Beckman’s Access SARS-CoV-2 IgG receives EUA

July 2, 2020—Beckman Coulter has received FDA emergency use authorization for its Access SARS-CoV-2 IgG assay.

The assay is a qualitative immunoassay that detects IgG antibodies directed to the receptor binding domain of the spike protein of the novel coronavirus. It uses immobilized virus antigens on magnetic particles to capture IgG antibodies from patient blood or serum samples. The test has a confirmed 100 percent positive percent agreement and 99.6 percent negative percent agreement and at 18 days post-PCR confirmed positive test. The assay can be used with a variety of Beckman Coulter analyzers, including the DxI 800, DxI 600, and DxCi and Access 2 analyzers, for large, mid-size, and small labs, respectively.

The company is able to deliver 30 million tests per month, and the test is available in all countries accepting FDA EUA and the CE mark.