



Client Update

MAY 2020 – COVID-19

Test Name	Test Code	Effective Date
COVID-19 Antibody	TH99-5	May 13

As announced Monday, April 27, BioReference now offers the **COVID-19 Antibody Test**, which utilizes a blood sample to measure SARS-CoV-2 specific antibody levels, which correlate with a patient’s immune response after COVID-19 infection. As always, we thank you for your patience during this unprecedented time as we work expeditiously to offer tests that yield high quality and accurate results.

We continue to add additional instruments as we increase capacity, and as platforms continue to be reviewed by the FDA. Each COVID-19 antibody test is now 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).

With this enhancement, test changes have been made, including the ability to accept specimen at ambient temperature. Results from these platforms are qualitative. Please refer to the table below for changes.

In addition, a new kit has been created for the COVID-19 Antibody Test. Clients may obtain this kit by ordering supply speed number #529. Please use the standard supply order form and fax it to 201-345-7048 or email CustomerService@bioreference.com. Orders can also be placed through your dedicated account executive.

	Previously Provided Test Information	New Test Information
Test Name	COVID-19 IgG Antibody	COVID-19 Antibody
Transportation Temperature	Refrigerated	Room Temperature or Refrigerated
Stability	3 Days Refrigerated, 30 Days Frozen	3 Days Room Temperature or Refrigerated, 30 Days Frozen
Reference Range	> 1.10 AU/mL or >14.9 AU/mL	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. 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.	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. 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.
Test Results	< 0.90 AU/mL Negative 0.90-1.10 AU/mL Equivocal > 1.10 AU/mL Positive or <15.0 AU/mL Negative > or=15.0 AU/mL Positive	Detected Not Detected