



The Diagnostic Specialist

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This document presents information regarding the use of the LIAISON[®] SARS-CoV-2 S1/S2 IgG test, in the context of the current COVID-19 pandemic.

For detailed technical information on this test, please refer to the Instruction for Use document available via DiaSorin's [Dialog documentation database](#).

All the information on this document is based on data from scientific publications available as of April 19th 2020. DiaSorin reserves the right to amend any information contained in this document, should new data become available which presents new relevant information.

FOR OUTSIDE THE US AND CANADA ONLY

[SARS-CoV-2 and COVID-19 background](#)

What is CoVID-19 and what are its symptoms?

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease was initially identified in December 2019 in Wuhan, Hubei province, China, and has since spread globally. [1] As of 19 April 2020, there are more than 2.3 million cases reported worldwide, resulting in more than 160,000 fatalities. [2]

Symptoms of COVID-19 vary in severity from no symptoms at all (being asymptomatic) to symptoms such as fever, cough, sore throat, loss of the sense of smell, general weakness and fatigue and muscular pain and in the most severe cases, severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock, all potentially leading to death. [3]

The SARS-CoV-2 Virus

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the pathogen responsible for COVID-19. It is a strain of severe acute respiratory syndrome-related coronavirus (SARSr-CoV) and has close genetic similarity to bat coronaviruses, suggesting it emerged from a bat-borne virus. [4]

The protein make-up of SARS-CoV-2

SARS-CoV-2 has four structural proteins, known as the S (spike), E (envelope), M (membrane), and N (nucleocapsid) proteins; the N protein holds the RNA genome, and



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the S, E, and M proteins together create the viral envelope. The spike protein, is the protein responsible for allowing the virus to attach to and fuse with the membrane of a host cell. [5]

[Immune response against SARS-CoV-2](#)

Timing of Immune response to SARS-CoV-2

Timing of seroconversion after exposure to SARS-CoV-2 provides key information to determine the time window in which serology tests can provide clinically useful information. A recent analysis of published literature [6] demonstrates that there is currently no definitive consensus on timing of seroconversion. Median seroconversion reported by different authors varies between 7 and 14 days after symptoms onset for IgG and 7 to 12 days for IgM.

Difference in IgG and IgM seroconversion

Seroconversion rates are an important aspect to determine usefulness of serology testing. A recent review [7] compares reported data on seroconversion for IgG and IgM antibodies for a number of authors. While positivity to IgG ranged between 95-100% for the majority of authors cited at day 14 post onset, positivity to IgM varied significantly more showing rates between 60% and 90%.

[Serology: use and limitations](#)

Does a positive result to a serology test mean that a patient is not infective anymore?

Recent publications [8] show that 50% of severe COVID-19 cases and 23% of mild cases were positive to viral RNA >20 days post onset. In the same study 100% of patients showed seroconversion to IgG by day 14. Since it is plausible for a patient to be positive to both viral RNA and IgG, a positive IgG result should not be interpreted as a sign that a patient has stopped being infective.



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Does a positive result to a serology test mean that a patient is protected from the disease?

Presence of antibodies against a pathogen, and particularly presence of neutralizing antibodies, is considered a sign of protection for many diseases. The effect of neutralizing antibodies must however be demonstrated for each disease, before any assumptions can be made both on their putative protective effect and its duration. Currently, no published data is available to determine if neutralizing IgG antibodies against SARS-CoV-2 protect patients against re-infection.

In consideration of the points above the results coming from any serology test against SARS-CoV-2 should not be used to presume protection against SARS-CoV-2 reinfection.

Does a negative result to the LIAISON[®] SARS-CoV-2 IgG test mean that a patient is not infective or has not been exposed to the SARS-CoV-2 virus?

Current data [6,7] shows that IgG antibodies appear in the majority of patients between 7-14 days after onset of symptoms, and in some limited cases could take longer. Due to the time needed for seroconversion, the test could provide a negative result in infected patients, if performed during the incubation period and in the early stages of infection. A negative result could also indicate the absence or a very low level of IgG antibodies against SARS-CoV-2.

As a consequence, negative serology results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

[LIAISON[®] SARS-CoV-2 S1/S2 IgG test: key facts](#)

Which SARS-CoV-2 antigens does the LIAISON[®] test use?

The LIAISON[®] SARS-CoV-2 tests uses magnetic beads coated with S1 & S2 Antigens. The antigens used in the tests are expressed in human cells to achieve proper folding, oligomer formation, and glycosylation, providing material similar to the native spikes. The S1 and S2 proteins are both targets to neutralizing antibodies. By using these antigens in our test, the likelihood of concordance to a neutralization assay is increased significantly.



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Does the test show cross reactivity to other strains of Coronavirus?

The test was evaluated and showed no cross-reactivity against HuCoV OC43, HuCoV HKU1 and a number of samples for HuCoV where the strain had not been further characterized.

Does the test show any Biotin interference?

Assessment of potential Biotin interference on the LIAISON[®] SARS-CoV-2 S1/S2 IgG test could not detect any interfering effect up to 3500 ng/ml.

Does the test provide data on Neutralizing antibodies?

The LIAISON[®] SARS-CoV-2 S1/S2 IgG test support the study of the immune status of infected patient by providing an indication of the presence of neutralizing IgG antibodies against SARS-CoV-2.

The test was evaluated for concordance with Plaque Reduction Neutralization Test (PRNT) by testing 304 samples collected during the outbreak from subjects whose PRNT result was available. 180 were PRNT negative and 124 were PRNT positive (i.e. titer above 1:40). Based on the evaluation the LIAISON[®] SARS-CoV-2 S1/S2 IgG test showed a 97.8% Negative agreement and 94.4% positive agreement with PRNT.

For full data on the concordance with PRNT, please consult the Instructions for Use.

As a Health Care Professional, can I purchase the LIAISON[®] SARS-CoV-2 S1/S2 IgG test?

Diagnostic laboratories interested in purchasing the LIAISON[®] SARS-CoV-2 S1/S2 IgG test should contact our local representative. For worldwide contacts, please [see here](#). Please note that the LIAISON[®] SARS-CoV-2 S1/S2 IgG test should be performed by trained Health Care Professionals, in the proper diagnostic laboratory environment, and exclusively on the LIAISON[®] XL analyser.

As a private citizen, can I purchase the LIAISON[®] SARS-CoV-2 S1/S2 IgG test?

The LIAISON[®] SARS-CoV-2 S1/S2 IgG test is not a test for home use, therefore it is not sold to the public. It should be performed by trained Health Care Professionals in the proper laboratory environment on the LIAISON[®] XL analyser.



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Can I send my samples to DiaSorin to be tested?

DiaSorin does not perform in-house testing of clinical samples, rather it supplies diagnostic laboratories with the tests and instruments required to analyse samples.

If you believe you may have contracted COVID-19 or if you suspect that you have been in contact with someone who has COVID-19, you should contact your local healthcare service for guidance.

References

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