BioCLIA® Autoimmune Control Set

Histone

Histone Assay Controls

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

BioCLIA® Autoimmune Control Set, Histone

Intended Use

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

Catalog Numbers

MY00312 (2 X 1 mL)

MY00363 (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), systemic lupus erythematosus (SLE), sjogren's syndrome, progressive systemic sclerosis, polymyositis/dermatomyositis, overlap syndrome, and limited types of progressive systemic sclerosis (CREST syndrome).

Histones (His) are DNA related proteins (11.2 - 21.5 kDa) with stable DNA double helix structure. There are five different types of His include H1, H2A, H2B, H3 and H4. They are participate in gene regulation mechanism and related to highly ordered nucleosome formation.

Anti-histone antibodies are found up to 75–95% in the serum of people with drug induced lupus and 75% of idiopathic SLE. Unlike anti-dsDNA antibodies in SLE, these antibodies do not fix complement. Although they are most commonly found in drug induced lupus, they are also found in some cases of SLE, scleroderma, rheumatoid arthritis and undifferentiated connective tissue disease. Many drugs are known to cause drug induced lupus and they produce various antigenic targets within the nucleosome that are often cross reactive with several histone proteins and DNA. Procainamide causes a form of drug-induced lupus that produces antibodies to the histone H2A and H2B complex. [2, 3]

Materials supplied

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

Histone	Control	L

Preservatives: 5-Bromo-5-Nitro-1, 3-Dioxane (BND) < 1%.

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

Histone	Control	H

Preservatives: 5-Bromo-5-Nitro-1, 3-Dioxane (BND) < 1%.

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. [4] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective 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 Histone. 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. Tan EM. Autoantibodies to nuclear antigens (ANA): their immunobiology and medicine. Advances in Immunology 1982;33:167-240.

2. Vasoo S. Drug-induced lupus: an update. Lupus 2006;15:757-61.

3. Katz U, Zandman-Goddard G. Drug-induced lupus: An update. Autoimmunity Reviews 2010;10:46-50.

4. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

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Technical Assistance

For technical assistance, contact your National Distributor.

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