US BioTek LABORATORIES

COVID-19 Immune Response Panel

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

SARS-CoV-2 Total Antibodies	Result	Interpretation	Reference Range
SARS-CoV-2 Nucleocapsid (N), Qualitative	Positive	Positive	Negative
SARS-CoV-2 Spike (S-RBD), Semi-Quantitative	198.000 U/mL	Positive	< 0.80 U/mL

What Your Results Mean

The serum combined IgM/IgG test measures the body's response to COVID-19 spike protein receptor binding domain (S-RBD) and nucleocapsid (N) protein exposure. These tests do not differentiate between IgM and IgG; studies indicate that joint testing of both antibodies is as, or more, reliable than individual IgM and IgG testing in confirming COVID-19 exposure.

The combination assay of the N and S-RBD antibodies has a $>$ 99% positive and negative predictive value 15 days after COVID-19 exposure[6]. Immunodeficient individuals may not mount a detectable response to COVID-19 virus exposure or vaccination. Both the N and S-RBD assays may be negative if it is very early in the infection process, very late in the post-COVID-19 recovery period (months) or if the patient is immunosuppressed.

While rare, it is possible for a COVID-exposed individual to raise only N or S antibodies and not both. If an early or active COVID-19 infection is suspected, consider diagnostic RT-PCR testing for COVID-19 viral RNA.

Interpretation	N-Antibody IgM/IgG	S-RBD antibody IgM/IgG	
Negative	Negative	Negative	Consider COVID-19 RT-PCR if indicated.
Equivocal	Positive	Negative	Possible COVID-19 exposure. Consider COVID-19 RT-PCR if indicated.
Inoculation-responsive	Negative	Positive	Successful response to inoculation by either vaccine or COVID-19 virus. Consider COVID-19 RT-PCR if indicated.
Positive	Positive	Positive	Exposure to COVID-19 virus within the last 6 months.

If the interpretation is Negative, then exposure to either the COVID-19 virus or the COVID-19 vaccine is unlikely.

If the interpretation is Equivocal, then it is likely that an exposure to the COVID-19 virus is either ongoing or has occurred within the last 3-6 months.

If the interpretation is Inoculation-Responsive, then the patient is raising antibodies the S-RBD protein RNA from either a COVID-19 vaccination or an exposure to the COVID-19 virus.

If the interpretation is Positive, then the patient is raising antibodies to both the N and the S-RBD protein RNA, and an ongoing or recent COVID-19 virus exposure within the last 3-6 months has occurred. N-protein antibodies have not yet been associated with COVID-19 vaccination.

If an early or active COVID-19 infection is suspected, consider diagnostic RT-PCR testing for COVID-19 viral RNA.

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About this test

Elecsys Anti-SARS-CoV-2 nucleocapsid and spike (Roche) tests have received FDA Emergency Use Authorization (EUA). These tests are electrochemiluminescence immunoassays intended for qualitative and semi-quantitative detection of antibodies to SARS-CoV-2 in human serum and plasma respectively. These tests are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. In addition, Anti-SARS-CoV-2 spike test is used 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.

These tests have 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 these tests are 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 Anti-SARS-CoV-2 (qualitative) Assay Anti-SARS-CoV-2 S (semi-quantitative) Assay; Cobas, Roche. MC-US-08237-1220.