














BioCLIA[®] Autoimmune Calibrator Set, Histone

Histone Assay Calibrators

Key to Symbols Used			
	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Calibrator 1		Contains Sufficient for < <i>n</i> > Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator

Set, Histone

Intended Use

The BioCLIA Autoimmune Calibrator Set, Histone is intended for the calibration of the BioCLIA Histone performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00210 (2 X 1 mL)

MY00261 (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 Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to Histone in stabilizers and preservatives.

Histone CAL 1

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

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

Histone CAL 2

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

Target value information is indicated in the 2D barcode localized 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 calibrators.

- The product is for *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.
- 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

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

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. Histone 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

This product is designed as calibrators for monitoring the performance of the BioCLIA Histone. These calibrators are subjected to the limitations of the assay system. Deviations may indicate 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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