

Ortho Clinical Diagnostics

Ortho Clinical Diagnostics and Quest Diagnostics to Broaden Availability of COVID-19 Antibody Testing

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Ortho Clinical Diagnostics, a global leader of in vitro diagnostics with a rich history of bringing critical tests for infectious diseases to market, today announced it is working with Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, to expand COVID-19 antibody testing to more than 20 Quest laboratories across the U.S.

Quest will use Ortho's VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 IgG Test (COVID-19 IgG antibody test) to test patients for detectable levels of SARS-CoV-2 antibodies, which are generated by the body in response to infection. Ortho's test, among only a small number in the world to be granted Emergency Use Authorization by the U.S. Food and Drug Administration, can be used as an aid in identifying patients with an immune response, indicating recent or prior infection, and may provide helpful information regarding decisions for getting people back to work. Individuals may have the virus for weeks after developing antibodies. The test offers 100% specificity, which helps prevent false positives.

"Together with Quest, Ortho Clinical Diagnostics is pleased to make available a high quality, large-scale COVID-19 testing solution to quickly reach millions of Americans," said Michael S. Iskra, president, North America Commercial Operations, Ortho Clinical Diagnostics. "100% specificity highlights the accuracy of Ortho's antibody test. In this widespread health crisis, Ortho strongly believes that every test is a life and is proud to join with Quest in the fight against coronavirus."

"Antibody testing can play an important role in helping individuals understand if they've been exposed to the virus that causes COVID-19 and may have mounted an immune response," said Jay G. Wohlgemuth, M.D., Senior Vice President and Chief Medical Officer for Quest Diagnostics. "Through our relationship with Ortho Clinical Diagnostics, we are broadening the range of high quality COVID-19 antibody test platforms we use in our laboratories to serve growing demand."

Quest offers two ways to access COVID-19 antibody testing. Healthcare providers can order testing on behalf of their patients, or individuals can initiate physician-directed testing online, without visiting a doctor's office, through QuestDirect.

Ortho currently offers two COVID-19 antibody tests. Ortho's total antibody test, granted Emergency Use Authorization on April 14, detects all COVID-19 related antibodies, including IgM, which appears in the early, acute stage of infection, and helps determine the onset of a patient's immune response by monitoring all antibodies generated through disease progression. Ortho's COVID-19 IgG test, granted Emergency Use Authorization on April 24, detects only the IgG antibody which appears in a patient's blood in the later phase of the infection and remains elevated even after recovery.

Both of Ortho's tests help health care professionals understand if a patient has been exposed to and has developed antibodies to the SARS-CoV-2 virus.

The tests run on Ortho's high-throughput, fully automated analyzers including its flagship 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. 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.

Ortho began shipping its antibody tests weeks ago to hotspot areas with highest priority and continues to ramp up its production. Ortho plans to manufacture several million COVID-19 IgG antibody tests each month for Quest Diagnostics and other laboratory providers.

Questions from laboratories, healthcare providers, or government officials regarding the COVID-19 antibody test can be directed to: OrthoCOVID19Test@orthoclinicaldiagnostics.com. For more information on Quest Diagnostics COVID-19 testing, visit: www.QuestDiagnostics.com.

Ortho's COVID-19 IgG 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. Patients should consult with their health care provider to discuss antibody testing and back-to-work options.

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.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics dedicated to improving and saving lives through innovative laboratory testing and blood-typing solutions.

Because Every Test is a Life™, we never stop innovating to offer streamlined, sustainable laboratory solutions that deliver fast, accurate, reliable test results that support exceptional patient care.

As a trusted partner of hospitals, hospital networks, blood banks, and labs around the world, we proudly serve the clinical laboratory and transfusion medicine communities with customized solutions that enhance clinical outcomes, improve lab performance, overcome staffing challenges and better manage costs.

We are powered by Ortho Care™, our global, award-winning, holistic approach to service, which supports customers with best-in-class technical support, award-winning field support, and remote service and inventory support.

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