



Client Communication

April 24, 2020

East Side Clinical Laboratory now offers IgG serology for SARS-CoV-2, the causative agent of COVID-19 clinical illness. The Abbott Architect chemiluminescent microparticle immunoassay (CMIA) is designed to detect IgG antibodies to the nucleocapsid protein of SARS-CoV-2 in serum from patients who have signs and symptoms of infection or are suspected of coronavirus disease (COVID-19) or in serum of subjects that may have been infected by SARS-CoV-2.

In accordance with Emergency Guidance from the US FDA, the test is offered for use prior to Emergency Use Authorization (EUA) or In-Vitro Diagnostic (IVD) designation by the manufacturer while FDA evaluation is underway (See Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (<https://www.fda.gov/media/135659/download>)). Under the FDA emergency guidance (provision D), FDA does not object to the distribution of serology tests provided the following is included in test catalogs and reports:

- This test has not been reviewed by the FDA.
- 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.
- 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.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Test Information:

Test Code: 11353

Test Name: SARS-CoV-2 IgG

Ordering Recommendations:

Ordering provider to determine patient risk level based on CDC Guidelines and clinical judgement. Currently, serology testing alone is not part of the CDC's return to work criteria for healthcare providers with confirmed or suspected COVID-19. The CDC's **molecular** test-based strategy (below) is the preferred method for determining when HCP may return to work in healthcare settings.



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Exclude from work until: Resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath), and Negative results of an FDA Emergency Use

Authorized molecular assay for COVID-19 from at least two consecutive nasopharyngeal swab specimens collected ≥ 24 hours apart (total of two negative specimens) [1]. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV). <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>

Specimen Requirements:

Sample Type:

- 2.0 ML Serum

Container Type: *Prefer dedicated collection device

- Serum Separator tube (SST®)
(Min:0.5 ML – minimum does not allow for repeat testing)

Handling Instructions:

SST - Collect specimen and centrifuge sample per tube manufacturer's instructions. Transport Refrigerated.

Transport: Refrigerated

Unsuitable Specimens: Heat-inactivated specimens. Pooled specimens. Specimens grossly hemolyzed. Specimens with obvious microbial contamination. Specimens with fungal growth.

Testing Capacity:

Methodology: Chemiluminescent Microparticle Immunoassay (CMIA)

- Testing is performed seven days a week.
- Expected TAT is 2-3 days
 - TAT may vary with changes in capacity and market demands.

CPT Codes: 86769

LOINC Codes: 94505-5