BioCLIA® Autoimmune Control Set
nRNP/Sm

nRNP/Sm Assay Controls

Key to Symbols Used

REF	Catalog Number		Expiration Date
IVD	For *In Vitro* Diagnostic Use	LOT	Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in European Union
		Σ	Contains Sufficient for < *n* > Tests
Control L	Control 1		
Control H	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA®Autoimmune Control Set, nRNP/Sm

Intended Use

The BioCLIA Autoimmune Control Set, nRNP/Sm is intended for the quality control purposes of the BioCLIA nRNP/Sm performed on the BioCLIA®1200 and BioCLIA®6500.

Catalog Numbers

MY00304 (2 X 1 mL)
MY00355 (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. [1] 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. [2, 3] 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. [4]

Materials supplied

- **nRNP/Sm Control 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to nRNP/Sm in stabilizers and preservatives (low). nRNP/Sm | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **nRNP/Sm Control 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to nRNP/Sm in stabilizers and preservatives (high). nRNP/Sm | Control | H

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on control information sheet 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. [5] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:

 Human serum is added in the controls.

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

- The product is for *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates. Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results. Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

Storage Conditions

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

The control procedure can be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Limitations

This product is designed as controls for monitoring

the performance of the BioCLIA nRNP/Sm. These controls are subjected to the limitations of the assay system. Deviations may indicate possible 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 systemicrheumatic 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.

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