

Cleveland Clinic Laboratories

Mitochondrial M2 IgG Serum

Mitochondrial M2 IgG test is offered at the Immunopathology laboratory at the main campus.

The test is a FDA-approved semi-quantitative assay to be used as an aid in diagnosing primary biliary cholangitis (PBC). The numerical values (ELISA units) are only reported for informational purposes and may not correlate with disease severity or response to treatment.

Mitochondrial M2 IgG ELISA typically detects M2 component of the mitochondrial antigens (E2 subunits of PDC, BCOADC,

and OGDC) as recombinant chimeric target expressing the immunodominant epitopes. The test offers improved sensitivity and specificity compared with the IFA, the latter also being labor-intensive.

The new test is able to detect anti-mitochondrial antibodies (AMA) in over two-third of the sera from AMA-negative PBC patients compared with the IFA. Correlation with clinical picture, imaging and other lab results are recommended.

Test Overview

| Test Name | Mitochondrial M2 IgG Serum |
|-----------------------|--|
| Ordering Mnemonic | MITOS |
| Methodology | Enzyme-linked immunosorbent assay (ELISA) (aka EIA) |
| Specimen Requirements | Primary container SST (Gold) 1.0 mL; Minimum 0.3 mL |
| Stability | After separation from cells: 24 hours (Ambient), 7 days (Refrigerated), 14 days (frozen ≤ -20°C) |
| Clinical Information | As an aid in diagnosing PBC |
| Reference Range | Negative; ≤20 |
| CPT Code | 86381 |
| Days Performed | Monday through Friday |

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202211.003