Marshfield Labs™

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COVID-19 IgG Antibody Serology Testing Available at Marshfield Labs

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Effective May 12, 2020, Marshfield Labs will begin COVID-19 IgG antibody serology testing using the FDA EUA-approved EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) assay.

Principle of the Test: The assay is an enzyme-linked immunosorbent assay intended for the qualitative detection of IgG class antibodies to SARS-CoV-2 virus in human serum or plasma. The antigen targeted for detection of IgG is the S1 domain of the spike protein of SARS-CoV-2 expressed as a recombinant protein. Patient results are reported as Negative, Positive, or Indeterminate.

Indications: COVID-19AB serology testing has very limited indications for use currently and is restricted for the following purposes:

- Identification of potential convalescent plasma donors
- Support for epidemiologic studies and surveillance purposes

Serologic testing should **NOT** be used for:

- Acute diagnoses (serologic antibody testing may result in false positive results, especially when prevalence of Covid-19 in the community is low)
- Assessment of protective immunity
- Return to work approvals
- Clearance for surgery

BEYOND numbers

While the assay displays a high level of specificity, the prevalence of COVID-19 is low in our community, which may increase the risk of false positives.

Clinical performance data as submitted to FDA by the manufacturer:

- Among PCR-positive patients, 100% developed detectable IgG antibodies to SARS-COV-2 after 20 days from onset of symptoms (n=6); 61% from 11 to 20 days after on-set of symptoms (n=36); and 14% at less than 10 days from on-set of symptoms (n=36).

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- Due to low homologies of the S1 protein within the coronavirus family, cross-reactions to other members are virtually excluded with the exception of SARS-COV-1 to which it is closely related.

- Cross-reactivity was detected rarely in patients with autoantibodies, RSV and bacterial pneumonia agents.

- Independent Clinical Agreement Validation Study Results Based upon a 5% Prevalence:

Measure	Estimate	Confidence Interval
IgG Sensitivity	90% (27/30)	(74.4%; 96.5%)
IgG Specificity	100% (80/80)	(95.4%; 100%)
Positive Predictive Value (PPV) for prevalence = 5%	100%	(46.1%; 100%)
Negative Predictive Value (NPV) for prevalence = 5%	99.5%	(98.6%; 99.8%)

Ordering Details: This test is designed for detection of antibodies to SARS-CoV-2 in either serum or plasma from individuals suspected to be recovering or recovered from COVID-19 by their healthcare provider.

HOW TO ORDER THIS TEST

- **Test Name:** COVID19, SARS-CoV-2 IgG Serology
- **Test Code:** COV19AB
- **Specimen:** Preferred: serum (red top, RTT), plasma (purple top, EDTA); Acceptable: plasma (lithium or sodium heparin green top, GTT), lithium-heparin plasma separator (PST) or serum separator tube (SST)
- **Specimen volume:** 500 uL.
- **Storage:** Refrigerated, stable for 14 days.
- **Test availability:** Monday through Friday
- **Qualitative interpretation:**

Reported as Negative, Positive, or Indeterminate
Indeterminate results are inconclusive. Repeat testing in 1-2 weeks may be considered to detect seroconversion

- **CPT Code:** 86769

Questions:

Test information is available in: Marshfield Labs' Test Reference Manual.

- Clinical and technical information: Joyce Flanagan, Ph.D., Sarah Bissonnette, Ph.D., Clinical chemists, Thomas Fritsche, M.D., Ph.D., Clinical Pathologist
- Phone number: 1-800-222-5835

References

1. Anti-SARS-CoV-2 ELISA (IgG), For emergency use authorization only. For in vitro diagnostic use. For prescription use Only: https://www.fda.gov/media/137609/download