Ortho's COVID-19 IgG antibody test receives CE mark

May 19, 2020—Ortho Clinical Diagnostics announced its second COVID-19 antibody test, the Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Test, received the CE mark. The test offers 100 percent specificity.

"The observed 100 percent specificity with Ortho's Vitros SARS-CoV-2 tests allows an extremely high level of confidence so that people will not be identified as having an immune response to the virus when in fact they do not," Christopher D. Hillyer, MD, president and CEO, New York Blood Center, said in a press statement from Ortho. "Statistically, the chance of error rises dramatically even with a very small decline from 100 percent in specificity, given our understanding of the prevalence of the COVID-19 virus today."

Ortho's COVID-19 IgG antibody test received emergency use authorization April 24. The test runs on Ortho's high-throughput, fully automated analyzers, including the Vitros XT 7600 integrated system, Vitros 3600 immunodiagnostic system, and Vitros 5600 integrated system, and will soon be available on Vitros ECi/ECiQ Immunodiagnostic systems.