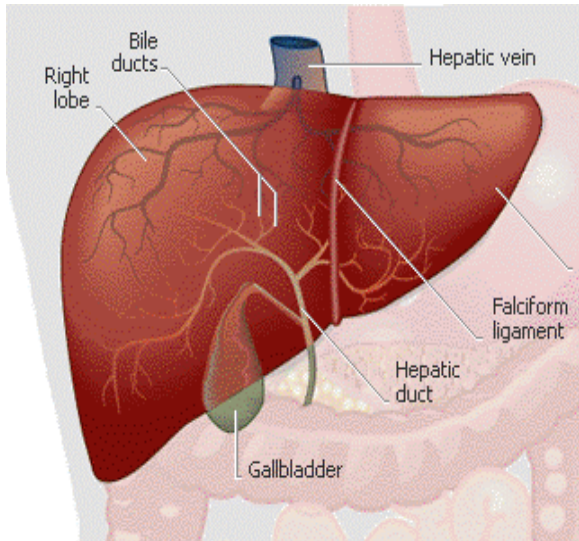


The REAADS anti-Mitochondria M2 Test Kit is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-mitochondrial antibodies in human serum as an aid in the diagnosis of primary biliary cirrhosis (PBC).



- Detects anti-mitochondrial antibodies specific to the M2 antigen using recombinant protein components of pyruvate dehydrogenase complex (PDC-E2)
- Highly sensitive and specific for primary biliary cirrhosis
- Improved sensitivity and specificity compared to immuno-fluorescent assays (IFA)
- Results are reported in semi-quantitative units, eliminating subjective interpretation required with IFA
- Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time

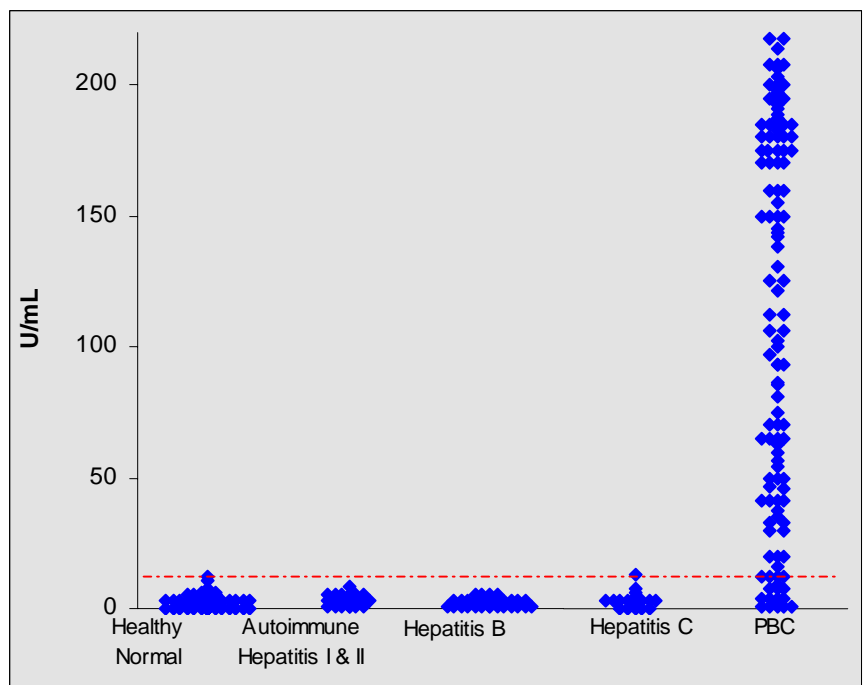
Assay Sensitivity:

Serum samples from 123 primary biliary cirrhosis (PBC) patients were tested on the REAADS anti-Mitochondria M2 Test Kit and resulted in a sensitivity of 90.2% (111/123) using an assay cutoff of 7 U/mL.

