Beckman launches fully quantitative COVID-19 IgG test

May 20, 2021—<u>Beckman Coulter</u> launched its Access SARS-CoV-2 IgG (1st IS), a fully quantitative lab-based immunoglobulin G serology test that measures the quantity of antibodies against the virus that causes COVID-19. The assay is traceable to the First WHO International Standard for anti-SARS-CoV-2, 20/136, and reports results aligned with BAU/mL established by the World Health Organization.

In a clinical study, the Access SARS-CoV-2 IgG (1st IS) test showed a clinical performance of 100 percent sensitivity and 99.8 percent specificity (exclusion of false-negatives and false-positives, respectively) in patients tested 15 days or more post-symptom onset.

The IgG (1st IS) test can be used in random access mode and integrated into existing workflows without batch processing. Results are delivered on the company's immunoassay analyzers, including its DxI 800 high-throughput analyzer, which is capable of processing up to 200 Access SARS-CoV-2 IgG (1st IS) samples per hour. The test is available to all customers in countries accepting the CE mark and to customers throughout the United States and Puerto Rico under FDA policy D.