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▶ **ANTI-MITOCHONDRIAL M2 EP (MIT3) AB**

Clinical Utilities:

Primary biliary cirrhosis (PBC) typically occurs between the ages of 30 and 65 and affects women more frequently than men (estimated female:male ratio of 9:1). Wide variations in geographic prevalence of PBC have been reported from estimates of 2 per 100,000 in Japan and Australia to 40 per 100,000 in the United States.

Serological assays are important aids to the recognition and diagnosis of PBC since many antibodies associated with PBC are present before symptoms become evident. Anti-mitochondrial antibodies (AMA) have been reported in up to 95% of PBC patients.

Early studies described 9 subtypes of mitochondrial antigens, termed M1-M9. The major autoantigens targeted by PBC patient sera recognize the M2 antigen fraction. First generation anti-M2 ELISA tests utilized PDC-E2 as the primary substrate to detect PBC-specific antibodies. While 80 - 90% of histologically proven PBC patients have anti-PDC-E2 antibodies, about 10% of PBC patients only react to BCOADC-E2 and/or OGDC-E2. Gershwin and Leung developed and patented a triple expression hybrid clone ("MIT3") which expresses the immunodominant epitopes of PDC-E2, BCOADC-E2 and OGDC-E2. The MIT3-based ELISA was shown to have enhanced performance over Indirect Immunofluorescence (IFA) or conventional PDC-E2 based ELISA tests and detected AMA in over two-thirds of the sera from "AMA-negative" (by IFA) PBC patients.

Since the presence of AMA can precede the development of symptomatic disease, the ability to more accurately identify the presence of markers for PBC can contribute to earlier diagnosis, treatment and may slow the progression of the disease.

Anti-mitochondrial M2 can be ordered alone or in the Autoimmune Liver Panel which also includes anti-smooth muscle ab, ANA & anti-liver/kidney microsomal, or the Comprehensive Autoimmune Liver Panel which also includes anti-actin ab, anti-liver/kidney ab, anti-soluble liver ag ab and P-ANCA .

Specimen Requirements: 1 mL serum ambient, refrigerated or frozen (minimum: 0.5 mL)

Methodology: EIA

Turnaround Time: 3 - 5 days

Normal Range: Normal: <=20 Units/mL
Equivocal: 20.1 - 24.9 Units/mL
Positive: >=25 Units/mL

CPT Code: 83516

Test Code #: 128