BioCLIA Autoimmune Control Set, LKM-1

Cat.No.	Kit Size
MY00320	2 X 1 mL
MY00371	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, LKM-1 is intended for the quality control purposes of the BioCLIA LKM-1 performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

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.

Anti-LKM-1 antibodies are specific binding to cytochrome P450 IID6 with the main immune response area at 33- amino acid. Autoimmune hepatitis (AIH) occurred mainly in young women with the syndrome of acute and multiple inflammation. About 82% of the patients may be converted to cirrhosis of the liver. [5] The serological features include hypergammaglobulinemia and anti-LKM-1 antibodies positive. Anti-LKM-1 antibodies indicate type II AIH. About 7% patients with hepatitis C or halothane hepatitis can also be confirmed Anti-LKM-1 antibodies positive.

MATERIALS SUPPLIED

- **LKM-1 Control N** Barcode labeled tubes with buffer containing human antibodies to LKM-1 in stabilizers and preservatives. Ready to use, 1 mL.

Control | N

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **LKM-1 Control P** Barcode labeled tubes with buffer containing human antibodies to LKM-1 in stabilizers and preservatives. Ready to use, 1 mL.

Control | P

Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Control Code contains controls' information is provided in each kit.

Target value and acceptance range for the controls are indicated on the card provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established!

Precautions:

 Human serum is added in the controls.

- 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. 7 Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened controls could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 35 controls, after which the reagent must be discarded.
- Avoid repeated freezing and thawing.

ASSAY PROCEDURE

Detailed information about operating the BioCLIA instruments can be taken from the Instrument User's Manual.

Note that, it is important to perform all routine maintenance procedures for optimal performance.

Control

The control procedure should be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Each Laboratory should establish its own reference ranges.

Programming and Running samples

1. Put the kit into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the kit can be uploaded into the instrument system through the scanning of reagent barcode, and can also be set through the supporting software of the instrument.
2. The information of calibrator / quality control is identified by scanning the calibrator / control barcodes, and the position of calibrator / quality control is assigned in the instrument system.
3. The sample to be tested is placed on the instrument sample rack chamber, and the corresponding test information is edited through the instrument supporting software.
4. Start the operation procedure, and all calibrator / quality control / sample processing steps will be automatically executed.

TRACEABILITY

The reported values were determined over multiple runs on the BioCLIA 6500 and BioCLIA 500 using specific lots of reagents against an in-house standard. DGP IgA results are reported in RU/mL which is interpreted from relative light unit (RLU). Method comparison test showed good sensitivity and specificity of tested assay.

LIMITATIONS

- The controls are designed for control of the same lot of BioCLIA Autoimmune Reagent Kit.
- The controls can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 35 controls are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper results.

SYMBOLS

REF	Catalog Number		Use-by date
IVD	In Vitro diagnostic medical device	LOT	Lot Number
+2°C +8°C	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Marking	Σ	Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

Control N	Negative Control
Control P	Positive Control

REFERENCE

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. Kerkar N, Ma Y, Davies E, Cheeseman P, Mieli-Vergani G, Vergani D. Detection of liver kidney microsomal type 1 antibody using molecularly based immunoassays. Journal of clinical pathology 2002;55:906-09.

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

CE IVD

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The eIFU is available on Website:
http://en.hob-biotech.com/usercenter/login.aspx

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

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