FDA authorizes first quantitative serology test

July 9, 2021—Today the FDA issued an emergency use authorization to Ortho Clinical Diagnostics for the 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 individuals 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.