BioCLIA Autoimmune Control Set, CENP-B

Cat.No.	Kit Size
MY00313	2 X 1 mL
MY00364	4 X 1 mL

INTENDED USE

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

SUMMARY AND EXPLANATION

Anti-nuclear antibodies (ANAs) are a class of auto-antibodies with different binding affinities specific to different nucleus antigens. Generally, ANAs include extractable nuclear antigen (ENA) antibodies and un-extractable nuclear antigen antibodies.[1] Determination of ANAs has significant correlation to the diagnosis of Sharp Syndrome, Systemic Lupus Erythematosus (SLE), Sjogren's Syndrome, progressive systemic sclerosis, polymyositis / dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Anti-centromere antibodies are associated with limited cutaneous systemic sclerosis, also known as CREST syndrome, primary biliary cirrhosis and proximal scleroderma. There are six known antigens, which are all associated with the centromere; CENP-A to CENP-F in which CENP-B is the main antigen. It is an 80 kDa DNA binding protein, located in the center of the chromosome centromeric region. It is related to the formation and function of centromere and kinetochore. [2]

Anti-CENP antibodies are of great significance to the diagnosis of primary biliary cirrhosis (PBC), or limited systemic sclerosis especially the CREST subtypes (patients with calcification, Renault's phenomenon, esophageal movement disorders, hard finger (toe) syndrome or blood capillary expansion). In addition, anti-CENP antibodies can be detected in patients with the Renault syndrome, tumor and other rheumatic diseases such as SLE, sjogren syndromes or rheumatoid arthritis. [3]

MATERIALS SUPPLIED

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

Control | N

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **CENP-B Control P** Barcode labeled tubes with buffer containing human antibodies to CENP-B 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		Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning
Control N	Negative Control		
Control P	Positive Control		

REFERENCE

1. Tan EM. Autoantibodies to nuclear antigens (ANA): their immunobiology and medicine. Advances in Immunology 1982;33:167-240.
2. Imboden JB, Hellmann DB, Stone JH. Current rheumatology diagnosis & treatment. A Lange Medical Book 2007.
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. 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.

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