BioCLIA Autoimmune Calibrator Set, dsDNA

Cat.No.	Kit Size
MY00199	2 X 1 mL
MY00250	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Calibrator Set, dsDNA is intended for the calibration of the BioCLIA dsDNA 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).

Anti-DNA antibody can be divided into two types: anti-double-stranded DNA (dsDNA) antibodies and anti-denatured single-stranded DNA (ssDNA) antibodies. Anti-dsDNA antibody can bind to the double helix of DNA skeleton, having interaction with ds- and ss-DNA. For the anti-ssDNA antibody, it only interacts with purine or pyrimidine base polymers.[2, 3] Anti-dsDNA antibody is generally seen as a diagnostic indicator for SLE because of its high specificity (40-90%) to SLE. Anti-dsDNA antibody determination helps the diagnosis of SLE activity that associated especially with SLE caused renal damage.[4,5]

Researchers showed that anti-dsDNA antibody may cause tissue damage in SLE patients. Macromolecular DNA concentration is rather high in the blood circulation of patients with SLE, and it combines with organs through the capillary, especially in kidney.[6] The anti-dsDNA antibodies and DNA molecules formed immune complex that will precipitate in tissues and cause diseases. For example, the immune complex deposite on the glomerular basement membrane or anti-dsDNA antibodies directly interacts with glomerulus antigens and lead to renal damages. According to the statistics, anti-dsDNA antibody positive patients take a risk of nephritis 12 times higher than anti-dsDNA antibody negative patients. Concentration of anti-dsDNA antibody will decrease or disappear as the control of disease activity.[7]

MATERIALS SUPPLIED

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

CAL	1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

CAL	2

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. [7] 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

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
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		

REFERENCE

1. Casals SP, Friou GJ, Myers LL. Significance of antibody to DNA in systemic lupus erythematosus. Arthritis & Rheumatism 1964;7:379-90.
2. Tan EM, Cohen AS, Fries JF, Masi AT, Mcshane DJ, Rothfield NF, et al. The 1982 revised criteria for the classification of systemic lupus erythematosus. Arthritis & Rheumatism 1982;25:1271-77.
3. Arana R, Seligmann M. Antibodies to native and denatured deoxyribonucleic acid in systemic lupus erythematosus. Journal of Clinical Investigation 1967;46:1867.
4. Gonzalez EN, Rothfield NF. Immunoglobulin class and pattern of nuclear fluorescence in systemic lupus erythematosus. New England Journal of Medicine 1966;274:1333-38.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.

CE IVD

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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.

Date of issue: 17th March 2019

Date of revision: 20th December 2021

Change Control Number: CN21129E

Version: A/1 (EN)