TEST: COVID-19 serology, IgG antibody

PRINCIPLE:

COVID-19 (coronavirus disease 2019) is a disease resulting from infection with coronavirus named SARS-CoV-2. COVID-19 serology test checks an individual's blood for presence of antibodies that develop if the individual had a previous infection with the virus. This test measures IgG antibodies generated as part of the adaptive immune response to SARS-CoV-2 exposure. Serologic test cannot be used as sole method to diagnose COVID-19. Suitable method for the diagnosis of COVID-19 is a direct testing for the virus (e.g. viral RNA testing by RT-PCR) from respiratory tract secretion samples such as nasopharyngeal swab.

IgG antibodies to SARS-CoV-2 are generally not detected until 7-10 days after infection. Negative results do not preclude COVID-19 infection and should not be used as the sole basis for patient management decisions. When IgG antibodies are present, it often indicates a past infection but does not exclude recent infection and a possibility that infected individual is still contagious. It is unknown how long the antibodies will remain present in the body and if they confer immunity to infection.

The Clinical Immunology Laboratory COVID-19 Serology, IgG antibody test is performed with FDA-authorized anti-SARS-CoV-2 ELISA (IgG) from EUROIMMUN [1]. EUROIMMUNE Fact Sheets for Healthcare Providers and Recipients are available for review at our website rfuclinlab.net under Infectious Diseases Assays, COVID-19 Serology.

EUROIMMUN anti-SARS-CoV-2 ELISA (IgG) specificity is 99.1 % (Borderline results evaluated as Pos) and 99.6% (Borderline results evaluated as Neg). The assay sensitivity depends on how many days passed after the onset of symptoms: 93.8% (>21 days), 75% (between 10 to 20 days) and 30.3% (<10 days) [2].

SPECIMEN REQUIREMENTS: 2 mL serum from blood collected in a red top tube without additive or in a serum separator tube with gel barrier. Serum should be separated from the clot to avoid hemolysis: red top tube – transfer serum into plastic transport vial, gel tube – spin. Transport to the lab at room temperature. Store at room temperature for up to 24 h, refrigerate for up to 48 h. Store frozen at -20'C or below if not tested within 48 h. Avoid repeat freeze-thaw cycles.

METHOD: ELISA

REFERENCES:

1. Anti-SARS-CoV-2 ELISA (IgG) FDA authorization https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd
2. Characteristics of EUROIMMUN ELISA for COVID-19 diagnosis https://www.coronavirus-diagnostics.com/antibody-detection-tests-for-covid-19.html

REFERENCE RANGE: NEGATIVE

RESULTS & INTERPRETATION:

POSITIVE	Indicates that antibodies to SARS-CoV-2 virus were detected and the individual was likely exposed to COVID-19
NEGATIVE	Indicates that antibodies to SARS-CoV-2 virus were not present in the specimen above the limit of detection. However, a negative result does not preclude COVID-19 infection and should not be used as the sole basis for patient management decisions
BORDERLINE	Indicates that a secure evaluation is not possible. It is recommended the patient should be re-tested one to two weeks later

Turnaround time: 1 week