

Client ALERT Communication

COVID-19 SARS-CoV-2 IgG Antibody Testing

Dear AEL Client

American Esoteric Laboratories (AEL) is now offering 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, are suspected of coronavirus disease (COVID-19) or may have been infected by SARS-CoV-2. In accordance with Emergency Guidance from the U.S. 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 link below: (<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 are 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 test 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 of infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 Coronavirus strains, such as Coronavirus HKU1, NL63, or 229E.

Test Information:

Test Code: W136

Specimen Requirements: 1 ml Serum from SST. Stable refrigerated 7 days.

Expected TAT: 1-3 days

CPT Code: 86769

Please call your AEL Representative or AEL Client Services for further information. AEL will continue to perform PCR testing for COVID-19.