Legacy Laboratory Services

Legacy Lab Alert

October 2021

An Important Message from Legacy Laboratory Services

Coronavirus SARS-CoV-2 IgG Antibody Testing by CIA in Serum

Effective **October 26, 2021,** Legacy Laboratory Services will perform COVID-19 IgG antibody testing using the semi-quantitative Liaison SARS-CoV-2 TrimericS IgG assay by Chemiluminescent Immunoassay (CIA). This assay will replace current qualitative COVID-19 testing using the Liaison SARS-CoV-2 S1/S2 IgG antibody.

I. Clinical Significance of Serology Testing for COVID-19

As COVID-19 is a novel virus and much about it is still unknown, clinical implications of COVID-19 serology are not entirely certain. The following limitations are acknowledged:

1. **COVID-19 IgG serology is not diagnostic for COVID-19 infection.** A positive antibody test result shows the person may have antibodies from a previous infection or from vaccination for the virus that causes COVID-19. COVID-19 PCR testing (not serology) is recommended for laboratory diagnosis of active COVID-19 infection.[1]

2. **Antibody testing does not determine if the person is immune to COVID-19 following COVID-19 vaccination.** Some antibody tests will not detect the antibodies generated by COVID-19 vaccines. Because these vaccines induce antibodies to specific viral protein targets, post-vaccination antibody test results will be negative in persons without history of previous infection, if the test used does not detect antibodies induced by the vaccine.[1]

3. **Coronaviruses are common and share significant degrees of similarity.** Little is known about antibody cross-reactivity between commonly circulating coronaviruses and SARS-CoV-2 (COVID-19).[1,2] Cross-reactivity, although apparently limited, may yield a false-positive result in a small percentage of tested individuals.

4. **Timing of specimen collection is important.** The semi-quantitative Liaison SARS-CoV-2 TrimericS IgG assay detects antibodies that develop approximately 15 or more days following symptom onset. Specimens collected before this time may produce a false negative result. [2] Also, immunocompromised individuals may not mount a detectable immune response.[1]

II. Specimen Requirements and Ordering Information

Table below compares current assay with new assay. The changes are indicated in red font.

Name		NEW - Effective 10/26/2021	CURRENT
		Coronavirus COVID-19 IgG Chemiluminescent Immunoassay	**Coronavirus COVID-19 IgG Chemiluminescent Immunoassay**
Performing Lab		Legacy Laboratory Services	Legacy Laboratory Services
Mnemonic		COV19 IGG	COV19 IGG
Collect		Serum, one 5.0 mL gold (SST), 7.0 mL red top.	Serum or plasma, one 5.0 mL gold (SST), 7.0 mL red top, or 3.0 mL mint green (lithium heparin, PST) top tube.
Handling		Allow serum to clot completely at room temperature (minimum: SST - 30 minutes and red top tubes – 60 minutes) Separate serum from cells before transport.	Allow serum to clot completely at room temperature (minimum: SST - 30 minutes and red top tubes – 60 minutes) Separate serum from cells before transport.
Preferred Volume		1.0 mL Serum	1.0 mL Serum or Plasma
Minimum Volume		0.5 mL Serum (1.2 mL minimum whole blood draw)	0.5 mL Serum or Plasma (1.2 mL minimum whole blood draw)
Transport		Refrigerated	Refrigerated
Rejection Criteria		Grossly hemolyzed specimens or lipemic samples. Samples containing particulate matter or exhibiting obvious microbial contamination.	Grossly hemolyzed specimens or lipemic samples. Samples containing particulate matter or exhibiting obvious microbial contamination.
Stability (After separation from cells)	**Room Temp (18-26°C)**	48 hours	72 hours
	Refrigerated (2-8°C)	21 days	7 days
	Frozen (≤ -10°C)	21 days	2 weeks
Note		This chemiluminescent immunoassay (CIA) is designed for qualitative detection of IgG antibodies against spike proteins of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Preliminary studies suggest minimal cross-reactivity with other coronaviruses. The performance characteristics of this test were validated in a manner consistent with CLIA requirements by Legacy Laboratory Services, 1225 NE Second Ave, Portland OR. This test has been approved by the FDA under EUA.	This chemiluminescent immunoassay (CIA) is designed for qualitative detection of IgG antibodies against spike proteins of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Preliminary studies suggest minimal cross-reactivity with other coronaviruses. The performance characteristics of this test were validated in a manner consistent with CLIA requirements by Legacy Laboratory Services, 1225 NE Second Ave, Portland OR. This test has been approved by the FDA under EUA.
Reference Values		Negative or Positive with a semi-quantitative result. Interpretation is provided for each result.	Negative or Positive Interpretation is provided for each result.
Performed		Monday - Saturday	Monday - Saturday
Reported		1 – 2 days	1 – 2 days
Method		Chemiluminescent Immunoassay	Chemiluminescent Immunoassay

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REFERENCES:

1. Center for Disease Control. Serology Testing for COVID-19. September 21, 2021. Website: Interim Guidelines for COVID-19 Antibody Testing | CDC

2. Liaison® SARS-CoV-2 TrimericS IgG Instructions for use, REF 311510D, US – 1 -2021-05.

For additional information, please contact your account representative, client services or consult our website:
Legacy Laboratory Client Services: 503-413-1234, 877-270-5566, www.legacyhealth.org\labservices