



May 1, 2020

**RE: Coronavirus COVID-19 SARS-CoV-2 Antibody testing**

**Background:**

The CCL COVID 19 IgM/IgG Duo test is a chromatographic immunoassay for the detection of IgM and IgG specific antibodies to SARS-CoV-2 present in human serum. It is an aid in the convalescent phase of the COVID 19 infection, as the patient first produces IgM immunity around 7 - 10 days after COVID 19 exposure, followed by more long-term IgG immunity. The antibody test option provides insight into an individual's immune response and recent exposure to the SARS-CoV-2 virus however **is NOT intended for diagnosis of active infection.**

Test Name	COVID-19 SARS-CoV-2 AB IgG	COVID-19 SARS-CoV-2 AB IgM	2019 Novel Coronavirus (COVID-19), NAA
<b>Available:</b>	05/04/2020	05/04/2020	04/01/2020
<b>Specimen:</b>	Red top tube (no gel barrier)	Red top tube (no gel barrier)	Oropharyngeal (OP) in viral transport medium Nasopharyngeal (NP) in viral transport medium
<b>Method:</b>	Immunoassay	Immunoassay	RT-PCR
<b>Reference Ranges:</b>	Negative	Negative	Not Detected
<b>Setup:</b>	7 Days a week	7 Days a week	Monday – Friday
<b>Reports:</b>	1-3 Days	1-3 Days	3-4 Days
<b>Price:</b>	Direct Pay: \$50.00*	Direct Pay: \$50.00*	Direct Pay: \$150.00*
<b>Comments:</b>	This test is a qualitative immunoassay used for the detection of SARS-CoV-2 (COVID-19) IgG. The test was validated by Central Clinical Labs. This test has not been reviewed by the FDA.	This test is a qualitative immunoassay used for the detection of SARS-CoV-2 (COVID-19) IgM. The test was validated by Central Clinical Labs. This test has not been reviewed by the FDA.	This test is used to determine active detection of SARS-CoV-2 to assist in the diagnosis of COVID-2019 infections using the Nucleic Acid Amplification (NAA) methodology. This test has not been reviewed by the FDA.
<b>How to Order?</b>	CCL Online Client Portal OR Fax/Email. Doc Order required <b>Must</b> provide patient condition: asymptomatic or symptomatic	CCL Online Client Portal OR Fax/Email. Doc Order required <b>Must</b> provide patient condition: asymptomatic or symptomatic	Fax/Email ONLY Doc Order required <b>Must</b> provide patient condition: asymptomatic or symptomatic
<b>Who Collects this Test</b>	CCL Mobile Service Team <b>OR</b> CCL in-office Phlebotomist <b>OR</b> CCL Phoenix/Tucson office**	CCL Mobile Service Team <b>OR</b> CCL in-office Phlebotomist <b>OR</b> CCL Phoenix/Tucson office**	The Ordering Facility <b>OR</b> Home Health Nurse <b>OR</b> Clinic Office Medical Assistant
<b>Interpretation Results note per FDA for the antibody test</b>	<ul style="list-style-type: none"> <li>This test has not been reviewed by the FDA.</li> <li>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.</li> <li>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</li> <li>A Positive result, in conjunction with the resolution of symptoms, indicates that the individual has recovered from SARS- CoV-2 infection, however these results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as: Coronavirus HKU1, NL63, OC43, or 229E.</li> </ul>		
<b>Other Guidelines</b>	*Please direct any questions regarding insurance coverage to your payer. CCL will bill insurance or charge non-insured patients at the time of service. AVAILABLE TO EMPLOYERS needing to test staff **CCL Phoenix: 3720 E. La Salle St, Phoenix, AZ 85040 (M-F 8AM TO 5PM) **CCL Tucson: 310 N. Wilmot Rd, Suite 103, Tucson AZ 85010 (M-F 7AM TO 3PM)		

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