BioCLIA Autoimmune Control Set, GBM

Cat.No.	Kit Size
MY00317	2 X 1 mL
MY00368	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, GBM is intended for the quality control purposes of the BioCLIA GBM performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

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 develops 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 Control N** Barcode labeled tubes with buffer containing human antibodies to GBM in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **GBM Control P** Barcode labeled tubes with buffer containing human antibodies to GBM in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.
The Control Code contains controls' information is provided in each kit.
Target value and acceptance range for the controls are indicated on the card provided in each kit.

WARNINGS AND PRECAUTIONS

- For professional *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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established!

Precautions:


Human serum is added in the controls.

- 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.

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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened controls could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 35 controls, after which the reagent must be discarded.
- Avoid repeated freezing and thawing.

ASSAY PROCEDURE

Detailed information about operating the BioCLIA instruments can be

taken from the Instrument User's Manual.

Note that, it is important to perform all routine maintenance procedures for optimal performance.

Control

The control procedure should be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.
Each Laboratory should establish its own reference ranges.

Programming and Running samples

1. Put the kit into the corresponding position of the reagent chamber of the fully automatic chemiluminescence analyzer. The information of the kit can be uploaded into the instrument system through the scanning of reagent barcode, and can also be set through the supporting software of the instrument.
2. The information of calibrator / quality control is identified by scanning the calibrator / control barcodes, and the position of calibrator / quality control is assigned in the instrument system.
3. The sample to be tested is placed on the instrument sample rack chamber, and the corresponding test information is edited through the instrument supporting software.
4. Start the operation procedure, and all calibrator / quality control / sample processing steps will be automatically executed.

TRACEABILITY

The reported values were determined over multiple runs on the BioCLIA 6500 and BioCLIA 500 using specific lots of reagents against an in-house standard. DGP IgA 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

- The controls are designed for control of the same lot of BioCLIA Autoimmune Reagent Kit.
- The controls can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 35 controls are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper results.

SYMBOLS

REF	Catalog Number		Use-by date
IVD	In Vitro diagnostic medical device	LOT	Lot Number
+2°C +8°C	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Marking		Contains Sufficient for<n>Tests
	Biological Risk		GHS07 Warning

Control N	Negative Control
Control P	Positive Control

REFERENCE

1. Savige J, Davies D, Falk RJ, Jennette JC, Wiik A. Antineutrophil cytoplasmic antibodies and associated diseases: a review of the clinical and laboratory features. Kidney International 2000;57:846-62.
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.

CE IVD

HOB Biotech Group Corp., Ltd.
C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park,
Suzhou, Jiangsu, 215123, China

CONTACT INFORMATION:
TEL (+86)512-69561996
Fax (+86)512-62956652
WEBSITE: www.hob-biotech.com
CUSTOMER SERVICE: HOB Biotech Group Co., Ltd
CUSTOMER SERVICE: TEL (+86)4008601202

EC REP

EUROPE REPRESENTATIVE: Emergo Europe
ADDRESS/LOCATION:
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

The eIFU is available on Website:
http://en.hob-biotech.com/usercenter/login.aspx

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

Date of issue: 17th March 2019

Date of revision: 20th December 2021

Change Control Number: CN21129E

Version: A/1 (EN)