SARS-CoV-2 (COVID-19)
IgG Antibody – Qualitative Assay

Effective June 23, 2020, Laboratory Alliance is offering a SARS-CoV-2 IgG (COVID-19) qualitative IgG serology test performed locally at our Operations Center Laboratory. This assay is performed on the Diasorin Liaison XL platform and has received FDA Emergency Use Authorization (EUA). The assay detects antibodies to the S1 and S2 subunits of the coronavirus spike (S) glycoprotein.

SARS-CoV-2 is a recently discovered coronavirus that causes the infectious disease commonly known as COVID-19. Symptoms range from none or mild to severe with acute respiratory distress and pneumonia. It is also associated with development of the complication in pediatric patients known as Multisystem Inflammatory Syndrome in Children. Diagnosis of acute disease is typically made in conjunction with a molecular test. Serology testing may be helpful in cases where molecular testing was not performed or was negative.

SARS-CoV-2 IgG testing may be indicated for individuals who have a history of symptoms of COVID-19, close contact with a person known to be positive for COVID-19 or are employed as a health care worker, first responder, or other essential worker who directly interacts with the public while working.

Test Interpretation

A positive test result with the SARS-CoV-2 IgG assay indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19. The presence of IgG antibodies has not been established to give definitive immunity to COVID-19, and individuals may still be infectious after development of antibodies. IgG serology can help identify individuals who have developed an immune response against SARS-CoV-2 but should not be used as the sole diagnostic method. Definitive laboratory diagnosis of COVID-19 should be made by a molecular test such as an RT-PCR assay.

COVID-19 IgG antibodies begin developing approximately 3-7 days after symptom onset and are likely to be detected in the majority of individuals after 14 days. Individuals tested early after infection may not have detectable IgG antibody despite active infection. When testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. False-positive results are possible in a small percentage of individuals and may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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Clinical Performance Characteristics for Diasorin SARS-CoV-2 IgG serology (COVIGG)[1]

Performance Measure	Estimate of Performance	95% Confidence Interval
Sensitivity at ≥ 15 days from diagnosis	97.6% (40/41)	(87.4%; 99.6%)
Specificity	99.3% (1082/1090)	(98.6%; 99.6%)
Positive predictive value at prevalence of 5%	88.0%	(76.7%; 92.9%)
Negative predictive value at prevalence of 5%	99.9%	(99.3%; 100%)

Test code:	COVIGG
Method:	Qualitative Chemiluminescent Immunoassay
Specimen requirements:	Collection – Serum separator tube (SST) or EDTA plasma (Note: Serum or plasma should be separated within 2 hours of collection)
Storage and Transport:	Refrigerated
Stability:	Refrigerated: 1 week; Frozen: 1 month
Unacceptable Conditions:	Specimens transported at ambient temperature Grossly hemolyzed, grossly icteric, or severely lipemic specimens
Testing Schedule	Mon-Fri
CPT Code:	86769
Billing Code:	2010303

Questions regarding this test may be directed to Bodhraj Acharya, PhD, Chemistry and Referral Testing Manager, at 315-410-7028 or bodhrajacharya@lacny.com

References

1) IFU – SARS-CoV-2 S1/S2 serology – DiaSorin Inc. – Stillwater, Minnesota 55082-0285, USA

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