







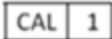

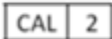




BioCLIA[®] Autoimmune Calibrator Set

Sci-70

Sci-70 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, Scl-70

Intended Use

The BioCLIA Autoimmune Calibrator Set, Scl-70 is intended for the calibration of the BioCLIA Scl-70 performed on the BioCLIA®BioCLIA®1200 and BioCLIA®6500.

Catalog Numbers

MY00205 (2 X 1 mL)

MY00256 (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 antibody.¹ Determination of ANA has significant correlation to the diagnosis of Sharp syndrome (MCTD), systemic lupus erythematosus (SLE), sjogren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Scl-70 antigen is a kind of DNA topoisomerase I. It is with the molecular weight of 100 kDa for natural type and most of them are hydrolyzed to form 70 kDa protein. DNA topoisomerase I exists in nucleoplasm and with a high concentration in nucleolus, participating in partially spiral release effect in DNA replication and transcription.

Anti-Scl-70 antibodies are specific markers of scleroderma patients (specificity of 98-100%).² Anti-Scl-70 antibodies are associated with diffuse skin lesion and pulmonary fibrosis. The sensitivity of the antibodies for scleroderma is approximately 34%, but is higher for cases with diffuse cutaneous involvement (40%), and lower for limited cutaneous involvement (10%). The specificity of the antibodies is 98% and 99.6% in other rheumatic diseases and normal individuals, respectively.^{3, 4} In addition to scleroderma, these antibodies are found in approximately 5% of individuals with SLE.⁵ The antigenic target of anti-Scl-70 antibodies is topoisomerase I.⁶

Materials supplied

- **Scl-70 Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Scl-70 in stabilizers and preservatives.

Scl-70 CAL 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **Scl-70 Calibrator 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Scl-70 in stabilizers and preservatives.

Scl-70 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 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®BioCLIA®1200 and BioCLIA®6500 User Manual.

See the BioCLIA®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®BioCLIA®1200 and BioCLIA®6500 using specific lots of reagents against an in-house standard. Scl-70 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 Scl-70. 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

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3. Kavanaugh A, Tomar R, Reveille J, Solomon DH, Homburger HA. Guidelines for clinical use of the antinuclear antibody test and tests for specific autoantibodies to nuclear antigens. *Archives of pathology & laboratory medicine* 2000;124:71-81.
4. Ho KT, Reveille JD. The clinical relevance of autoantibodies in scleroderma. *Arthritis Res Ther* 2003;5:1.
5. Mahler M, Silverman ED, Schulte-Pelkum J, Fritzler MJ. Anti-Scl-70 (topo-I) antibodies in SLE: myth or reality? *Autoimmunity reviews* 2010;9:756-60.
6. Guldner H-H, Szostecki C, Vosberg H-P, Lakomek H-J, Penner E, Bautz FA. Scl 70 autoantibodies from scleroderma patients recognize a 95 kDa protein identified as DNA topoisomerase I. *Chromosoma* 1986;94:132-38.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

EUROPE REPRESENTATIVE: Emergo Europe

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Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019

Revision 9



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