BioReference LABORATORIES an OPKO Health Company

COVID-19

Information for Healthcare Providers: Antibody Testing

The novel coronavirus disease (COVID-19) is a new virus of global health significance caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. At BioReference, our priority remains in the health and safety of the physicians, patients and communities we serve, and we are doing our part to deliver answers during these uncertain times.

ANTIBODY TESTING FOR COVID-19

BioReference offers an immunoassay which measures SARS-CoV-2 specific antibodies, correlating with the patient's adaptive immune response after COVID-19 infection. Antibodies are expected to be detectable in the majority of patients by 14 days after the onset of symptoms, and are presumed to remain elevated for some time after recovery.

This test plays a critical role in the fight against COVID-19 by assessing the antibody response in individuals and populations. It identifies patients who have been exposed to COVID-19 in the past, allowing for detection after the infection has resolved. This is especially important for asymptomatic or mildly symptomatic COVID-19 patients, who may not have been diagnosed with molecular testing. It can also help providers and health authorities understand the prevalence of COVID-19 in their area, and the change in prevalence over time.

For many pathogens, testing positive for antibodies after infection usually indicates some level of immunity from re-infection. However, whether antibodies to COVID-19 indicate a lower risk of infection is still unclear, and ongoing studies will further detail COVID-19 specific immunity.

COVID-19 ANTIBODY TECHNOLOGY

BioReference offers an immunoassay for antibody testing with high sensitivity and specificity. Each COVID-19 antibody test is performed utilizing the Roche Elecsys Anti-Sars CoV-2 assay or the DiaSorin Liaison Sars CoV-2 S1/S2 assay. The performance of these high-volume instruments were tested against large sets of positive and negative clinical samples by the manufacturers. The data showing high sensitivity and specificity were submitted to the FDA, and both platforms have a FDA Emergency Use Authorization (EUA).

UTILIZATION OF SEROLOGY AND MOLECULAR TESTING

- Many patients with COVID-19 will be asymptomatic or have mild symptoms, and will not have been diagnosed with PCR. Antibody testing can be used to identify these past infections.
- Patients with symptoms who test negative with molecular tests may still be suspected of having COVID-19. If antibodies are detectable in these patients, they are likely to have been infected and had a false negative PCR result.

IMPORTANT NOTES

- BioReference uses antibody tests with demonstrated high accuracy and lack of cross reactivity with other common coronaviruses.
- Antibody testing should not be used alone to diagnose acute COVID-19 infections, and antibodies are unlikely to be detected in the first few days of infection.
- COVID-19 patients with detectable antibody levels may still be infectious during the acute phase of infection.

Antibody testing for COVID-19 is an integral part of the public health response when assessing individual and population exposure to the virus. This is especially important for healthcare and other essential workers, and informs decisions about easing social distancing in the general population.

BLOOD COLLECTION

Blood specimen collection for antibody testing is available at select BioReference Patient Service Center locations within AZ, CA, FL, IN, MA, MD, NJ, NY, TX and VA. Please visit individual PSC location listings on our website to confirm if serology blood specimens will be collected. Blood specimen can also be collected at physician offices, hospitals or other clinic settings. Please remember that a patient cannot order their own tests, and a doctor's requisition or lab script is required for all testing.

CDC GUIDELINES

Healthcare providers should notify their local or state health department immediately in the event of a patient under investigation for COVID-19. Please refer to the most current CDC guidelines for further information. **www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html**

TEST DETAILS

	Test Information
Test/Name	**TH99 - COVID-19 Antibody**
Sample Type	Serum
Primary Container	SST
Minimum Volume	2 mL Serum
Alternate Container	Unspun SST Aliquot Serum, Red Top (ALQRD) or Aliquot Tube-Serum (ALQS)
Turn Around Time*	3 Days
Transportation Temperature	Room Temperature or Refrigerate (2-8°C)
Stability	3 Days Room Temperature or Refrigerated, 30 Days Frozen
Methodology	Chemiluminescence
Reference Range	Detected
Test Results	Detected Not Detected
Collection Instructions	Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes. Place in specimen bag and label with "COVID-19 ANTIBODY" and submit to laboratory. Unspun specimen will also be accepted. Please Note: COVID-19 antibody tests must be collected in a separate SST tube, and the specimen bag should be labeled with "COVID-19 ANTIBODY". Testing cannot be combined with other tests, and add-ons will not be accepted.
Collection Note	Patients under investigation of COVID-19 and seeking evaluation of the disease will not be collected at BioReference Patient Service Centers. Specimen should be collected at physician offices, hospitals or other clinic settings.
Price	Patient Self-Pay $55
CPT**	86769
Clinical Utility	To measure IgG seroconversion after an infection with COVID-19

** TAT is based upon receipt of the specimen at the laboratory.*

*** CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*

SOURCES

US Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Last Accessed May 15, 2020. www.cdc.gov/coronavirus/2019-ncov/index.html

US Food and Drug Administration (FDA). Coronavirus (COVID-19) Update: Serological Tests. Last Accessed May 15, 2020. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests

Diazyme. DZ-Lite SARS CoV-2 IgM and IgG CLIA Kits Frequently Asked Questions (FAQs). Last Accessed May 15, 2020. www.diazyme.com/dz-lite-sars-cov-2

FOR MORE INFORMATION PLEASE VISIT

www.bioreference.com/coronavirus/

OR CALL 833-684-0508

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