














# BioCLIA<sup>®</sup> Autoimmune Calibrator Set

SS-B/La

SS-B/La 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, SS-B/La

### Intended Use

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

### Catalog Numbers

MY00201 (2 X 1 mL)

My00252 (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.<sup>1</sup> 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-SS-B antibodies, also known as anti-La antibodies, are commonly found in primary Sjögren's Syndrome, an autoimmune disorder that affects the exocrine glands. The presence of anti-SS-B and anti-SS-A (anti-Ro antibodies) are found in 30-60% of Sjögren's Syndrome patients, but anti-SS-B antibodies are rarely found alone.<sup>2,3</sup>

Anti-SS-B antibodies are also found in SLE; however, Sjögren's Syndrome is normally also present.<sup>4</sup> In Sjögren's Syndrome, anti-SS-B antibodies correlate with early onset, increased disease duration, parotid gland enlargement, disease outside the glands and infiltration of glands by lymphocytes.<sup>5</sup> The La antigen is a 48 kDa transcription termination factor of RNA polymerase III, which associates with the Ro-RNP complex.<sup>6, 7, 8, 9</sup>

The La antigens are expressed on the surface of cells undergoing apoptosis and may cause the inflammation within the salivary gland by interaction with cells of the immune system. The antibodies may also be produced through molecular mimicry, where cross reactive antibodies bind to both virus and human proteins. This may occur with one of the La antigens and may subsequently produce antibodies to other proteins through a process known as epitope spreading. The retroviral gag protein shows similarity to the La protein and is proposed as a possible example for molecular mimicry in Sjögren's Syndrome.<sup>5, 10</sup>

### Materials supplied

- **SS-B/La Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human

antibodies to SS-B/La in 0.1 M Tris (pH7.4) buffer.

SS-B/La	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **SS-B/La Calibrator 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to SS-B/La in 0.1 M Tris (pH7.4) buffer.

SS-B/La	CAL	2
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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.<sup>10</sup> 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. Routinely 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. SS-B/La 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 SS-B/La. 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. 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.
2. 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;10:123-25.
3. Kassan SS, Moutsopoulos HM. Clinical manifestations and early diagnosis of Sjögren syndrome. Archives of internal medicine 2004;164:1275-84.
4. Yamamoto K. Pathogenesis of Sjögren's syndrome. Autoimmunity reviews 2003;2:13-18.
5. Wenzel J, Gerdson R, Uerlich M, Bauer R, Bieber T, Boehm I. Antibodies targeting extractable nuclear antigens: historical development and current knowledge. British Journal of Dermatology 2001;145:859-67.
6. 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;10:123-25.
7. Deshmukh US, Bagavant H, Lewis J, Gaskin F, Fu SM. Epitope spreading within lupus-associated ribonucleoprotein antigens. Clinical Immunology 2005;117:112-20.
8. Ben-Chetrit E. The molecular basis of the SSA/Ro antigens and the clinical significance of their autoantibodies. Rheumatology 1993;32:396-402.
9. Venables PJ. Sjögren's syndrome. Best Practice & Research Clinical Rheumatology 2004;18:313-29.
10. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



**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](http://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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HOB Biotech Group Co., Ltd

C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park,

Suzhou, Jiangsu, 215123, China