BioCLIA Autoimmune Calibrator Set, ENA Screen I

Cat.No.	Kit Size
MY00249	2 X 1 mL
MY00300	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Calibrator Set, ENA Screen I is intended for the calibration of the BioCLIA ENA Screen I performed on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Extractable Nuclear Antigens are over 100 different soluble cytoplasmic and nuclear antigens. Autoantibodies to these antigens are associated with particular connective tissue disorders. Six of eight main antigens used in immunological laboratories for detection are Ro52, SS-B/La, Sm, nRNP/Sm, Scl-70 and Jo-1, [1] which are screened for by ouchterlony double immuno diffusion techniques and confirmed by immunoblotting. Ro60 and CENP-B are also specific ENA antigens. [2, 3]

Anti-ENA is a group of antibodies often used to screen for mixed connective tissue disease (MCTD), Sjögren's syndrome and systemic lupus erythematosus (SLE) and is commonly composed of eight tests: anti-Sm for SLE, anti-nRNP/Sm for MCTD, anti-SS-B/La for Sjögren's, anti-Ro52 for Sjögren's Syndrome, anti-Scl-70 for Scleroderma, anti-Jo-1 for Dermatomyositis, anti-Ro60 for Sjögren's Syndrome, anti-CENP-B for CREST syndrome. [4-6]

MATERIALS SUPPLIED

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

CAL	1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **ENA Screen I Calibrator 2** Barcode labeled tubes with buffer containing human antibodies to ENA Screen 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	Σ	Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

CAL 1	Calibrator 1
CAL 2	Calibrator 2

REFERENCE

1. Prince HE, Hogrefe WR. Evaluation of a line immunoblot assay for detection of antibodies recognizing extractable nuclear antigens. Journal of Clinical Laboratory Analysis 1998;12:320-4.
2. Kumar Y, Bhatia A, Minz RW. Antinuclear antibodies and their detection methods in diagnosis of connective tissue diseases: a journey revisited. Diagnostic Pathology 2009;4:1-10.
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. Lock RJ, Unsworth DJ. Antibodies to extractable nuclear antigens. Has technological drift affected clinical interpretation? Journal of Clinical Pathology 2001;54:187-90.
5. Hernández-Molina G, Leal-Alegre G, Michel-Peregrina M. The meaning of anti-Ro and anti-La antibodies in primary Sjögren's syndrome. Autoimmunity Reviews 2011;10:123-5.
6. Stahnke G, Meier E, Scanarini M, Northemann W. Eukaryotic Expression of Recombinant Human Centromere Autoantigen and its use in a Novel ELISA for Diagnosis of CREST Syndrome. Journal of Autoimmunity 1994;7:107-18.
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.

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