BioReference LABORATORIES an OPKO Health Company

COVID-19
Information for Patients: Antibody Testing

The novel coronavirus disease (COVID-19) is a new virus of global health significance caused by infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.

WHAT ARE ANTIBODY TESTS

Antibodies are proteins produced by the body's immune system to try to fight infection. The antibody test offered by BioReference measures IgG. This type of antibody can usually be detected several weeks after an infection starts, and remains elevated for a significant period of time after.

Antibody tests offered by BioReference are performed on high-volume instruments, have been verified for sensitivity and specificity. They have been reviewed by appropriate state Departments of Health, and registered with the FDA.

WHY IS COVID-19 ANTIBODY TESTING IMPORTANT?

Antibody results plays a critical role in the fight against COVID-19, by helping healthcare professionals and public health authorities assess the immune response in populations and individuals. Many COVID-19 patients have mild or no symptoms, and may not have been diagnosed when infected.

Antibody testing can provide information about who has been infected, and who may potentially be immune from re-infection. Antibody blood testing from BioReference can help healthcare professionals in making decisions about people returning to work, and easing social distancing measures and shelter-in-place measures.

HOW IS A SAMPLE COLLECTED?

Antibody testing is completed with a blood sample. Patients under investigation of COVID-19 and seeking evaluation of the disease will not be collected at BioReference Patient Service Centers, and blood specimen will need to be collected at physician offices, hospitals or other clinic settings.

Please note that patients cannot order their own tests, and a doctor's requisition or lab script is required for all testing.

WHAT DO MY RESULTS MEAN?

Testing positive for COVID-19 antibodies provides likely evidence of previous infection with the COVID-19 virus. It may also mean that a patient has immunity to re-infection, based on information about other infections. Studies looking specifically at COVID-19 are ongoing, and will provide more data on how immunity works for this virus.

If you suspect that you have COVID-19 and are seeking evaluation of the disease, please contact your healthcare provider and local or state health department immediately.

FDA POLICY

This test is provided pursuant to the US Food and Drug Administration (FDA) guidance that immunoassays for COVID-19 are less complex than molecular assays, and therefore notification is sufficient to allow use by a high complexity laboratory. The following applies from the FDA's "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" issued on March 16, 2020:

- This test has not been reviewed by the FDA.
- 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.

RESOURCES

US Centers for Disease Control and Prevention (CDC)
www.cdc.gov/coronavirus/2019-ncov/index.html

World Health Organization (WHO)
www.who.int/emergencies/diseases/novelcoronavirus-

FOR MORE INFORMATION PLEASE VISIT
www.bioreference.com/coronavirus/
OR CALL 833-684-0508

BioReference LABORATORIES
an OPKO Health Company

481 Edward H. Ross Drive, Elmwood Park, NJ 07407 ▪ **T** 1 800 229 5227 ▪ **F** 1 201 345 7048 ▪ www.BioReference.com