BioCLIA® Autoimmune Calibrator Set

GBM

GBM 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 Set, GBM

Intended Use

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

Catalog Numbers

MY00215 (2 X 1 mL)

MY00266 (4 X 1 mL)

Summary and Principles of the Procedure

Serological detection of anti-neutrophil cytoplasmic antibodies (ANCAs) contributes to the autoimmune diseases diagnosis include Wegener's granulomatosis, acute progressive glomerulonephritis, polyarteritis, ulcerative colitis, and primary sclerosing cholangitis. [1, 2] PR3, MPO and GBM are general indicators for the detection of ANCAs, which can greatly improve the early diagnostic rate of renal vasculitis.

The main component of the glomerular basement membrane (GBM) is the extracellular matrix protein including type IV collagen, laminin, fibronectin and proteoglycans. The epitope of anti-GBM antibodies are located on the type IV collagen. Type IV collagen molecule is composed of three chains of 170 kDa. These chains form several triple-helix domains, and the domains are separated by the amino acid sequence which cannot form the helix. A tight spiral zone (7S domain) is located at the amino terminal and a spherical handle shaped structure (NC1 domain) at the carboxy terminal. The target antigen of anti-GBM antibodies is in NC1 domain of α-3 (IV) chain.

Anti-GBM antibody is a serological indicator for all anti-GBM glomerulonephritis including Goodpasture's syndrome. [3, 4] In cases with no lung disorders, the positive rate of anti-GBM antibody is 60% while it is 80% - 90% in cases with lung disorders. Although the incidence of Goodpasture's syndrome is relatively low (only 0.5% of all kidney disorder patients), but the disease develop rapidly. If not treated well, the mortality rate will as high as 75-90%. [5, 6] Early diagnosis and proper treatment can significantly reduce the mortality.

Materials supplied

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

GBM | CAL | 1

Preservatives: 0.0015% < Proclin 300 < 0.6%

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

GBM | 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 c 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. GBM 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 GBM. 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

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2. Bossuyt X. Serologic markers in inflammatory bowel disease. Clinical Chemistry 2006;52:171-81.
3. Hellmark T, Johansson C, Wieslander J. Characterization of anti-GBM antibodies involved in Goodpasture's syndrome. Kidney International 1994;46:823-9.
4. Salama AD, Levy JB, Lightstone L, Pusey CD. Goodpasture's disease. Lancet 2001;358:917–20.
5. Herody M, Bobrie G, Gouarin C, Grünfeld JP, Noel LH. Anti-GBM disease: predictive value of clinical, histological and serological data. Clinical Nephrology 1993;40:249-55.
6. Kathuria P, Sanghera P, Stevenson FT, Sharma S, Lederer E, Lohr JW, Talavera F, et al. Goodpasture Syndrome Treatment & Management. Medscape Reference. 2013.
7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

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EC REP

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Technical Assistance

For technical assistance, contact your National Distributor.

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