BioCLIA Autoimmune Control Set, Scl-70

Cat.No.	Kit Size
MY00307	2 X 1 mL
MY00358	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, Scl-70 is intended for the quality control purposes 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 antibodies (ANAs) are 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 ANAs has significant correlation to the diagnosis of Sharp Syndrome, 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 Control N** Barcode labeled tubes with buffer containing human antibodies to Scl-70 in stabilizers and preservatives. Ready to use, 1 mL.

Control | N

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

Control | P

Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Control Code contains controls' information is provided in each kit.

Target value and acceptance range for the controls are indicated on the card provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *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.
- 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 controls.

- 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.

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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened controls could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 35 controls, 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.

Control

The control procedure should be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.
Each Laboratory should establish its own reference ranges.

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 controls are designed for control of the same lot of BioCLIA Autoimmune Reagent Kit.
- The controls can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 35 controls are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper results.

SYMBOLS

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

Control N	Negative Control
Control P	Positive Control

REFERENCE

1. Tan EM. Autoantibodies to nuclear antigens (ANA): their immunobiology and medicine. Advances in Immunology 1982;33:167-240.
2. Jimenez SA, Derk CT. Following the molecular pathways toward an understanding of the pathogenesis of systemic sclerosis. Annals of internal medicine 2004;140:37-50.
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.

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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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