	Positive	Sensitivity
REAADS anti-mitochondria M2 Test Kit	>7 U/mL	90.2%

Clinical Performance:

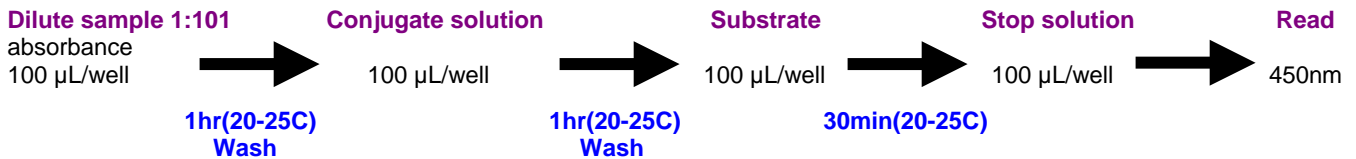
Serum samples from liver disease groups were tested to determine the clinical specificity and sensitivity of the REAADS anti-Mitochondria M2 Test Kit. These groups included autoimmune hepatitis type I (AIH I; n=27) and type II (AIH II; n=4), hepatitis B virus (HBV; n=44), hepatitis C virus (HCV; n=46) and primary biliary cirrhosis (PBC; n=123). Anti-mitochondrial antibodies are specific for primary biliary cirrhosis and should not be found in other liver disease patients. In addition, a population of healthy blood donors (n=168) was also tested. The REAADS anti-Mitochondria M2 Test Kit demonstrated 98.2% specificity in the healthy blood donor population and greater than 95% specificity in the various liver disease control groups compared with a 90.2% sensitivity (positive rate) in the PBC population. Results are shown in the graph.



REAADS Anti-Mitochondria M2 Test Kit
For In Vitro Diagnostic Use

Primary biliary cirrhosis (PBC) is an autoimmune liver disease named in 1950 by Ahrens, et al. PBC is a disease caused by chronic inflammation of the thin bile ducts of the liver, making it difficult for the bile to flow, causing it to remain in the liver. Anti-mitochondrial antibodies (AMA) occur frequently in patients with PBC and their presence constitutes one of the diagnostic criteria of the disease. Berg, et al. classified the corresponding antigens to AMA into M1 to M9 and found that anti-M2 antibody is the most specific antibody to PBC, present in 96% of patients histologically and clinically defined with PBC. No other patient groups tested positive for mitochondria M2 antibodies, including other liver diseases. In 1988, it was reported by Gershwin, et al. that the main corresponding antigen to anti-M2 antibody is the E2 component of pyruvate dehydrogenase complex (PDC-E2). It is further reported that the subunits, branched chain 2-oxo-acid dehydrogenase complex (BCOADC) and 2-oxo glutarate dehydrogenase complex (OGDC) of the enzyme that belong to 2-oxo-acid dehydrogenase complex are corresponding antigens of M2 antibodies. Also, it is reported by Motegi, et al. that antibodies which react only to one of these antigens is present in approximately 5-6% of sera from patients with PBC.

Assay Procedure



Correlation with indirect immunofluorescence (IIF) method

A comparison analysis was performed on 123 primary biliary cirrhosis samples with the REAADS anti-mitochondria M2 Test Kit and an IIF method resulting in a 90% relative agreement. The ten patients that resulted positive on the ELISA, but negative by IIF, were tested on a western blot assay where eight resulted as positive. In addition, the four patients that were negative on the REAADS test kit and positive by IIF were also negative on the western blot.

		IIF method	
		Positive	Negative
REAADS	Positive	101	10
	Negative	4	8

Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Calibrator-1 (0 U/mL) (ready to use)	1.5 mL
Calibrator-2 (100 U/mL) (ready to use)	1.5 mL
Positive Control	0.2 mL
Negative Control	0.2 mL
Conjugate Reagent (IgG,IgM and IgA)	15 mL
Assay Diluent	50 mL
Wash Concentrate (10x)	100 mL
Substrate (ready to use)	20 mL
Stop Solution (ready to use)	20 mL



Corgenix, Inc.

12061 Tejon Street
Westminster, Colorado 80234
Toll Free: 800-729-5661
Telephone: 303-457-4345
Fax: 303-457-4519
Email: techsupport@corgenix.com
www.corgenixonline.com

Corgenix (UK) Ltd.

75 Broadway
Peterborough, PE1 1SY UK
Telephone: +44 (0) 1733 296800
Fax: +44 (0) 1733 296809
Email: sales@corgenix.co.uk
www.corgenix.co.uk

REAADS anti-Mitochondria M2 Test Kit

Product # 10877
Quantity: 96 tests
Storage: 2-8 C
Stability: 12 months