Provider FAQs for COVID-19 IgG Semi-Quantitative Testing

What is the order name for the new COVID-19 Serology (Antibody Testing)?

- COVID IgG Antibody, Spike-Quantitative Assay

Will the old COVID-19 Serology (Antibody Testing) be available?

- No, this will be the primary assay for IgG testing for COVID-19

Which Power Plans will include this test?

- COVID 19 Management
- COVID 19 Testing

Will this test be available to BMG providers and Outreach?

- Yes, it will available to BMG providers and Outreach similar to the previous COVID-19 Serology test.

What are the benefits of using the COVID-19 IgG Antibody, Spike-Quantitative Assay?

- The antigen target for this assay is the spike glycoprotein, whereas the previous IgG serology test targeted the nucleocapsid protein. This test allows detection of IgG antibodies in both patients with previous COVID-19 infection and those who have been vaccinated with any of the SARS-CoV-2 vaccines available in the US. In addition, this test will provide a positive or negative result like the previous test, but will also provide a specific numerical value.

What numerical results will be provided and what is the interpretation?

- The IgG antibody is measured in AU/mL or Arbitrary Units. The cutoff for a positive result is **50.0 AU/mL**. Any result that is measured below **50.0 AU/mL**, will be reported as "**Negative**" and any result between **50.0 to 25,000.0 AU/mL** will be reported as "**Positive**". If the result is above 25,000 AU/mL, this means it is beyond the measurement range of the instrument and will be reported as "**Positive, >25,000.0 AU/mL**".

Will a specific numerical value equate to immunity or protection from COVID-19?

- No, the numerical value (index) should not be interpreted as an indicator of the degree of immunity or protection from infection at this time. On-going studies by the NIH, CDC, etc may show a specific value that relates to immunity in the future (similar to other serology tests).

Can this test be used to diagnose COVID-19?

- No, definitive diagnosis of COVID-19 is made by detection of SARS CoV-2 RNA by molecular or antigen testing methods. There are no FDA-approved serological tests that have been validated to diagnosis a COVID-19 infection.

If COVID-19 IgG is not used for diagnosis, what is the purpose?

- The primary purpose of COVID-19 IgG is to identify exposure to SARS-CoV-2 through natural infection as well as identification of a positive antibody response through vaccination. It will also help the medical community identify the immune response of COVID-19 over time with proper clinical follow-up. It may also be used to screen possible convalescent plasma donors and for epidemiology studies in the community.

Can a positive antibody test exclude the possibility of transmission by an asymptomatic individual?

- No, a positive IgG cannot exclude the possibility of transmission. Antibodies develop after about 10 days of infection. It is not definitively known for how long asymptomatic individuals are infectious although they can shed virus for longer than 10 days. If there is concern for an active infection, a COVID PCR test should be done.

Can a positive antibody test be used for return to work?

- It is premature to use this test result for this purpose as there is no assurance of immunity or recovery from active infection (both symptomatic and asymptomatic).

What are the analytical performance characteristics of this assay?

- According to the product insert and internal validation studies at BayCare Laboratories, the negative percent agreement (specificity) and positive percent agreement (sensitivity) is >99%. We were able to validate these claims at BayCare using known PCR+ samples and known negative samples from the pre-COVID pandemic.

What is the suggested timing for this test?

- At least 21 days since the onset of symptoms, combined with a clinical assessment of recovery.

What is the turn-around-time once the sample reaches the lab?

- Results return within approximately 24 hours.

What is the CPT Code?

- CPT 86769

What ICD-10 codes could be used? Please see below for two common suggestions:

- U07.1 - Antibody testing for patients with history of confirmed COVID-19
- Z11.59 - Antibody testing to screen for COVID-19

Is there cross-reactivity with other coronaviruses?

- Initial validation studies for the IgG antibody at BayCare Laboratories shows excellent specificity, however this has not been clearly established in clinical studies or formally validated by the FDA. Clinicians should interpret these results in the appropriate clinical context. Cross-reactivity may be seen due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Is this test reliable?

- This test was properly validated by the BayCare Laboratory and approved by the Laboratory Medical Directors; the test shows excellent analytical performance characteristics. This performance is similar to many other serological tests and will be run in a high-complexity laboratory. However, all current COVID-19 tests have not gone through formal clinical trials and were granted Emergency Use Authorization (EUA) by the FDA in response to this global pandemic, therefore clinical sensitivity and specificity have not been evaluated on any of these tests.

Will the IgM test for COVID-19 still be available?

- Yes, there will be no changes to the currently available IgM test.

What is the interpretative comment for these test results in Power Chart?

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, OR 229E.
- Not for screening of donated blood.
- **Comment**: This test is for the semi-quantitative detection of IgG antibodies against the spike glycoprotein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19. A positive result indicates prior infection and/or vaccination. While the numerical value (index) corresponds to the relative amount of IgG antibodies detected, a positive result nor the index should be interpreted as an indicator of the degree of immunity or protection from infection. A negative result indicates SARS-CoV-2 IgG antibodies were not detected but does not exclude a recent or prior infection. This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under CLIA.

What are potential uses of antibody testing in the future?

- Risk stratification of Health Care Workers in terms of exposure
- Retrospective diagnosis when patients present late and did not have access to PCR testing when infected
- Contribute to an understanding of the clinical course and immune response when an individual's PCR test results are inconsistent with clinical picture
- Help determine between a primary infection and a reinfection (in the event of the occurrence of reinfections)
- Determine immune response (seroconversion) in immunocompromised patients
- Determine immune response to vaccination based on on-going studies.

For what purposes should antibody testing NOT be used at this time?

- To diagnose or rule out an active COVID infection
- To assume immunity from COVID-19 infection based on a positive test result