

Ortho Clinical Diagnostics

Ortho's Total Antibody Test for COVID-19 Receives Emergency Use Authorization from FDA

April 14, 2020



The U.S. Food and Drug Administration (FDA) today announced it granted Emergency Use Authorization to Ortho Clinical Diagnostics' total antibody assay for COVID-19—the VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and Calibrators. This test is one of the first high-throughput, automated* COVID-19 antibody tests to be granted Emergency Use Authorization.

Across the globe, health care professionals, researchers, and government officials are racing to find solutions to better manage COVID-19 and prevent it from impacting additional lives. Ortho's COVID-19 total antibody test can help determine who can responsibly be permitted to go back to work by aiding in the identification of currently infected or previously exposed individuals who may have developed immunity.

"The COVID-19 pandemic continues to impact individuals, families, and communities around the world," said Chris Smith, chief executive officer, Ortho Clinical Diagnostics. "Ortho is proud to be working toward large-scale solutions that will help people return to work, reducing the strain on both employees and the economy as a whole. Our focus on improving patients' lives through diagnostics led us to rapidly develop this test, providing the one of the key resources needed for diagnosing and treating COVID-19. We remain committed to helping laboratories deliver fast, accurate, reliable results to healthcare professionals, patients and the researchers developing the long-term, sustainable management of this disease."

The tests can be run on Ortho's flagship laboratory analyzer, the VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System, the VITROS® 5600 Integrated System and will soon be available on VITROS® ECi/ECiQ Immunodiagnostic Systems.¹ VITROS Systems, already installed in more than 1,000 hospitals and reference labs in the U.S., are self-contained and do not require an external water source to run, offering labs placement flexibility.

A limited quantity of tests kits have already been shipped to areas of highest priority. Ortho will be in full production in the coming weeks and plans to manufacture several million SARS-CoV-2 antibody tests over the next month, with rapid production expansion following thereafter.

Following Ortho's April 3 launch of the test under the FDA's notification pathway for serology tests, Ortho further worked with the FDA to secure additional review of the data under its Emergency Use Authorization pathway, which allows the FDA to expedite review and authorization of SARS-CoV-2 diagnostic tests to rapidly expand testing capacity during the COVID-19 public health emergency.

The VITROS® Anti-SARS-CoV-2 antibody tests are designed and solely intended to be performed by laboratory professionals and cannot be directly used by patients as they are not for home use.

Questions from laboratories, healthcare providers, government, or media regarding the COVID-19 antibody test can be directed to: OrthoCOVID19Test@orthoclinicaldiagnostics.com.

*High Throughput: If an instrument has high throughput, it can output a large number of test results in a short period of time. When running infectious disease tests such as our COVID-19 tests, Ortho's instruments can process up to 150 tests per hour.

If an instrument is fully automated, it doesn't require a lab employee to perform each test by hand. Instead, each patient tube is loaded in bulk into the instrument, and the instrument automatically mixes the patient sample with test solutions. The ensuing chemical reaction provides the patient result. That result is automatically sent to the hospital's laboratory information systems and ultimately, the physician.

¹ System based on country availability

The VITROS Anti-SARS-CoV-2 Total and IgG tests have not been FDA cleared or approved. They have 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 VITROS Antibody tests have been authorized only for the detection of either Total or IgG antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis. These tests are 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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