COVID-19 Adaptive Immune Response

Qualitative detection of antibodies (IgG) specific to anti-SARS-CoV-2 spike protein S1 domain

COVID-19 Self-Collected Antibody Test System

Patient Information	
Patient Name	**Race/Ethnicity**
Date of Birth	**Phone#**
Gender	
Address	

Provider Information	
Provider Name	**Phone#**
Facility	**Order Date**
Address	

Sample Information		
Sample Type	Dried Blood Spot	**Received Date**
Collection Date		**Accession#**
Test Report Date		

Results

Anti-SARS-CoV-2 Spike Protein (S1) Antibody (IgG) NOT DETECTED

Reference Range: Not Detected; Anti-SARS-CoV-2 Spike Protein (S1) Antibody (IgG) Negative.

Comments: This test is intended as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2 (COVID-19), indicating recent or prior infection. The results of this qualitative test should not be interpreted as an indication of degree of immunity or protection from reinfection. Individuals who have been vaccinated with a SARS-CoV-2 spike or receptor-binding domain vaccine may be positive with this test; however, the clinical significance of a positive antibody result for individuals who have received a COVID-19 vaccine is unknown, in part because the test's performance characteristics have not been established for that population. It is not known how long antibodies persist following infection or vaccination and if the presence of antibodies confers protective immunity. This assay should not be used to diagnose acute SARS-CoV-2 infection.

A "Borderline" result finding means the test analysis was unable to produce a definitive positive or negative result finding for IgG Antibodies against the SARS-CoV-2 spike protein S1 receptor binding domain. For definitive analysis, we recommend re-collecting and re-testing in 7 to 14 days.

Indication: Qualitative detection of IgG antibodies to SARS-CoV-2 (spike protein S1 receptor binding domain) in human fingerstick blood dried blood spot (DBS) specimens that are self- collected at home by an individual age 18 years or older or collected by an adult from an individual 5 years of age and older using the COVID-19 Self-Collected Antibody Test System Collection Kit when determined to be appropriate by a healthcare provider. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. Testing is limited to Symbiotica, Inc., located at 1350 Burton Drive, Ste 210, Vacaville, CA 95687 which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meets requirements to perform high complexity tests (CLIA# 05D2181231).

- COVID-19 Self-Collected Antibody Test System EUA Summary: June 24, 2021: https://www.fda.gov/media/147368/download
- Fact Sheet for Healthcare Providers: https://www.fda.gov/media/147366/download
- Fact Sheet for Recipients: Syhttps://www.fda.gov/media/147367/download