BioCLIA® Autoimmune Control Set

MPO

MPO 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, MPO

Intended Use

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

Catalog Numbers

MY00315 (2 X 1 mL)
MY00366 (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.

Peroxidase, also called myeloperoxidase (MPO), is an important iron contained lysosome, exists in the aniline blue particles of myeloid cells (mainly neutrophils and monocytes). MPO is an indicator for the myeloid cells, the activity of neutrophils, or function of eosinophilic polymorphonuclear leukocyte (PMN). In addition, MPO is considered to be the target antigen of most pANCA. pANCA may occur in diseases other than vasculitis. [3, 4, 5]

MPO is closely related to the occurrence and development of human diseases such as the microscopic arterial inflammation (MPA), necrotizing crescents glomerulonephritis (NCGN), variational granulomatous vasculitis (CSS), *etc.* The antibody titer concerns disease activity and can be used for early diagnosis, treatment, recurrence and guidance of treatment. The highly expression of MPO antibody indicates the occurrence of necrotizing vasculitis or idiopathic NCGN, which can reach 99% specificity for the diagnosis of Panca. [6, 7, 8, 9]

Materials supplied

- **MPO Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains human antibodies to MPO in stabilizers and preservatives (Low). MPO | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **MPO Control 2** A tube contains 1mL, ready to use reagent. Control 2 contains human antibodies to MPO in stabilizers and preservatives (High). MPO | Control | H

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

Precautions:

 Human serum is added in the controls.

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

- 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 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 MPO. 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. 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. Blairjohnson M, Fiedler T, Fenna R. Human myeloperoxidase: structure of a cyanide complex and its interaction with bromide and thiocyanate substrates at 1.9 A resolution. Biochemistry 2001;40:13990-7.
4. Klebanoff SJ. Myeloperoxidase: friend and foe. Journal of Leukocyte Biology 2005;77:598-625.
5. Jr KJ, Pember SO, Barnes KC, Shapira R, Spitznagel JK, Martin LE. Differential distribution of distinct forms of myeloperoxidase in different azurophilic granule subpopulations from human neutrophils. Biochemical & Biophysical Research Communications 1983;114:296-303.
6. Zhang R, Brennan M-L, Fu X, Aviles RJ, Pearce GL, Penn MS, et al. Association between myeloperoxidase levels and risk of coronary artery disease. Jama 2001;286:2136-42.
7. Nicholls SJ, Hazen SL. Myeloperoxidase and cardiovascular disease. Arteriosclerosis, thrombosis, and vascular biology 2005;25:1102-11.
8. Lau D, Baldus S. Myeloperoxidase and its contributory role in inflammatory vascular disease. Pharmacology & therapeutics 2006;111:16-26.
9. Csernok E, Moosig F. Current and emerging techniques for ANCA detection in vasculitis. Nature Reviews Rheumatology 2014;10:494-501.
10. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

CE IVD

HOB Biotech Group Co., Ltd

C6 Building, No. 218 Xinghu Road, SuzhouIndustrial Park,

Suzhou, Jiangsu, 215123, China

REGISTRANT/MANUFACTURE: HOB Biotech Group Co., Ltd

ADDRESS/LOCATION:

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 CONTACT: TEL (+86)4008601202

EC REP

EUROPE REPRESENTATIVE: Emergo Europe

ADDRESS/LOCATION:

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019

Revision 9