BioCLIA® Autoimmune Calibrator Set

ENA Screen I

ENA Screen I Assay Calibrators

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
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator Set, ENA Screen I

Intended Use

The BioCLIA Autoimmune Calibrator Set, ENA Screen I is intended for the calibration of the BioCLIA ENA Screen I performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00249 (2 X 1 mL)

My00300 (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 Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to ENA Screen I in stabilizers and preservatives.

ENA Screen I	CAL	1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

ENA Screen I	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. [7] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective gloves and 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. 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. ENA Screen I 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 ENA Screen I. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

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References

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3. Nakamura M, Kondo H, Mori T, Komori A, Matsuyama M, Ito M, et al. Anti-gp210 and anti-centromere antibodies are different risk factors for the progression of primary biliary cirrhosis †. Hepatology 2007;45:118-27.
4. Lock RJ, Unsworth DJ. Antibodies to extractable nuclear antigens. Has technological drift affected clinical interpretation? Journal of Clinical Pathology 2001;54:187-90.
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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EC REP

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Technical Assistance

For technical assistance, contact your National Distributor.

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