MiraVista DIAGNOSTICS
Rapid Fungal Testing. Accurate Results.

CLINICAL DIAGNOSIS

MVista® *Coccidioides* Antibody IgG and IgM EIA

TEST CODE: 325

External Test Name
MVista® *Coccidioides* Antibody IgG and IgM EIA

Internal Test Name
anti-*Coccidioides* IgG and IgM EIA

CPT Code
86635 x2

LOINC Code
93836-5 (IgG)
93835-7 (IgM)

Clinical Significance
IgM and IgG antibodies to *Coccidioides* antigen usually appear during the first month of infection and decline over the next 3-6 months but remain detectable for approximately 18-24 months in some cases with self-limited illnesses. Antibodies may persist in patients with chronic pulmonary complications or progressive extrapulmonary (disseminated) coccidioidomycosis. Antibodies may be falsely negative in some progressive or chronic cases. Follow-up testing may be considered at weeks 2-4 to determine if antibody levels are increasing, especially in patients with low positive results. An increase in antibody concentration would suggest recent infection. Antibodies may also be detected in healthy subjects who are asymptomatic as a result of sub-clinical infection within the last 18-36 months.

During validation testing, the combined sensitivity was found to be 92.00% and specificity 94.00% with an assay cutoff of 1.0 EU. It offers an improvement over the current method of detecting antibodies by FID, where sensitivity has been reported as only 32%. Complement fixation is even less sensitive than FID.

Methodology
Semi-Quantitative Indirect Enzyme Immunoassay (EIA)

Limitations
Specimens positive for *Aspergillus* spp., *Histoplasma capsulatum, Paracoccidioides brasiliensis*, or *Talaromyces marneffei* may cross-react with the *Coccidioides* Antibody EIA (IgG and IgM detection) and test positive.

A variety of interfering substances were investigated (hemoglobin/blood, total cholesterol, triglycerides, glucose, bilirubin, total protein, fluconazole, itraconazole, amphotericin B, voriconazole, vancomycin, piperacillin, tazobactam, ceftriaxone, tobramycin) and none affected the *Coccidioides* Antibody EIA sensitivity or specificity.

Specimen Collection
Serum: Collect serum specimens into a serum separator or red top tube. Allow blood to clot for 30 minutes, then centrifuge. Pipette serum separated from clot into a sterile, leak-proof container.

CSF: Sterile transport tube

HEADQUARTERS
4705 Decatur Blvd. | Indianapolis, Indiana 46241 USA

866.647.2847

miravistalabs.com

Version 1 | May 2023

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Minimum Specimen Requirements
Serum/CSF: 0.5 mL

Specimen Stability
Room Temperature: 30 days
Refrigerated: 30 days
Frozen: 30 days

Specimen Rejection
>30 days old

Two unique patient identifiers are required on the specimen container.

Any specimen type other than serum or cerebrospinal fluid (CSF)

For specimen submissions that do not meet these criteria, please call Customer Service.

Transport Temperature
Ambient/Refrigerated/Frozen

Shipping
Ship to arrive Monday–Friday using a next day delivery service. Samples may be shipped on dry ice, frozen ice packs, or ambient.

Turnaround Time
Testing is performed Monday through Friday and reported the by the next day

Reference Range
Negative

Interpretative Information
Negative: <1.0 EU
Positive: ≥1.0 EU

CSF will be run with a non-validated disclaimer.

Results should be correlated with clinical presentation and history.

Additional Information
This test was developed, and its analytical performance characteristics determined by MiraVista Diagnostics. It has not been cleared or approved by the FDA; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Complete Test Information Available
https://miravistalabs.com/medical-fungal-infection-testing/antibody-detection/coccidioides-antibody-igg-igm-eia/

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