**BioCLIA Autoimmune Calibrator Set, LKM-1**

| Cat.No. | Kit Size |
|---|---|
| MY00218 | 2 X 1 mL |
| MY00269 | 4 X 1 mL |

**INTENDED USE**

The BioCLIA Autoimmune Calibrator Set, LKM-1 is intended for the calibration 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 indicatiors 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 Calibrator 1** Barcode labeled tubes with buffer containing human antibodies to LKM-1 in stabilizers and preservatives. Ready to use, 1 mL.

CAL 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **LKM-1 Calibrator 2** Barcode labeled tubes with buffer containing human antibodies to LKM-1 in stabilizers and preservatives. Ready to use, 1 mL.

CAL 2

Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Calibrator Code contains calibrators' information is provided in each kit.

**WARNINGS AND PRECAUTIONS**

- For professional *in vitro* diagnostic use only.
- Do not use any calibrators beyond their expiration dates.
- Do not mix calibrators from different lots unless specified.
- Instructions must be carefully followed for using and storing of calibrators. Any modification in procedure may interfere with the results.
- Calibrators 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 calibrators.

- 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 gloves and clothing.

- Proclin 300 is added in the calibrators at concentration between 0.0015% - 0.6%.
- Calibrators contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with calibrators happens, rinse immediately the contact surface with plenty of water 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 calibrators could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 20 calibrations, 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.

***Assay Calibration***

The BioCLIA Autoimmune Reagent Kit utilizes a predefined lot specific Master Curve which is uploaded into the instrument via the barcode provided in the main reagent kit. The Calibrator Code contains calibrator information is then scanned. Based on the results of running two calibrators, the instrument specific Working Calibration

Curve is generated and is used to calculate the concentration from the RLU obtained for each patient.

For each new lot of reagent, please calibrate prior to the first time use, and every 28 days thereafter. The software will not allow the lot to be used if the above requirements are not meet.

***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 calibrators are designed for calibration of the same lot of BioCLIA Autoimmune Reagent Kit.
- The calibrators can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 20 calibrations are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper calibration of the assay and which can give 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 | | Contains Sufficient for<n>Tests |
| | Biological Risk | | GHS07 Warning |
| CAL 1 | Calibrator 1 | | |
| CAL 2 | Calibrator 2 | | |

**REFERENCE**


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CE IVD


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EC REP

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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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