







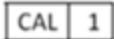






# BioCLIA<sup>®</sup> Autoimmune Calibrator Set

nRNP/Sm

nRNP/Sm 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, nRNP/Sm

### Intended Use

The BioCLIA Autoimmune Calibrator Set, nRNP/Sm is intended for the calibration of the BioCLIA nRNP/Sm performed on the BioCLIA®1200 and BioCLIA®6500.

### Catalog Numbers

MY00202 (2 X 1 mL)

MY00253 (4 X 1 mL)

### 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.<sup>1</sup> Determination of ANA has significant correlation to the diagnosis of Sharp syndrome (MCTD), SLE, sjogren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Anti-nuclear ribonucleoprotein (anti-nRNP) antibodies, also known as anti-U1-RNP antibodies, are found in 30–40% of SLE. They are often found with anti-Sm antibodies, but they may associate with different clinical associations. In addition to SLE, these antibodies are highly associated with mixed connective tissue disease. Anti-nRNP antibodies recognise the A and C core units of the snRNPs and because of this they primarily bind to the U1-snRNP.<sup>2</sup> <sup>3</sup> The immune response to RNP may be caused by the presentation of the nuclear components on the cell membrane in apoptotic blebs. Molecular mimicry has also been suggested as a possible mechanism for the production of antibodies to these proteins because of similarity between U1-RNP polypeptides and Epstein-Barr virus polypeptides.<sup>4</sup>

### Materials supplied

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

nRNP/Sm	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

nRNP/Sm	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>5</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. nRNP/Sm 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 nRNP/Sm. 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. von Mühlen C A, Tan E M. Autoantibodies in the diagnosis of systemic rheumatic diseases[C]//Seminars in arthritis and rheumatism. WB Saunders. 1995;24(5): 323-358.
3. Benito - Garcia E, Schur PH, Lahita R. Guidelines for immunologic laboratory testing in the rheumatic diseases: Anti - Sm and anti - RNP antibody tests. *Arthritis Care & Research* 2004;51:1030-44.
4. Venables PJ. Mixed connective tissue disease. *Lupus* 2006;15:132-37.
5. Richmond JY, McKinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

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#### **Technical Assistance**

For technical assistance, contact your National Distributor.