

BioCLIA Autoimmune Control Set, PR3

Cat.No.	Kit Size
MY00316	2 X 1 mL
MY00367	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, PR3 is intended for the quality control purposes of the BioCLIA PR3 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 (ANCA) 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 ANCA, 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 Wegener's granulomatosis (WG). The sensitivity of anti-PR3 antibody is about 65% in WG patients when pathological changes have not yet affected the respiratory system. Sensitivity will 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 N** Barcode labeled tubes with buffer containing human antibodies to PR3 in stabilizers and preservatives. Ready to use, 1 mL.

Control	L
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **PR3 Control P** Barcode labeled tubes with buffer containing human antibodies to PR3 in stabilizers and preservatives. Ready to use, 1 mL.

Control	P
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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

- 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.
- 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.
- 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.
- 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

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

Control	N	Negative Control
Control	P	Positive Control

REFERENCE

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The eIFU is available on Website:

<http://en.hob-biotech.com/usercenter/login.aspx>

TECHNICAL ASSISTANCE

For technical assistance, contact your National Distributor.

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