BioCLIA® Autoimmune Control Set

dsDNA

dsDNA Assay Control

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
			Contains Sufficient for < *n* > Tests
Control L	Control 1		Chemical Risk Warning
Control H	Control 2		Biological Risk Warning

BioCLIA® Autoimmune Control Set, dsDNA

Intended Use

The BioCLIA dsDNA Control Set is intended for the quality control purposes of the BioCLIA dsDNA performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00301 (2 x 1 mL)
MY00352 (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 antibodies. 1 Determination of ANA has significant correlation to the diagnosis of Sharp syndrome (MCTD), 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 while ssDNA antibody only interacts with purine or pyrimidine base polymers.2, 3 Anti-dsDNA antibodies are recognized as the major serologic marker of SLE. Their specificity and their sensitivity give them a high diagnostic value. Therefore they are a part of the clinical and biological criteria established in 1982 by the American Rheumatism Association (ARA) for the diagnosis of the SLE. The detection of anti-dsDNA antibodies is particularly useful in two different ways: as an aid to the diagnosis of SLE and as a tool to monitor the course of the disease. For the second purpose repeated serum sampling of individual patients can be very informative about the clinical course of the disease because a clear-cut relationship exists between anti-DNA and diseases activity : flares of SLE are generally preceded by a rise in anti-dsDNA levels, followed by a steep drop during the exacerbation (particularly in nephritis). Furthermore different treatments of patients have varying influences on anti-dsDNA levels and can be adapted by a regular follow-up of these antibodies.

Materials supplied

- **dsDNA Control 1** A tube contains 1mL ready to use reagent. Control contains human antibodies to dsDNA in stabilizers and preservatives (Low).

Preservatives: NaN3 < 0.1%. dsDNA | Control | L

- **dsDNA Control 2** A tube contains 1mL ready to use reagent. Control contains human antibodies to dsDNA in stabilizers and preservatives (High).

Preservatives: NaN3 < 0.1%. dsDNA | Control | H

Target value and acceptable range for the controls are indicated on control information sheet 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. [5] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective gloves and clothing.

Precautions: 

Human serum is added in the controls.

- The product is for *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.
- 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

The kit is stable until the expiration date, if it is stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a control 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.

The control procedure can be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Limitations

This product is designed as controls for monitoring the performance of the BioCLIA dsDNA. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

References

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.

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Technical Assistance

For technical assistance, contact your National Distributor.

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