# BioCLIA® Autoimmune Control Set

## *SLA/LP*

**SLA/LP Assay Controls**

## Key to Symbols Used

| | | | |
|---|---|---|---|
| REF | Catalog Number | | Expiration Date |
| IVD | For *In Vitro* Diagnostic Use | LOT | Lot Number |
| | Store between +2°C and +8°C | | Consult Instruction for Use |
| | Manufacturer | EC REP | Authorized Representative in European Union |
| | | Σ | Contains Sufficient for < *n* > Tests |
| Control L | Control 1 | | |
| Control H | Control 2 | | Chemical Risk Warning |
| | | | Biological Risk Warning |

# BioCLIA® Autoimmune Control Set, SLA/LP

**Intended Use**

The BioCLIA Autoimmune Control Set, SLA/LP is intended for the quality control purposes of the BioCLIA SLA/LP performed on the BioCLIA® 1200 and BioCLIA® 6500.

**Catalog Numbers**

MY00323 (2 X 1 mL)

MY00374 (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 indicatiors such as AMA, CENP-B, LKM-1 and SLA/LP has significant correlation to ALD diagnosis.

Currently, soluble liver antigen (SLA) and liver pancreas antigen (LP) are considered to be the same antigen. SLA/LP is a 50 kDa cytosol molecule, which is known as the UGA inhibitor tRNA related protein. Anti-SLA/LP antibodies are highly specific antibodies to type I autoimmune hepatitis (AIH) with sensitivity of 10% ~ 30%. [5, 6] It exists alone or along with other direct antibody in patients' sera from ANA, SMA or AIH with anti-LKM-1 antibody negative ones. It is more likely to happen on young women with hyperimmunoglobulinemia. The determination of anti-SLA/LP antibodies is significant to clinical diagnosis of AIH.

**Materials supplied**

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

SLA/LP | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

SLA/LP | 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. [7] 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 each 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 SLA/LP. 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. Herkel J, Heidrich B, Nieraad N, Wies I, Rother M, Lohse AW. Fine specificity of autoantibodies to soluble liver antigen and liver/pancreas. Hepatology 2002;35:403-08.
6. Wies I, Brunner S, Henninger J, Herkel J, Kanzler S, Lohse AW. Identification of target antigen for SLA/LP autoantibodies in autoimmune hepatitis. Lancet 2000;355:1510-5.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

CE IVD

HOB Biotech Group Co., Ltd

C6 Building, No. 218 Xinghu Road, SuzhouIndustrial Park,

Suzhou, Jiangsu, 215123, China

**REGISTRANT/MANUFACTURE:** HOB Biotech Group Co., Ltd

**ADDRESS/LOCATION:**

C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123 China

**CONTACT INFORMATION:** TEL (+86)512-69561996 Fax (+86)512-62956652

**WEBSITE:** www.hob-biotech.com

**CUSTOMER SERVICE:** HOB Biotech Group Co., Ltd

**CUSTOMER SERVICE CONTACT:** TEL (+86)4008601202

EC REP

**EUROPE REPRESENTATIVE:** Emergo Europe

**ADDRESS/LOCATION:**

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

**Technical Assistance**

For technical assistance, contact your National Distributor.

17th April 2019

Revision 9