

# Client Update

APRIL 2021

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Test Name	Test Code	Effective Date
COVID-19 Antibody, Qual/Quant	M160	March 29, 2021

BioReference is pleased to announce the availability the **Roche Elecsys Anti-SARS-CoV-2 S immunoassay (Test Code M160)**. This test can measure the quantity of antibodies to the receptor-binding domain (RBD) of the spike (S) 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. This test includes the qualitative and quantitative values and provides evidence of immunity based on either previous infection or successful vaccination\*.

**Please note:** The new test (M160) eliminates the need to order the existing qualitative test (TH99). M160 and TH99 should not be ordered together in any combination. If M160 and TH99 are ordered on the same accession, the laboratory will block TH99 and only M160 will be performed.

*\*Detection of COVID-19 antibodies targeting the N protein are indications of an actual infection since the coronavirus must first enter the host cells before the N protein is detected and the body's immune response reacts. Measuring antibodies to spike protein allows the assay to indicate immunity based on the administration of an mRNA vaccine OR from a primary exposure to virus.*

Please see below for full test details.

Test Information	
Test Name/Codes	M160 – COVID-19 Antibody, Qual/Quant
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	7 Days Room Temperature or Refrigerated
Methodology	Chemiluminescence
Reference Range	Detected
Test 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.
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 submit to laboratory.
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 assess for antibodies to the Covid-19 spike protein complex, which should be occur after infection and/or immunization.

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Test Name	Test Code	Effective Date
21st Century Cures Act	N/A	May 1
<p>As of April 5, 2021, the Information Blocking (IB) provisions 45 CFR Part 170 and 171 of the 21st Century Cures Act restricts healthcare providers, including laboratories, from exercising any form of IB, which is the practice of interfering with access, exchange or use of electronic health information (EHI). This includes the ability to intentionally delay the release of test results to patients (unless the delay meets the conditions of one or more exceptions.)</p> <p>Therefore, effective May 1, BioReference Laboratories, Inc. and its subsidiaries and divisions (collectively BioReference) will not delay test results from being released to patients, including results for clinical and pathology test results, unless a request to delay test results falls within one of the narrow exceptions. All test results will be released to the patient in the BioReference Patient Portal at or about the same time the results are released to the ordering provider via InsightDx, EMR or other delivery method. Only patients with a BioReference Patient Portal account will automatically receive electronic test results. Patients without a BioReference Patient Portal account can sign up at <a href="https://www.bioreference.com/patient-portal">https://www.bioreference.com/patient-portal</a> or request their test results via phone or secure email through our Patient Portal support group, which can be reached at (888) 279-0967 or <a href="mailto:Patientportal@bioreference.com">Patientportal@bioreference.com</a></p> <p>For more information about the 21st Century Cures Act and IB, please visit <a href="http://bit.ly/CuresIB">http://bit.ly/CuresIB</a>, and for more information about IB exceptions, please visit <a href="http://bit.ly/IBexceptions">http://bit.ly/IBexceptions</a>.</p>		

**\*\* 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.**