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Ortho's VITROS® COVID-19 Antigen Test Capable of Accurate Mass-Scale Testing Achieves CE Mark

- Ortho's new SARS-CoV-2 antigen test offers 98.9% concordance to real-time PCR tests, making it a viable alternative suitable for mass-scale testing
- Ortho's new SARS-CoV-2 antigen test is the latest addition to the company's COVID-19 solutions, which include two CE Marked and FDA EUA COVID-19 antibody tests – Total and IgG

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, today announced that its new VITROS® SARS-CoV-2 Antigen test, designed to detect active SARS-CoV-2 infection, achieved CE Mark for distribution throughout the EU. The company also filed an Emergency Use Notification and submitted an Emergency Use Authorization (EUA) request to the U.S. Food and Drug Administration (FDA).

With 97.8% sensitivity and 99.2% specificity, Ortho's SARS-CoV-2 antigen test offers exceptional utility for mass-scale testing where appropriate. Ortho's test is a viable alternative to real-time polymerase chain reaction (PCR) testing for individuals with known or suspected exposure to SARS-CoV-2 or who are displaying symptoms suggestive of viral infection. Patients whose tests have a PCR cycle threshold (CT— a measure of viral load) of 35 or more carry little to no live virus. Compared to PCR, Ortho's test may be better able to identify individuals with COVID-19 who are infectious because it is offered with 100% sensitivity to less than 32 CT and 97.8% sensitivity to less than 34 CT.

"At Ortho, we never stop innovating. As COVID-19 cases continue to rise across the globe, the world is in urgent need of highly accurate tests that detect active infection and can be processed in high volumes," said Chris Smith, chairman and chief executive officer, Ortho Clinical Diagnostics. "Ortho continues to bring to market COVID-19 solutions that help labs and healthcare professionals identify, treat and ultimately contain this virus."

According to Smith, the VITROS SARS-CoV-2 Antigen test is the latest addition to Ortho's suite of COVID-19 testing solutions. Ortho also manufactures two COVID-19 antibody tests—Total and IgG—which were granted Emergency Use Authorization by the FDA in April and achieved CE Mark in May. Millions of COVID-19 tests per day can be processed through the more than 5,600 Ortho immunodiagnostic systems currently in operation worldwide.

The VITROS SARS-CoV-2 Antigen test also is the first test to run on Ortho's high-throughput, fully automated VITROS® platform from swabs rather than the blood and body fluid samples typically run by the systems. Samples for Ortho's SARS-CoV-2 antigen test can be collected in bulk, stored at room temperature for up to 24 hours or 48 hours if refrigerated, and contrary to PCR tests which can take hours to obtain results, run on Ortho's high-throughput VITROS® Systems, which are capable of processing up to 130 antigen samples/hour.

Ortho's SARS-CoV-2 antigen test runs on Ortho's VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System, and the VITROS® 5600 Integrated System. Ortho's VITROS Systems are self-contained and do not require an external water source to run.

Ortho manufactures its SARS-CoV-2 antigen test in Rochester, New York, and will soon scale up production in Pencoed, U.K. The test will be available worldwide in large volumes beginning in early November.

Questions from laboratories, health care providers, or government officials regarding Ortho's COVID-19 solutions can be directed to: OrthoCOVID19Test@orthoclinicaldiagnostics.com.

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The VITROS SARS-CoV-2 Antigen test has met the requirements for a diagnostic test cited in Section IV, Policy C in the following FDA Guidance: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff --Document issued on the web on May 11, 2020. The VITROS SARS-CoV-2 Antigen test has been validated but the FDA's independent review of the labeling and validation is pending.

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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