Ortho Clinical Diagnostics

Ortho Announces Plans to Accelerate COVID-19 Antigen and Antibody Test Development Through New Contract with BARDA and the Department of Defense

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- The new contract will deliver Ortho with funding for capacity expansion to provide up to 6.7 million COVID-19 tests per month dedicated for the U.S. market over the next 12-14 months

RARITAN, N.J., March 31, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play IVD companies, today announced that through its continued partnership with the Biomedical Advanced Research and Development Authority (BARDA) and the U.S. Department of Defense, the company been awarded an undefinitized contract which will lead to a $53.7 million contract that will support a more than three-fold increase in domestic production capabilities for its COVID-19 serological and diagnostic testing solutions.

As part of BARDA's and the federal government's ongoing COVID-19 medical countermeasure development efforts, the new contract will deliver funding for capacity expansion to provide up to 6.7 million COVID-19 tests per month dedicated for the U.S. market by Q2 2022. The capacity expansion is designated for the company's VITROS® Systems and two COVID-19 antibody tests – Total and IgG – as well as for its VITROS® SARS-CoV-2 Antigen Test, the first high-volume antigen test to receive Food and Drug Administration (FDA) Emergency Use Authorization (EUA) in the United States.

"Ortho's ongoing partnership with BARDA and the Department of Defense to significantly expand our COVID-19 testing manufacturing capabilities underscores the continued and critical importance of bolstering the nation's testing infrastructure by leveraging highly accurate, automated and scalable diagnostic and serological tests that are FDA emergency use authorized," said Chris Smith, chairman and chief executive officer, Ortho Clinical Diagnostics. "Our high-volume testing solutions have already been an indispensable asset for hospitals, reference labs, and public health leaders across the country, particularly in rural and underserved communities. We look forward to expanding the availability of these testing solutions to communities in need."

About Ortho's VITROS® COVID-19 Testing Solutions

Authorized for use in the U.S. in January 2021, Ortho's VITROS® SARS-CoV-2 Antigen Test offers reliable detection of acute COVID-19 infection with high sensitivity and specificity. With utility for mass-scale testing and same-day results for labs, Ortho's antigen test can be processed at a rate of up to 130 tests per hour on a single analyzer, bolstering the ability of hospitals and reference labs to address testing backlogs, supply shortages, and delayed results that have undermined previous testing efforts. The VITROS® SARS-CoV-2 Antigen Test also offers a practical and cost-effective testing alternative to polymerase-chain reaction (PCR) tests, which, while highly accurate, can be expensive and require long processing times during testing surges.

Ortho's Total Antibody Test, designed to indicate recent or prior SARS-CoV-2 infection, detects all COVID-19 related antibodies (IgA, IgM and IgG). The company's COVID-19 IgG antibody test detects the IgG antibody, which appears in a patient's blood in the later phase of infection and remains elevated even after recovery. Offering high sensitivity and specificity, both the Total and IgG tests – which have FDA EUA and CE Mark – provide public health leaders with an exceptional tool in tracking viral community spread, bolstering serological surveillance efforts, and managing patient treatment pathways.

The tests – including Antigen, IgG, and Total – are processed on Ortho's trusted VITROS® system, which is already installed in more than 1,000 labs across all 50 states in the U.S. This includes more than 500 analyzers located in rural regions, where coronavirus testing needs are especially urgent.

This project has been funded with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, under Contract No. FA8726-21-C-0005.

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/.

The VITROS Anti-SARS-CoV-2 Total and IgG Antibody Tests and the VITROS SARS-CoV-2 Antigen Test have not been cleared or approved by the U.S Food and Drug Administration (FDA). They have been authorized by the FDA under an Emergency Use Authorization (EUA) 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. The VITROS antigen 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.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics (Nasdaq: OCDX) is one of the world's largest pure-play in vitro diagnostics (IVD) companies.

More than 800,000 patients across the world are impacted by Ortho's tests each day. *Because Every Test is a Life*™, Ortho provides hospitals, hospital networks, clinical laboratories and blood banks around the world with innovative technology and tools to ensure test results are fast, accurate, and reliable. Ortho's customized solutions enhance clinical outcomes, improve efficiency, overcome lab staffing challenges and reduce costs.

From launching the first product to determine Rh+ or Rh- blood type, developing the world's first tests for the detection of antibodies against HIV and hepatitis C, introducing patented dry-slide technology and marketing the first U.S. Food and Drug Administration-authorized high-volume antibody and antigen tests for COVID-19, Ortho has been a pioneering leader in the IVD space for over 80 years.

The Company is powered by Ortho Care™, an award-winning, holistic service and support program that ensures best-in-class technical, field and remote service to laboratories in more than 130 countries and territories around the globe.

For more information, visit Ortho's website or social media channels: LinkedIn, Twitter, Facebook and YouTube.

View original content:http://www.prnewswire.com/news-releases/ortho-announces-plans-to-accelerate-covid-19-antigen-and-antibody-test-development-through-new-contract-with-barda-and-the-department-of-defense-301260165.html

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