Ortho Clinical Diagnostics

Ortho's VITROS® SARS-CoV-2 Antigen Test for Accurate, Mass-Scale COVID-19 Testing is the First Widely-Available High-Volume Test to Receive FDA Emergency Use Authorization

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- Ortho's VITROS® SARS-CoV-2 Antigen Test is the first high-volume COVID-19 antigen test to receive Food and Drug Administration (FDA) Emergency Use Authorization (EUA).
- With utility for mass-scale testing and same-day results for labs, Ortho's latest COVID-19 solution can run up to 130 tests per hour.
- The test is run on Ortho's high-volume VITROS® Systems, which are installed in over 5,600 laboratories around the world with 1,500 installed in the U.S.

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, today announced that its VITROS® SARS-CoV-2 Antigen Test, designed to detect active infection, has become the first high-volume COVID-19 antigen test to receive Food and Drug Administration (FDA) Emergency Use Authorization (EUA). U.S. distribution of the test commenced in November 2020 under an FDA Emergency Use Notification (EUN); the test was also granted CE Mark in November 2020.

Ortho's antigen test comes at a critical time—a recentRockefeller Foundation report estimates that the U.S. will need to increase coronavirus testing capacity by nearly 10-fold -- from 21 million to 193 million tests per month -- in order to reopen schools safely and protect nursing homes.

With utility for mass-scale testing and same-day results for labs, Ortho's latest COVID-19 solution can run up to 130 tests per hour and immediately help hospitals and reference labs address testing backlogs, supply shortages, and delayed results.

> ***"As the pandemic continues to devastate our communities and economy, laboratory professionals have been working under extraordinary circumstances to deliver critical COVID-19 testing data to patients, clinicians and communities," said Chris Smith, chairman and chief executive officer, Ortho Clinical Diagnostics. "Even as vaccine inoculation programs roll out, mass-scale testing remains an essential tool in fighting COVID-19. Ortho's accurate, high-volume COVID-19 antigen test can play a pivotal role in the global response to this virus."***

About the VITROS® SARS-CoV-2 Antigen Test

The VITROS® SARS-CoV-2 Antigen Test produces accurate[i], clinically reliable results on Ortho's high-volume VITROS® Systems, which are installed in over 5,600 laboratories around the world. More than 1,500 VITROS analyzers are operational across the U.S. – including more than 500 located in rural regions, where coronavirus testing needs are especially urgent.

These analyzers normally run a broad menu of over 150 different tests from blood and body fluid samples, but now are also able to run samples derived from swabs. Additional analyzers are available for shipment and can be installed rapidly to further increase capacity since they don't require an external water source to operate.

Ortho's COVID-19 antigen test is an alternative to real-time polymerase chain reaction (PCR) testing, which although highly sensitive, can be expensive and require long processing times during testing surges. Roughly one-third of individuals who underwent a PCR test waited more than four days for a result —including 10% who waited more than 10 days, according to an article published by researchers from Harvard, Northeastern, Northwestern, and Rutgers.[ii]

Other COVID-19 diagnostic testing platforms, including rapid antigen tests, have limited capacity to run multiple tests simultaneously or require short time windows to read results, making it challenging to test more than a handful of patients at a time.

Ortho is currently able to deliver 5 million tests per month and can scale up to 15 million tests per month in February.

About Ortho's VITROS® COVID-19 Testing Solutions

Ortho's new SARS-CoV-2 Antigen Test is the latest addition to the company's COVID-19 solutions, which include two COVID-19 antibody tests — Total and IgG — both of which have FDA EUA and CE Mark.

Because Ortho's VITROS Systems are already installed worldwide, reporting times may be further improved because lab staff require no additional training, and the instruments are already connected to existing laboratory information systems and software. These systems are self-contained and do not require an external water source to run.

Questions from laboratories, health care providers, or government officials regarding Ortho's COVID-19 solutions can be directed to: OrthoCOVID19Test@orthoclinicaldiagnostics.com. For more information visit: https://www.orthoclinicaldiagnostics.com/global/covid19/.

This project has been funded with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response under Contract No. 75A50120P00103.

The VITROS SARS-CoV-2 Antigen 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 or high complexity tests. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.

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.

i Sensitivity: 80.0% (95% CI: 56.6–88.5%) Specificity: 100.0% (95% CI: 95.2–100.0%)

ii Lazer, David. The COVID-19 Consortium for Understanding the Public's Policy Preferences Across States. Northeastern University, Harvard University, Rutgers University, and Northwestern University.

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