

FDA authorizes POC antibody test for COVID-19

January 2021—The FDA issued an emergency use authorization for the first serology antibody point-of-care test for COVID-19. The Assure COVID-19 IgG/IgM Rapid Test Device (Azure Biotech) was first authorized in July for emergency use by certain labs to help identify individuals with antibodies to SARS-CoV-2. The EUA has been reissued to authorize the test for POC use using fingerstick blood samples. The lateral flow assay is authorized for use with venous whole blood, serum, plasma, and fingerstick whole blood.

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