














BioCLIA[®] Autoimmune Control Set

AMA-M2

AMA-M2 Assay Controls

Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Control 1		Contains Sufficient for < n > Tests
	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Control Set,

AMA-M2

Intended Use

The BioCLIA Autoimmune Control Set, AMA-M2 is intended for the quality control purposes of the BioCLIA AMA-M2 performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00322 (2 X 1 mL)

MY00373 (4 X 1 mL)

Summary and Principles of the Procedure

Autoimmune liver diseases (ALD) include autoimmune hepatitis (AIH), ^{1, 2} primary biliary cirrhosis (PBC) ³ and primary sclerosing cholangitis (PSC). ⁴ Determination of indicators such as AMA, CENP-B, LKM-1 and SLA/LP has significant correlation to ALD diagnosis.

The main target antigens for anti-mitochondrial antibody are the pyruvate dehydrogenase complexes in the mitochondrial respiratory chain. 9 antigens with unknown molecular structure are considered to be the AMA target antigens, named M1 - M9 in which AMA-M2 is the most important antibody of target antigen. AMA-M2 has a very high specificity to PBC patients that approximately 90% of PBC patients are AMA-M2 positive. ^{5, 6, 7}

Materials supplied

- **AMA-M2 Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains human antibodies to AMA-M2 in stabilizers and preservatives (Low).

AMA-M2 Control L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **AMA-M2 Control 2** A tube contains 1mL, ready to use reagent. Control 2 contains human antibodies to AMA-M2 in stabilizers and preservatives (High).

AMA-M2 Control H

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on control information sheet in each kit.

Warnings and Precautions

The human derived material in this product was tested by FDA approved methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV 1/2 antibodies. Handle as if potentially infectious. ⁸ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:



Human serum is added in the controls.



Proclin 300 is added in the controls at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates. Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results. Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if it is stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a control tube is opened, it is good for a total of 15 times, no more than 2 hours per time when kept uncapped, onboard the instrument, after which the reagent must be discarded. Three freeze-thaw cycles before testing has no effect on the kit reagents.

Assay Procedure

Note that, for obtaining optimal performance, it is important to perform all routine maintenance procedures as defined in the BioCLIA® 1200 and BioCLIA® 6500 User Manual.

See the BioCLIA® 1200 and BioCLIA® 6500 User Manual for preparation, setup, dilutions, adjustment, assay and quality control procedures. The control procedure can be done before running the specimens every day. Users also can adjust the control procedure period according to their own lab frequency.

Limitations

This product is designed as controls for monitoring the performance of the BioCLIA AMA-M2. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

References

1. Czaja AJ. Autoimmune liver disease. Current Opinion in Gastroenterology 2007;23:255-62.
2. Manns MP, Czaja AJ, Gorham JD, Krawitt EL, Mieli - Vergani G, Vergani D, Vierling JM. Diagnosis and management of autoimmune hepatitis. Hepatology 2010;51:2193-213.
3. Nakamura M, Kondo H, Mori T, Komori A, Matsuyama M, Ito M, et al. Anti - gp210 and anti - centromere antibodies are different risk factors for the progression of primary biliary

cirrhosis. Hepatology 2007;45:118-27.

4. T Tabibian JH, Lindor KD. Primary sclerosing cholangitis: a review and update on therapeutic developments. Expert review of gastroenterology & hepatology 2013;7:103-14.

5. Oertelt S, Rieger R, Selmi C, Invernizzi P, Ansari AA, Coppel RL, et al. A sensitive bead assay for antimitochondrial antibodies: Chipping away at AMA-negative primary biliary cirrhosis †. Hepatology 2007;45:659-65.

6. Berg PA, Klein R. Antimitochondrial Antibodies in Primary Biliary Cirrhosis and Other Disorders: Definition and Clinical Relevance. Digestive Diseases 1992;10:85-101.

7. Leung PS, Rossaro L, Davis PA, Park O, Tanaka A, Kikuchi K, et al. Antimitochondrial antibodies in acute liver failure: implications for primary biliary cirrhosis. Hepatology 2007;46:1436-42.

8. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



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Technical Assistance

For technical assistance, contact your National Distributor.

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