

# COVID-19

## Information for Healthcare Providers: Antibody Testing

Antibody testing plays a critical role in the fight against COVID-19 by assessing the antibody response in individuals and populations. Testing identifies patients who have been successfully vaccinated or have been previously exposed to COVID-19 in the past.

### ANTIBODY TESTING FOR COVID-19

BioReference offers immunoassays which measures SARS-CoV-2 specific antibodies, correlating with the patient's adaptive immune response after COVID-19 infection or successful COVID-19 vaccination. Most patients will have detectable antibody levels by 14 days after vaccination or onset of symptoms and levels are presumed to remain elevated for some time. At this time, it is not known how long antibodies will persist following vaccination or infection.

### AVAILABLE TEST

- BioReference offers Roche Elecsys Anti-SARS-CoV-2 S immunoassay technology (Test Code M160). This test can measure the quantity of antibodies to the receptor-binding domain (RBD) of the spike protein of the SARS-CoV2 virus, which is the causative agent of COVID-19. The RBD-spike protein complex is the part of the virus that binds to human cells, which is required for the virus to enter the host cells and replicate.

### TEST BENEFITS

- This test can play an important part in characterizing a vaccine-induced immune response. Many current candidate vaccines aim to induce an antibody response against the SARS-CoV-2 spike protein. Tests that quantify antibodies to the spike protein could be used to measure the level of that response and track that measurement over time.
- This test can help in the determination of seroprevalence (i.e. the frequency of individuals with antibody to the virus), in a given population. Knowing a given population's seroprevalence is important in understanding how to contain the spread of the virus, as well as how to safely ease lockdown restrictions.
- This test can complement diagnostic tests of SARS-CoV-2 infection. Many patients with COVID-19 will be asymptomatic or have mild symptoms, and may not have been diagnosed with PCR. Antibody testing can be used to identify these past infections.

### RESULTS

Qualitative results are provided as Detected (Positive) or Not Detected (Negative), and semi-quantitative results are provided as a numerical value ranging from 0.80 to 2,500 U/mL.

### SENSITIVITY AND SPECIFICITY

The test has both a high clinical specificity of 99.98% (N=5991) and sensitivity of 98.8% (N=1423), 14 days or later after diagnosis with PCR. Additionally, across panels of potentially cross-reactive samples (N=1100) from endemic human coronaviruses, infectious respiratory diseases, other infectious diseases, auto-immune and liver related diseases, the test demonstrated zero cross-reactivity.

### BLOOD COLLECTION

Antibody testing is completed with a blood specimen. Blood specimen collection for antibody testing is available at all BioReference Patient Service Centers. Please remember that a patient cannot order their own tests, and a healthcare provider's requisition or laboratory script is required for 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](http://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html)

This test has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

*Antibody tests can help healthcare providers assess individual and population exposure to the virus, as well as measuring a person's vaccine-induced immune response. This is especially important as decisions continue to be made about how society moves forward amid the pandemic.*

## TEST INFORMATION

	Test Information
<b>Name/Code</b>	M160 – COVID-19 Antibody, Qual/Quant
<b>Sample Type</b>	Serum
<b>Primary Container</b>	SST
<b>Minimum Volume</b>	2 mL Serum
<b>Alternate Container</b>	Unspun SST Aliquot Serum, Red Top (ALQRD) or Aliquot Tube-Serum (ALQS)
<b>Turn Around Time*</b>	3 Days
<b>Transportation Temperature</b>	Room Temperature or Refrigerate (2-8°C)
<b>Stability</b>	7 Days Room Temperature or Refrigerated
<b>Methodology</b>	Chemiluminescence
<b>Reference Range</b>	Detected
<b>Test Results</b>	Qualitative results are provided as Detected (Positive) or Not Detected (Negative), and semi-quantitative results are provided as a numerical value ranging from 0.80 to 2,500 U/mL.
<b>Collection Instructions</b>	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 submit to laboratory.
<b>Collection Note</b>	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.
<b>Price</b>	Patient Self-Pay \$55
<b>CPT**</b>	86769
<b>Clinical Utility</b>	To assess for antibodies to the Covid-19 spike protein complex, which should be occur after infection and/or immunization

\* 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 February 17, 2020. [www.cdc.gov/coronavirus/2019-ncov/index.html](http://www.cdc.gov/coronavirus/2019-ncov/index.html)

Zhu FC et al. (2020). Immunogenicity and safety of a recombinant adenovirus type-5-vectored COVID-19 vaccine in healthy adults aged 18 years or older: a randomised, double-blind, placebo-controlled, phase 2 trial. *The Lancet* 396:479 - 4882

Masters PS (2006). The molecular biology of coronaviruses. *Advances in Virus Research*. Academic Press. 66: 193–292; (2) Hoffmann, Markus et al. (2020). *Cell*. 81(2):271-280.e8;

Full specifications of the Roche immunoassay systems can be found on the Roche website <https://diagnostics.roche.com/us/en/products/params/electsys-anti-sars-cov-2-s.html>

**FOR MORE INFORMATION PLEASE VISIT**

**[www.bioreference.com/coronavirus/](http://www.bioreference.com/coronavirus/)**

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