






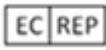







BioCLIA[®] Autoimmune Calibrator Set

Ribosomal P

Ribosomal P 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, Ribosomal P

Intended Use

The BioCLIA Autoimmune Calibrator Set, Ribosomal P is intended for the calibration of the BioCLIA Ribosomal P performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00207 (2 X 1mL)

MY00258 (4 X 1mL)

Summary and Principles of the Procedure

Anti-nuclear antibody (ANA) is 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 ANA has significant correlation to the diagnosis of Sharp syndrome (MCTD), systemic lupus erythematosus (SLE), sjogren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

P0 (38 kDa), P1 (19 kDa) and P2 (17 kDa) are three kinds of ribosomal protein located in the 60S ribosomal subunit. As the main components of the ribosome, acidic ribosomal P proteins are involved in protein synthesis, maintaining life stability, and also functioned in DNA repair, cell differentiation and cell growth regulation. These three proteins contain the same 17 amino acid sequence, with the main antigenic epitope on the carboxyl end. Specifically, anti-P0 antibodies exist in 10% of SLE patients sera; P1 is a supplementary antigen aiming the special case of SLE; function of P2 is unclear.^{2, 3, 4, 5}

Anti-P0 antibodies are one of the specific antibodies for SLE that about 10% - 20% SLE patients are anti-P0 antibodies positive. Also they are found relating to the complications of central nervous system or kidney or other organs disease. Anti-ribosomal P protein antibodies are not found in healthy human serum or patients sera from progressive systemic sclerosis, sjogren's syndrome or dermatomyositis/polymyositis.

Materials supplied

• **Ribosomal P Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Ribosomal P in stabilizers and preservatives.

Ribosomal P | CAL | 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

• **Ribosomal P Calibrator 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Ribosomal P in stabilizers and

preservatives.

Ribosomal P | 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.⁶ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:



Human serum 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. Avoiding ingestion 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. Ribosomal P 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

This product is designed as calibrators for monitoring the performance of the BioCLIA Ribosomal P. 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

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2. Wool IG, Chan YL, Glück A. Structure and evolution of mammalian ribosomal proteins. *Biochemistry & Cell Biology* 1995;73:933-47.
3. Rich BE, Steitz JA. Human acidic ribosomal phosphoproteins P0, P1, and P2: analysis of cDNA clones, in vitro synthesis, and assembly. *Molecular & Cellular Biology* 1987;7:4065-74.
4. Tchórzewski M, Krokowski D, Rzeski W, Issinger O-G, Grankowski N. The subcellular distribution of the human ribosomal "stalk" components: P1, P2 and P0 proteins. *The international journal of biochemistry & cell biology* 2003;35:203-11.
5. Tchórzewski M, Boldyreff B, Issinger O-G, Grankowski N. Analysis of the protein-protein interactions between the human acidic ribosomal P-proteins: evaluation by the two hybrid system. *The international journal of biochemistry & cell biology* 2000;32:737-46.
6. 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.

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