














BioCLIA[®] Autoimmune Control Set

ENA Screen I

ENA Screen I Assay Controls

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
	Control 1		Contains Sufficient for $< n >$ Tests
	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Control Set,

ENA Screen I

Intended Use

The BioCLIA Autoimmune Control Set, ENA Screen I is intended for the quality control purposes of the BioCLIA ENA Screen I performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00351 (2 X 1 mL)

MY00402 (4 X 1 mL)

Summary and Explanation

Extractable Nuclear Antigens are over 100 different soluble cytoplasmic and nuclear antigens. Autoantibodies to these antigens are associated with particular connective tissue disorders. Six of eight main antigens used in immunological laboratories for detection are Ro52, SS-B/La, Sm, nRNP/Sm, Scl-70 and Jo-1, ¹ which are screened for by Ouchterlony double immuno diffusion techniques and confirmed by immunoblotting. Ro60 and CENP-B are also specific ENA antigens. ^{2,3}

Anti-ENA is a group of antibodies often used to screen for mixed connective tissue disease (MCTD), Sjögren's syndrome and systemic lupus erythematosus (SLE) and is commonly composed of eight tests: anti-Sm for SLE, anti-nRNP/Sm for MCTD, anti-SS-B/La for Sjögren's, anti-Ro52 for Sjögren's Syndrome, anti-Scl-70 for Scleroderma, anti-Jo-1 for Dermatomyositis, anti-Ro60 for Sjögren's Syndrome, anti-CENP-B for CREST syndrome. ⁴⁻⁶

Materials supplied

- **ENA Screen I Control 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to ENA Screen I in stabilizers and preservatives (Low).

ENA Screen I | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **ENA Screen I Control 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to ENA Screen I in stabilizers and preservatives (High).

ENA Screen I | 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. ⁷ 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 ENA Screen I. 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

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for detection of antibodies recognizing extractable nuclear antigens. Journal of Clinical Laboratory Analysis 1998;12:320-4.

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5. 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;10:123-5.

6. Stahnke G, Meier E, Scanarini M, Northemann W. Eukaryotic Expression of Recombinant Human Centromere Autoantigen and its use in a Novel ELISA for Diagnosis of CREST Syndrome. Journal of Autoimmunity 1994;7:107-18.

7. 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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