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FDA grants EUN to Ortho’s VITROS SARS-CoV-2 Antigen test

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Ortho Clinical Diagnostics, a global leader of in vitro diagnostics based in the US, announced that the US Food and Drug Administration (FDA) accepted the company's Emergency Use Notification (EUN) for the new VITROS® SARS-CoV-2 Antigen test, designed to detect active SARS-CoV-2 infection. On October 23, 2020, Ortho submitted an Emergency Use Authorisation (EUA) request to the FDA and achieved CE Mark, allowing test distribution throughout the European Union (EU).

With high sensitivity and 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. Compared to PCR, Ortho's test may be better able to identify individuals with COVID-19 who are infectious because the test is offered with 100 per cent sensitivity with samples with a CT count of less than 34.

"As COVID-19 cases continue to rise across the globe, Ortho is working to bring to market COVID-19 solutions that help labs meet an ever-growing testing demand and best serve their communities with high-quality, accurate, cost-effective tests that run at high volumes," said Chris Smith, Chairman, CEO, Ortho Clinical Diagnostics.

The VITROS SARS-CoV-2 Antigen test is also 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 per hour.

Ortho manufactures its SARS-CoV-2 antigen test in Rochester, New York, and will soon scale up production in Pencoed, UK. The test will be available worldwide in large volumes beginning in early November 2020.