BioCLIA® Autoimmune Control Set

PR3

PR3 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, PR3

Intended Use

The BioCLIA Autoimmune Control Set, PR3 is intended for the quality control purposes of the BioCLIA PR3 performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00316 (2 X 1 mL)

MY00367 (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.

Proteinase 3 (PR3) is a serine protease existing in neutrophils cytoplasm eosinophilic azure particles, with molecular weight about 29 kD. PR3 can degrade many kinds of extracellular matrix such as elastin, hemoglobin and type IV collagen. PR3 promotes platelet activation by cathepsin G and makes the C1 inhibitor inactivation. [3] According to its karyotype of fluorescence performance in ethanol fixed neutrophils, ANCA can be divided into cytoplasm ANCA (cANCA) and peripheral ANCA (pANCA). PR3 is with ethanol fixed neutrophils cANCA fluorescence mode in indirect immunofluorescence test. [4]

Anti-PR3 antibody is with specificity of 90% to wiig granulomatosis (WG). The sensitivity of anti-PR3 antibody is about 65% in WG patients when pathological changes have not yet affected the respiratory system. Sensitivitywill increase to 90% when WG patients have respiratory system or kidney damage. A few of WG patients have not been treated are anti-PR3 antibody negative but will eventually turn to positive. The antibody concentration will decrease when WG patients are treated and it is taken as an indicator for monitoring and guiding clinical treatment. Anti-PR3 antibody has affinity to the respiratory tract, causing the upper and lower respiratory tract necrosis and granuloma formation. [5, 6]

Materials supplied

- **PR3 Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains human antibodies to PR3 in stabilizers and preservatives (Low).

PR3	Control	L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **PR3 Control 2** A tube contains 1mL, ready to use reagent. Control 2 contains human antibodies to PR3 in stabilizers and preservatives (High).

PR3	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. [7] 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 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.

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 PR3. 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

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2. Bossuyt X. Serologic markers in inflammatory bowel disease. Clinical Chemistry 2006;52:171-81.

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4. Van der Geld Y, Limburg P, Kallenberg C. Proteinase 3, Wegener's autoantigen: from gene to antigen. Journal of leukocyte biology 2001;69:177-90.

5. Watorek E, Boratynska M, Klinger M. Wegener's granulomatosis-autoimmunity to neutrophil proteinase 3. ARCHIVUM IMMUNOLOGIAE ET THERAPIAE EXPERIMENTALIS-ENGLISH EDITION- 2003;51:157-68.

6. Sturrock AB, Franklin KF, Rao G, Marshall BC, Rebentisch MB, Lemons RS, Hoidal JR. Structure, chromosomal assignment, and expression of the gene for proteinase-3. The Wegener's granulomatosis autoantigen. Journal of Biological Chemistry 1992;267:21193-99.

7. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO.1999.

IVD

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Technical Assistance

For technical assistance, contact your National Distributor.

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