














BioCLIA[®] Autoimmune Calibrator Set

CENP-B

CENPB Assay Calibrators

Key to Symbols Used			
	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Calibrator 1		Contains Sufficient for $< n >$ Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator

Set, CENP-B

Intended Use

The BioCLIA Autoimmune Calibrator Set, CENP-B is intended for the calibration of the BioCLIA CENP-B performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00211 (2 X 1 mL)

MY00262 (4 X 1 mL)

Summary and Principles of the Procedure

Anti-nuclear antibodies (ANAs) are a class of auto-antibodies with different binding affinities specific to different nuclear 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 Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1 contains human antibodies to CENP-B in stabilizers and preservatives.

CENP-B CAL 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **CENP-B Calibrator 2** A tube contains 1mL, ready to use reagent. Calibrator 2 contains human antibodies to CENP-B in stabilizers and preservatives.

CENP-B CAL 2

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value information is indicated in the 2D barcode localized 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.⁴ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:



Human serum is added in the calibrators.



Proclin 300 is added in the calibrators at concentration between 0.0015% - 0.6%.

- The product is for *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.
- 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

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator 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.

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA®

6500 using specific lots of reagents against an in-house standard. CENP-B 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.

17th April 2019

Revision 9

Limitations

This product is designed as calibrators for monitoring the performance of the BioCLIA CENP-B. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

References

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.



HOB Biotech Group Co., Ltd

C6 Building, No. 218 Xinghu Road, Suzhou Industrial 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



EUROPE REPRESENTATIVE: Emergo Europe

ADDRESS/LOCATION:

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Technical Assistance

For technical assistance, contact your National Distributor.