Ortho Clinical Diagnostics

Ortho Launches Second COVID-19 Antibody Test With 100% Specificity

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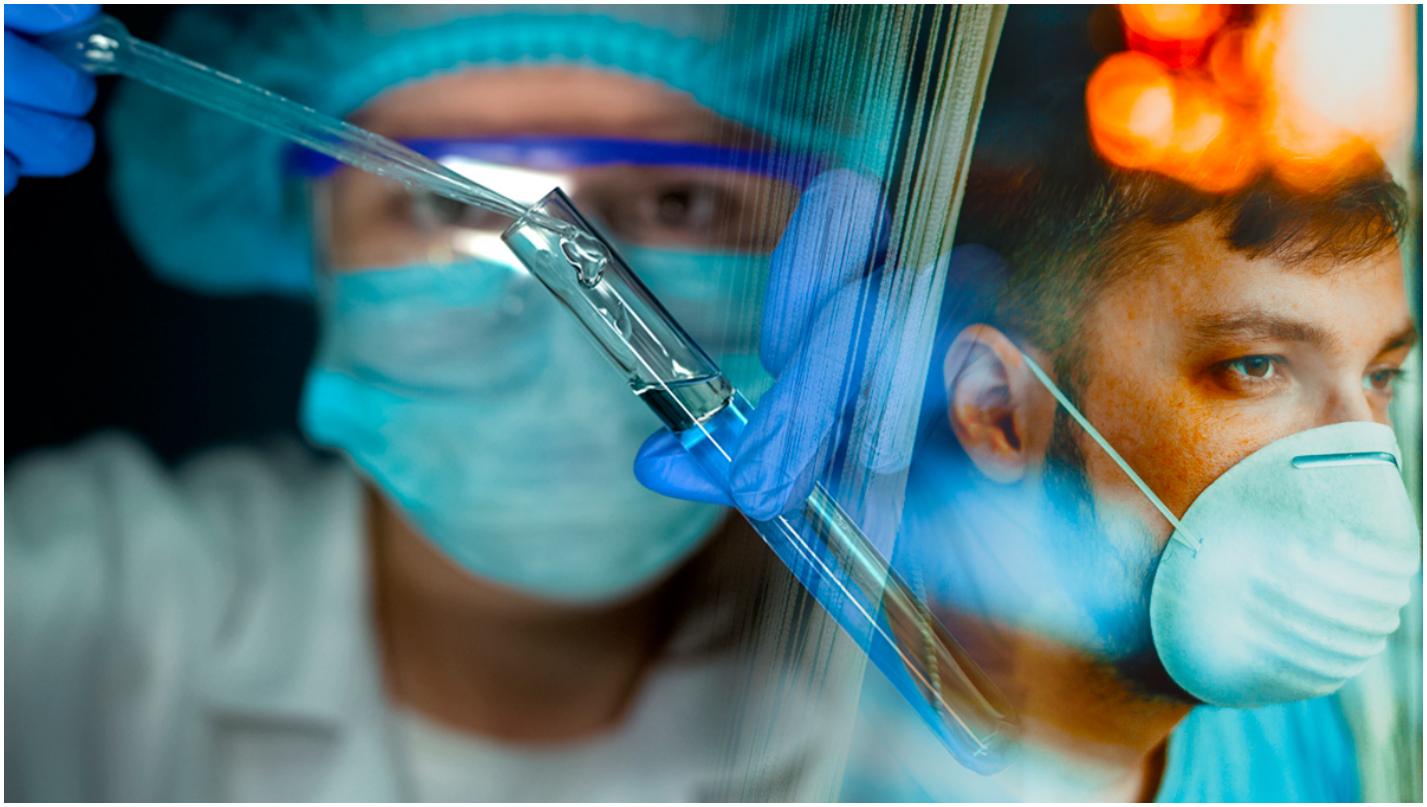

- Ortho announces FDA Emergency Use Authorization received for its second COVID-19 antibody test
- Similar to Ortho's total COVID-19 antibody test, Ortho's IgG test demonstrated **100% specificity** and can be used to support decisions for getting people back to work
- Ortho has already begun shipping its antibody test to customers in highly impacted geographies and plans to manufacture several million COVID-19 antibody test each month
- Both tests can run on Ortho's VITROS® platform already installed in more than 1,000 hospitals and labs across the U.S.

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics with a rich history of bringing critical tests for infectious diseases to market, today introduced and announced the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization to its second COVID-19 antibody test—the VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 IgG Test (COVID-19 IgG antibody test). This test is one of only a handful of antibody tests to be granted Emergency Use Authorization.

Ortho previously received FDA Emergency Use Authorization for its COVID-19 total antibody test on April 14, 2020. Of note, both tests have 100% specificity.

> ***"The observed 100% specificity with Ortho's VITROS SARS-CoV-2 tests allows an extremely high level of confidence so that people will not be identified as having an immune response to the virus when in fact they do not," said Christopher D. Hillyer, MD, President and CEO, New York Blood Center. "Statistically, the chance of error rises dramatically even with a very small decline from 100% in specificity, given our understanding of the prevalence of the COVID-19 virus today."***

"Ortho is proud that both of our COVID-19 total and IgG tests are achieving 100% specificity," said Chris Smith, Ortho Clinical Diagnostics' Chief Executive Officer. "During this health crisis, good is simply not good enough. This high level of specificity is a testament to Ortho's strong belief that every test is a life."

Ortho's total antibody test's launch to market in the U.S. was announced on April 3, 2020. It 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 newest test 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 COVID-19 virus.

> ***"COVID-19 is a novel virus and is being both researched and treated in real-time," said Michael P. Busch, M.D., Ph.D., director, Vitalant Research Institute. "One of the main areas of research is identifying the time and level certain antibodies appear in the blood, which can help confirm whether a patient has been infected and whether or not they have developed antibodies. Ortho's tests, which can detect both IgG and total antibodies, will help further our understanding of both infection and immunity to facilitate proper clinical guidance.""***

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.

"Both tests run on the widely used Ortho VITROS platform and the results will paint a vivid picture of a patient's immune response status," said Chockalingam Palaniappan, Ph.D., chief innovation officer, Ortho Clinical Diagnostics. "Clinicians will now have invaluable information that will allow them to make decisions about the propriety of a patient returning to work. This is critical information for first responders, health care professionals and other essential personnel working with affected populations."

Ortho plans to manufacture several million COVID-19 IgG antibody tests each month.

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

Press contact:
For media inquiries please contact

Ortho Media Relations
Ortho Clinical Diagnostics
media@orthoclinicaldiagnostics.com
(+1) 908 704 8256