US BioTek LABORATORIES

COVID-19 Vaccine Response Screen

Provider:	**Sex:**	**Collected:**
Patient:	**Sample Type:**	**Received:**
Date of Birth:	**Accession #:**	**Completed:**

S-RBD Total Antibodies	Result	Interpretation	Reference Range
SARS-CoV-2 Spike, Semi-Quantitative	> 250 U/mL	Positive	<0.80 U/mL

What Your Results Mean

Negative:

The S-RBD (SARS-CoV-2 spike protein receptor binding domain) total antibody assay is non-reactive (negative). Non-reactive S-RBD assays mean that the body's current production of S-RBD antibodies is inconsistent with active or recent infection or other COVID-19 S-RBD exposure (vaccination). Individual immune responses can vary, and some individuals can take longer than expected to mount an adequate antibody defense. Immunodeficient individuals may not mount a detectable response to COVID-19 virus exposure or vaccination.

Positive:

The S-RBD antibody assay is reactive (positive). S-RBD antibodies increase after exposure to the COVID-19 virus or after exposure to a vaccine containing S-RBD protein RNA.

About This Test

Elecsys Anti-SARS-CoV-2 spike (Roche) test has received FDA Emergency Use Authorization (EUA). This test is an electrochemiluminescence immunoassay intended for semi-quantitative detection of antibodies to SARS-CoV-2 in human serum and plasma respectively. This test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS CoV 2, indicating recent or prior infection, and to evaluate vaccine-induced immune response.

It has not been determined what quantity of antibodies to SARS-CoV-2 spike protein correlates to immunity against SARS-CoV-2. Studies are underway to determine the levels of specific SARS-CoV-2 antibodies following natural recovery or vaccination, which will provide valuable insights into the correlation between protection from vaccination and quantity of antibodies.

This test has not been FDA cleared or approved as IVD (In Vitro Diagnostic Medical Device). When there are no FDA-approved or cleared tests available, and other criteria are met, the FDA can make tests available under an emergency access mechanism called an EUA. The EUA for this test is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect, meaning this test can be used, for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by the FDA, after which the test may no longer be used.

The test performance has been validated by US BioTek Laboratories according to high-complexity testing under Clinical Laboratory Improvement Amendments (CLIA). US BioTek is required to report SARS-CoV-2 Antibody test results to appropriate public health authorities.

This assay has no biotin interference in serum concentrations up to 1200 ng/mL (300 mg single dose of biotin).

References: 1.Germain N, Herwegh S, Hatzfeld AS, Bocket L, Prévost B, Danzé PM, Marchetti P. Retrospective study of COVID-19 seroprevalence among tissue donors at the onset of the outbreak before implementation of strict lockdown measures in France. Cell Tissue Bank. 2021 Feb 1. doi: 10.1007/s10561-021-09901-3. 2.Guo CC, Mi JQ, Nie H. Seropositivity rate and diagnostic accuracy of serological tests in 2019-nCoV cases: a pooled analysis of individual studies. Eur Rev Med Pharmacol Sci. 2020 Oct;24(19):10208-10218. 3.Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus Res.2020;288:198114. doi:10.1016/j.virusres.2020.198114. 4.Long, QX., Liu, BZ., Deng, HJ. et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med. 2020;26:845–848. 5.Sampath Kumar NS, Chintagunta AD, Jeevan Kumar SP, Roy S, Kumar M. Immunotherapeutics for Covid-19 and post vaccination surveillance. 3 Biotech. 2020 Dec;10(12):527. doi: 10.1007/s13205-020-02522-9. 6.A Clinical Overview of Roche SARS-CoV-2 Antibody Tests: Elecsys AntiSARS-CoV-2 (qualitative) Assay Anti-SARS-CoV-2 S (semi-quantitative) Assay; Cobas, Roche. MC-US-08237-1220.

Tel:206-365-1256 | Fax:206-363-8790 | Director:Jillian Harrington, PhD, HCLD (ABB) | Address: 16020 Linden Ave North, Shoreline, WA 98133, USA
http://www.usbiotek.com CLIA : 50D0965661 CAP accredited