The importance of KNOWING

SARS-CoV-2 antibody testing plays a critical role in the fight against COVID-19

SARS-CoV-2 antibody testing from Quest Diagnostics provides insights into a patient’s recent or prior infection, or immune response to a COVID-19 spike vaccine.

Insights when they are needed most

At Quest, we know that the accuracy and reliability of SARS-CoV-2 (COVID-19) antibody tests have been under scrutiny at a time when clarity and insights are needed most. Today, the FDA requires companies to submit Emergency Use Authorization (EUA) applications for all antibody tests. The following test systems that are used by Quest Diagnostics have been granted EUAs:

NEW! SARS-CoV-2 Antibody (IgG), Spike, Semi-Quantitative (test code 34499)

A semi-quantitative test that provides a numerical result with an index value of >1.00. This positive result can indicate a potential immune response to a recent or prior SARS-CoV-2 infection or SARS-CoV-2 spike mRNA vaccine.

- Estimated assay sensitivity is >99.9% for specimens collected at least 15 days post-symptom onset, based on positive percent agreement (PPA) of SARS-CoV-2 IgG serology results among SARS-CoV-2 RNA-positive patients.
- Estimated assay specificity is approximately 99.9% based on negative percent agreement (NPA) assessed by performing cross-reactivity studies utilizing serum specimens positive for antibodies to other respiratory viruses pre- and post-COVID-19 time periods.

SARS-CoV-2 Antibody (IgG), Nucleocapsid, Qualitative (test code 39749)

This test is used to detect IgG antibodies in serum (blood) samples and aids in identifying an immune response to recent or prior natural infection with SARS-CoV-2.

- Estimated assay sensitivity is >99.6% for specimens collected at least 15 days post-symptom onset, based on PPA of SARS-CoV-2 IgG serology results among SARS-CoV-2 RNA-positive patients.
- Estimated assay specificity is >99.9%, based on NPA assessed by performing cross-reactivity studies utilizing serum specimens positive for antibodies to other respiratory viruses pre- and post-COVID-19 time periods.

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Qualitative (test code 39504)

A qualitative test for SARS-CoV-2 IgG antibodies to spike protein.

- Estimated assay sensitivity is approximately 90.0% for specimens collected at least 15 days post-symptom onset, based on PPA of SARS-CoV-2 IgG serology results for specimens from patients positive for SARS-CoV-2 RNA.
- Estimated assay specificity is >99.9%, based on NPA assessed by performing cross-reactivity studies utilizing serum samples positive for antibodies to other respiratory viruses pre- and post-COVID-19 time periods.

SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), Qualitative (a component of the IgM/IgG panel [test code 31672])

This combined qualitative antibody (serum) panel detects IgG and IgM antibodies to SARS-CoV-2. Separate results are provided for IgG and IgM.

- Estimated assay sensitivity is 95% for specimens collected at least 15 days post-symptom onset, based on PPA of SARS-CoV-2 IgM serology results on patients who are SARS-CoV-2 RNA-positive.
- Estimated specificity is >99% based on NPA assessed by performing SARS-CoV-2 IgM tests on serum specimens positive for antibodies to other respiratory viruses pre- and post-COVID-19 time periods.

The antibody response to SARS-CoV-2 usually starts with IgM being detectable first, followed by the longer-lasting and more specific IgG. Data suggest that IgM antibodies can be detected within a few days and IgG antibodies will be detectable from 10 days after SARS-CoV-2 exposure or symptom onset.

Order antibody testing to help gain insight into an individual’s potential previous exposure to COVID-19 or call your sales representative for more information, 1.866.MYQUEST (1.866.697.8378)
Antibody testing can provide the following insight and guidance:

Helping people understand whether they have been previously infected
According to the CDC, SARS-CoV-2 (COVID-19) IgG antibody tests check for antibodies in the blood, which may indicate a past infection with the virus that causes COVID-19.10

Developing and maintaining ongoing care paths
With new evidence suggesting COVID-19 may be linked to potential long-term medical disorders, understanding an individual's status can assist in developing and maintaining ongoing care paths.11

Supporting complex diagnoses
Serologic testing should be offered as a method to help support a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.12

Physicians and public health experts have identified potential clinical applications for SARS-CoV-2 serology testing

Clinical assessment of individuals who present 9 - 14 days after illness onset
In conjunction with molecular testing per CDC guidelines12

Treating high-risk individuals
Treating individuals who are vulnerable and at higher risk of severe clinical outcomes from COVID-19 (e.g., patients with COPD or cardiovascular risks)13

Blood donors
Individuals whose blood contains antibodies may be eligible to serve as blood donors of convalescent plasma, which may provide an avenue for possible treatment for those who are hospitalized due to COVID-1914

Continuing to expand our clinical understanding of COVID-19
While antibody testing cannot stand on its own as the primary indicator of health status in response to COVID-19, it can be a valuable tool as part of a comprehensive response to the global pandemic.15,16

But, it is not yet known:
• How long antibodies persist after infection
• If the presence of antibodies affords immunity, how long immunity might last
• Whether the presence of antibodies provides full protection from reinfection

Antibody 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 or an immune response to a COVID-19 mRNA spike-targeted vaccine. Results are for the detection of SARS-CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARS-CoV-2 is necessary. The tests should not be used to diagnose acute SARS-CoV-2 infection. False-positive results for the test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. The sensitivity of the IgM test early after infection is unknown. Due to the risk of false-positive results, confirmation of positive results should be considered using a second, different IgM assay or an IgG assay. Samples should only be tested for IgM from individuals with 15 days to 30 days post–symptom onset. SARS-CoV-2 antibody negative samples collected 15 days or more post–symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG. The results of the semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from reinfection.

• These tests have not been FDA cleared or approved;
• These tests have been authorized by FDA under EUAs for use by authorized laboratories;
• These tests have been authorized only for the detection of IgG and IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
• These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

References

Test codes may vary by location. Please contact your local laboratory for more information.

Image content features a model and is intended for illustrative purposes only.

QuestDiagnostics.com
Quest, Quest Diagnostics, any associated logos, and all associated Quest Diagnostics registered or unregistered trademarks are the property of Quest Diagnostics. All third-party marks—® and TM—are the property of their respective owners. © 2021 Quest Diagnostics Incorporated. All rights reserved. SB9561 2/2021