

## BioCLIA Autoimmune Calibrator Set, Scl-70

Cat.No.	Kit Size
MY00205	2 X 1 mL
MY00256	4 X 1 mL

### INTENDED USE

The BioCLIA Autoimmune Calibrator Set, Scl-70 is intended for the calibration of the BioCLIA Scl-70 performed on the BioCLIA 6500 and BioCLIA 500.

For professional *in vitro* diagnostic use only.

### SUMMARY AND EXPLANATION

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), 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%).<sup>2</sup> 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.<sup>3, 4</sup> In addition to scleroderma, these antibodies are found in approximately 5% of individuals with SLE.<sup>5</sup> The antigenic target of anti-Scl-70 antibodies is topoisomerase I.<sup>6</sup>

### MATERIALS SUPPLIED

- Scl-70 Calibrator 1** Barcode labeled tubes with buffer containing human antibodies to Ro60 in stabilizers and preservatives. Ready to use, 1 mL.

CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- Scl-70 Calibrator 2** Barcode labeled tubes with buffer containing human antibodies to Ro60 in stabilizers and preservatives. Ready to use, 1 mL.

CAL	2
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Calibrator Code contains calibrators' information is provided in each kit.

### WARNINGS AND PRECAUTIONS

- For professional *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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established!

### Precautions:



Human serum is added in the calibrators.

- 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>7</sup> Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective gloves and clothing.



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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened calibrators could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 20 calibrations, after which the reagent must be discarded.
- Avoid repeated freezing and thawing.

## ASSAY PROCEDURE

Detailed information about operating the BioCLIA instruments can be taken from the Instrument User's Manual.

Note that, it is important to perform all routine maintenance procedures for optimal performance.

### Assay Calibration

The BioCLIA Autoimmune Reagent Kit utilizes a predefined lot specific Master Curve which is uploaded into the instrument via the barcode provided in the main reagent kit. The Calibrator Code contains calibrator information is then scanned. Based on the results of running two calibrators, the instrument specific Working Calibration Curve is generated and is used to calculate the concentration from the RLU obtained for each patient.

For each new lot of reagent, please calibrate prior to the first time use, and every 28 days thereafter. The software will not allow the lot to be used if the above requirements are not meet.

### Programming and Running samples

1. Put the kit into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the kit can be uploaded into the instrument system through the scanning of reagent barcode, and can also be set through the supporting software of the instrument.
2. The information of calibrator / quality control is identified by scanning the calibrator / control barcodes, and the position of calibrator / quality control is assigned in the instrument system.
3. The sample to be tested is placed on the instrument sample rack chamber, and the corresponding test information is edited through the instrument supporting software.
4. Start the operation procedure, and all calibrator / quality control / sample processing steps will be automatically executed.

## TRACEABILITY

The reported values were determined over multiple runs on the BioCLIA 6500 and BioCLIA 500 using specific lots of reagents against an in-house standard. DGP IgA 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

- The calibrators are designed for calibration of the same lot of BioCLIA Autoimmune Reagent Kit.
- The calibrators can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 20 calibrations are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper calibration of the assay and which can give improper results.

## SYMBOLS

	Calibrator 1
	Calibrator 2

	Catalog Number		Use-by date
	In Vitro diagnostic medical device		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in the European Community
	CE Marking		Contains Sufficient for <n> Tests
	Biological Risk		GHS07 Warning

## REFERENCE

1. Kumar Y, Bhatia A, Minz RW. Antinuclear antibodies and their detection methods in diagnosis of connective tissue diseases: a journey revisited. *Diagnostic pathology* 2009;4:1.
2. 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;10:123-25.
3. Defendenti C, Atzeni F, Spina MF, Grosso S, Cereda A, Guercilena G, et al. Clinical and laboratory aspects of Ro/SSA-52 autoantibodies. *Autoimmunity reviews* 2011;10:150-54.
4. Venables PJ. Sjögren's syndrome. *Best Practice & Research Clinical Rheumatology* 2004;18:313-29.
5. Scofield RH. Autoantibodies as predictors of disease. *The Lancet* 2004;363:1544-46.
6. Yamamoto K. Pathogenesis of Sjögren's syndrome. *Autoimmunity reviews* 2003;2:13-18.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



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The eIFU is available on Website:

<http://en.hob-biotech.com/usercenter/login.aspx>

## TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

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