Ortho Clinical Diagnostics

COVID-19 Total Antibody Test from Receives CE Mark

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- Ortho's COVID-19 total antibody test receives CE Mark
- Ortho's total antibody test may be used as aid in diagnosis and to support decisions for getting people back to work
- The test offers excellent performance, with 100 percent specificity and sensitivity
- Ortho began shipping its antibody test to customers in highly impacted geographies and plans to manufacture several million COVID-19 antibody tests each month
- Ortho has over 5,600 Immunodiagnostic systems installed around the world

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 its COVID-19 total antibody test received CE Mark. The test offers excellent performance, with 100 percent specificity and sensitivity.

Ortho's total antibody test detects all COVID-19 related antibodies (IgA, IgM and IgG), 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. It can help health care professionals understand if a patient has been exposed to and has developed antibodies to the SARS-CoV02 virus causing COVID-19.

The test runs 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 are self-contained and do not require an external water source to run, offering labs placement flexibility.

> ***"Ortho's test runs 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 may assist 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 total antibody tests each month in Rochester, New York and Pencoed, Wales.

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 total antibody test is 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.

Ortho launched the test to market in the U.S. on April 3, 2020. It received U.S. Food and Drug Administration (FDA) Emergency Use Authorization on April 14, 2020.

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 and 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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