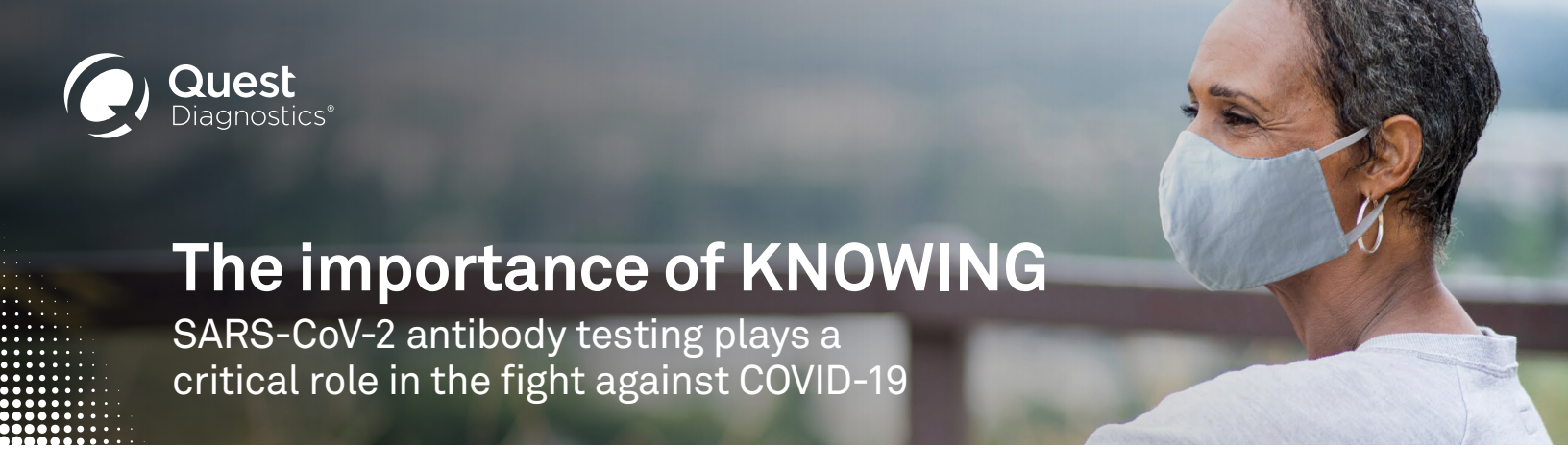

# The importance of KNOWING

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

### Insights when they are needed most

Antibody tests are intended for use as aids in identifying individuals with an adaptive immune response to SARS-CoV-2 (COVID-19). **The following test systems that are used by Quest Diagnostics have been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories:**[1-6]

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

A semi-quantitative spike antibody test can be useful in providing evidence of an immune response over time. This may be an especially valuable insight for individuals enrolled in ongoing clinical trials, and vulnerable patient populations.

The results of the semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from reinfection. Results obtained with this assay may not be used interchangeably with values obtained with different manufacturers' test methods.[7]

This test result is reported as positive at an index[2] of ≥1.00 which may indicate that an individual has developed an immune response to a SARS-CoV-2 infection.[2]

Conversely, a negative result is reported at an index[3] of <1.00 which indicates that the patient serum specimen had no SARS-CoV-2 spike IgG antibodies, or that the relative level of antibodies in the patient specimen was below the index cutoff.[2,3]

- Estimated assay sensitivity is >99.9% for specimens collected at least 15 days post–symptom onset,[4,5] based on positive percent agreement (PPA)[1] of SARS-CoV-2 IgG serology results among SARS-CoV-2 RNA–positive patients[4,5]
- Estimated assay specificity is approximately 99.9%[4,5] based on negative percent agreement (NPA)[2] assessed by performing cross-reactivity studies utilizing serum specimens positive for antibodies to other respiratory viruses pre– and post–COVID-19 time periods[4,5]

Quest also offers the **SARS-CoV-2 Total Antibody, Spike, Semi-Quantitative** test (test code 39820) performed on the Roche platform.

**SARS-CoV-2 Antibody (IgG), Nucleocapsid, Qualitative**
(a component of the IgG/IgM panel, test code 31672)
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,[2] based on positive percent agreement (PPA)[1] of SARS-CoV-2 IgG serology results among SARS-CoV-2 RNA–positive patients
- Estimated assay specificity[2] is >99.9%, based on negative percent agreement (NPA)[1] assessed by performing cross-reactivity studies utilizing serum specimens positive for antibodies to other respiratory viruses pre– and post–COVID-19 time periods[2]

**SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), Immunoassay** test code 31672

The results from this qualitative test for SARS-CoV-2 IgM can be positive (reactive) or negative (non-reactive).[3-8] Separate results are provided for IgG and IgM.

- Estimated assay sensitivity is 95% for specimens collected at least 15 days post–symptom onset,[3] based on PPA[1] of SARS-CoV-2 IgM serology results among SARS-CoV-2 RNA–positive patients[3]
- Estimated specificity[3] is >99%, based on NPA[1] 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[3]

The antibody response to SARS-CoV-2 usually starts with IgM being detectable first, followed by the longer-lasting and more specific IgG.[7] Data suggest that IgM antibodies can be detected within a few days post-infection and IgG antibodies will be detectable from some individuals by 10 days after COVID-19 symptom onset.[1-6]

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)**

# The value of antibody testing goes beyond any one individual patient

## Antibody testing can provide the following insight and guidance:

### Identify prior infections

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.[9]

### Develop and maintain ongoing care paths

With 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.[10]

### Support complex diagnoses

Serologic testing can help support a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.[7]

## 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 guidelines[7]

### Treating high-risk individuals

Treating individuals who are vulnerable and at higher risk of severe clinical outcomes from COVID-19 (eg, patients with COPD or cardiovascular risks)[11]

### 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-19[12]

## 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.[13,14]

**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

**Learn more** about how Quest is delivering the crucial insights you need

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. 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 antibody tests have not been FDA cleared or approved
- The antibody tests have been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories
- The antibody tests have been authorized only for detecting antibodies against SARS-CoV-2, not for any other viruses or pathogens
- The SARS-CoV-2 Total Antibody, Spike, Semi-Quantitative test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests
- The IgM serology test component has been authorized only for the detection of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens
- These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner


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

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