BioCLIA® Autoimmune Calibrator

LC-1

LC-1 Assay Calibrators

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
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA®Autoimmune Calibrator, LC-1

Intended Use

The BioCLIA Autoimmune Calibrator, LC-1 is intended for the calibration of the BioCLIA LC-1 performed on the BioCLIA®1200 and BioCLIA® 6500.

Catalog Numbers

MY00219 (2 X 1 mL)

MY00270 (4 X 1 mL)

Summary and Principles of the Procedure

Autoimmune liver diseases (ALD) include autoimmune hepatitis (AIH), [1, 2] primary biliary cirrhosis (PBC) [3] and primary sclerosing cholangitis (PSC). [4] Determination of indicatiors such as AMA, CENP-B, LKM-1 and SLA/LP has significant correlation to ALD diagnosis.

Anti liver cytosol 1 antibodies (anti-LC-1 antibodies) are specific bind to a 60 kDa protein which is identified as formiminotransferase (cyclodeaminase). Anti-LC-1 antibodies are highly correlated to anti-LKM-1 antibodies, both can be detected in young AIH patients. About 50% - 60% of anti-LKM-1 antibodies positive ones are anti-LC-1 antibodies positive. [5, 6]

Materials supplied

- **LC-1 Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1 contains human antibodies to LC-1 in stabilizers and preservatives. LC-1 | CAL | 1

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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. [7] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:

 Human serum is added in the Calibrators.

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

- 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. LC-1 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 LC-1. 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. Czaja AJ. Autoimmune liver disease. Current Opinion in Gastroenterology 2007;23:255-62.

2. Manns MP, Czaja AJ, Gorham JD, Krawitt EL, Mieli‐Vergani G, Vergani D, Vierling JM. Diagnosis and management of autoimmune hepatitis. Hepatology 2010;51:2193-213.

3. Nakamura M, Kondo H, Mori T, Komori A, Matsuyama M, Ito M, et al. Anti‐gp210 and anti‐centromere antibodies are different risk factors for the progression of primary biliary cirrhosis. Hepatology 2007;45:118-27.
4. T Tabibian JH, Lindor KD. Primary sclerosing cholangitis: a review and update on therapeutic developments. Expert review of gastroenterology & hepatology 2013;7:103-14.
5. Martini E, Abuaf N, Cavalli F, Durand V, Johanet C, Homberg JC. Antibody to liver cytosol (anti‐LC1) in patients with autoimmune chronic active hepatitis type 2. Hepatology 1988;8:1662-66.
6. Han S, Tredger M, Gregorio GV, Mieli‐Vergani G, Vergani D. Anti‐liver cytosolic antigen type 1 (LC1) antibodies in childhood autoimmune liver disease. Hepatology 1995;21:58-62.
7. 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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Revision 9