COVID-19 Adaptive Immune Response

4U Health

Anti-SARS-CoV-2 (IgG) antibodies

COVID-19 Self-Collected Antibody Test System

Semi-quantitative detection of antibodies specific to SARS-CoV-2 spike protein (S1) domain with qualitative detection of antibodies specific to the SARS-CoV-2 nucleocapsid (N) protein

Accession#:

Report Date:

PATIENT INFORMATION	ORDER INFORMATION	SAMPLE INFORMATION
Name:	**Provider Name:**	**Sample Type:** Dried blood spot
Date of Birth:	**Facility:**	**Collection Date:**
Gender at Birth:	**Phone#:**	**Received Date:**

Phone#:
Address:

COVID-19 IgG Antibody Test Results

	Interpretation	*Value*
Anti-SARS-CoV-2 Spike Protein (S1)	**DETECTED**	**969.8** RU/mL
Anti-SARS-CoV-2 Nucleocapsid Protein (N)	**N/A**	

Reference Range: Not Detected

- Anti-SARS-CoV-2 Spike Protein (S1) Antibody (IgG) Negative and <8 RU/mL. (The upper detection limit of this assay is 120 RU/mL. Samples undergo a dilution to report out antibody levels up to 1200 RU/mL. Values >1200 RU/mL are reported as ">1200 RU/mL".)
- Anti-SARS-CoV-2 Nucleocapsid Antibody (IgG) Negative. (This is a qualitative test that provides a "DETECTED" or "NOT DETECTED" result. Nucleocapsid antibody results do not include an antibody value.)

Interpretation: A negative NOT DETECTED (S1) test result (< 8 RU/mL) means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. A positive DETECTED (S1) test result (>11 RU/mL) indicates that SARS-CoV-2 specific antibodies were present in the specimen above the limit of detection, suggestive of an adaptive immune response to the SARS-CoV-2 virus and/or vaccine, clinical correlation suggested. A BORDERLINE (S1) result finding (8 to 11 RU/mL) means the test analysis was unable to produce a definitive positive or negative result for IgG antibodies SARS-CoV-2. A negative NOT DETECTED (N) test result means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. A positive DETECTED (N) test result indicates that SARS-CoV-2 specific antibodies were present in the specimen above the limit of detection, suggestive of a recent or past COVID-19 infection. A BORDERLINE (N) result finding means the test analysis was unable to produce a definitive positive or negative result for IgG antibodies to SARS-CoV-2. An N/A (N) test result indicates that the sample was not interrogated for nucleocapsid antibodies, as it was not requested by the ordering provider. For definitive analysis, consider re-collecting and re-testing BORDERLINE samples in 7 to 14 days.

Comments: Current vaccines authorized in the U.S.A. aim to elicit antibodies specific to the SARS-CoV-2 spike protein. As such, the spike protein (S1) assay may detect antibodies induced by currently available SARS-CoV-2 vaccines, while the Nucleocapsid Protein (N) assay will not detect antibodies induced by the currently available SARS-CoV-2 vaccines. A NOT DETECTED result does not preclude COVID-19 infection and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.

Intended Use: 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. **This test is not intended to be used to diagnose an acute SARS-CoV-2 current infection**.

Test Limitations: Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target antibodies. The results of this 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 flag positive for the (S1) assay; however, the clinical significance of a positive antibody result for individuals who have received a COVID-19 vaccine is unknown. It is not known how long antibodies persist following infection or vaccination and if the presence of antibodies confers protective immunity. False negative results may occur for immune-compromised individuals or individuals who receive immunosuppressive therapy. The test results should be interpreted considering the total clinical presentation of the patient, including symptoms, clinical history, data from additional tests, and other appropriate information. (Full list of limitations can be found in the EUA Summary)

Test Method: Semi-quantitative detection of IgG antibodies to SARS-CoV-2 (spike protein S1 receptor binding domain) and qualitative detection of IgG antibodies to SARS-CoV-2 (nucleocapsid protein) 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.

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 Services (HHSs) 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 183 Butcher Rd, Ste C, 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: https://www.fda.gov/media/147367/download