FDA authorizes Ortho quantitative serology test

September 2021—The FDA issued an emergency use authorization to Ortho Clinical Diagnostics for its Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative test.

The test measures IgG antibodies to SARS-CoV-2 from a serum or plasma sample to aid in identifying people with an adaptive immune response to SARS-CoV-2 and is for use on samples from people that are 15 days or more post–symptom onset. Results are traceable to the certified reference material First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human), NIBSC code 20/136.

The test is performed using the Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack and Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator on the Vitros ECi/ECiQ/3600 immunodiagnostic systems and the Vitros 5600/XT 7600 integrated systems.

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