BioCLIA Autoimmune Control Set, sp100

Cat.No.	Kit Size
MY00319	2 X 1 mL
MY00370	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, sp100 is intended for the quality control purposes of the BioCLIA sp100 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.

By indirect immune-fluorescence method, a special fluorescence karyotype was detected (Anti-centromere antibodies positive) in Primary Biliary Cirrhosis (PBC) and chronic arthritis patients. 5-20 scattered point-like particles with different sizes distribute are visible in the cell nucleus in the cell split phase. It is specific to sp100 antigen (100 kDa) which is a soluble acidic phosphorylation nucleoprotein.

Anti-sp100 antibodies are closely related to primary biliary cirrhosis (PBC) that the specificity is about 97% and sensitivity is 10% ~ 30%. For PBC patients, sensitivity of anti-sp100 antibodies is 60% for anti-mitochondrial antibodies (AMA) negative ones and 20% for AMA positive ones, therefore anti-sp100 antibodies is of great significance for the diagnosis of AMA in PBC patients. [5, 6]

Other than PBC, anti-sp100 antibodies are also found in the rheumatism ones associated with PBC but in a lower sensitivity (about 5% for progressive scleroderma and 1.5% for SLE).

MATERIALS SUPPLIED

- **sp100 Control N** Barcode labeled tubes with buffer containing human antibodies to sp100 in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **sp100 Control P** Barcode labeled tubes with buffer containing human antibodies to sp100 in stabilizers and preservatives. Ready to use, 1 mL.

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. Szostecki C, Guldner H, Netter H, Will H. Isolation and characterization of cDNA encoding a human nuclear antigen predominantly recognized by autoantibodies from patients with primary biliary cirrhosis. The Journal of Immunology 1990;145:4338-47.
6. Blüthner M, Schäfer C, Schneider C, Bautz FA. Identification of major linear epitopes on the sp100 nuclear PBC autoantigen by the gene-fragment phage-display technology. Autoimmunity 1999;29:33-42.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

CE IVD

HOB Biotech Group Corp., Ltd.
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: TEL (+86)4008601202

EC REP

EUROPE REPRESENTATIVE: Emergo Europe
ADDRESS/LOCATION:
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

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

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

Date of issue: 17th March 2019

Date of revision: 20th December 2021

Change Control Number: CN21129E

Version: A/1 (EN)