chief innovation officer. "It's inspiring to think of the good the healthcare community can do by advancing the learning about this virus."***

The test will run on Ortho's flagship analyzer, the VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System, the VITROS® 5600 Integrated System and VITROS® ECi/ECiQ Immunodiagnostic Systems and can process approximately 150 tests in an hour. The systems are designed to remove barriers and adaptable for non-traditional laboratory environments because they don't require an external water supply to run and are already installed in more than 1,000 hospital and reference labs throughout the United States.

> ***"Given the incredible demand for information to change the tide of this pandemic, Ortho felt it was necessary to market as quickly as possible with a notification to the FDA," said Smith. "We are working to make our antibody test kit available to the areas with the greatest need first and will be working in parallel to both increase our test kit production and follow additional regulatory pathways to secure further approvals."***

As a trusted partner of hospitals, hospital networks, blood banks, and labs around the world for over 80 years, Ortho has a rich history of developing solutions that provide fast, accurate, reliable testing results. The test was developed at Ortho's Global Center of Excellence for R&D in Rochester, New York.

The VITROS Anti-SARS-CoV-2 Total test has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests. The test has been authorized only for the detection of total antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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