

BioCLIA Autoimmune Control Set, β 2 Glycoprotein 1 IgM

Cat.No.	Kit Size
MY00330	2 X 1 mL
MY00381	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, β 2 Glycoprotein 1 IgM is intended for the quality control purposes of the BioCLIA β 2 Glycoprotein 1 IgM performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

β -2 glycoprotein I (or called apolipoprotein H) antigens are plasma proteins existing free or bound to low density lipoprotein. They act as an auxiliary factor for cardiolipin and anti-cardiolipin antibody combination. ^{1, 2} In autoimmune disease, anti- β -2 glycoprotein I antibodies, also called anti-apolipoprotein H (AAHA) antibodies, comprise a subset of anti-cardiolipin antibodies and lupus anticoagulant.

These antibodies are involved in sclerosis and are strongly associated with thrombotic forms of lupus, as a result they are strongly implicated in autoimmune deep vein thrombosis. ³ About 30-60% anti-phospholipid syndrome (APS) patients are anti- β -2 glycoprotein I antibodies positive. They are also closely associated with thrombosis. Determination of anti- β -2 glycoprotein I antibodies can significantly increase the prediction rate of thrombosis complications. ⁴ As these antibodies only appear in autoimmune disease patients, they are regarded as autoimmune thrombus markers to distinguish autoimmune diseases and infectious diseases. ⁵ Anti- β -2 glycoprotein I antibodies have a specificity of 98% while anti-cardiolipin antibodies (aCL) of 75% for APS diagnosis; however, the sensitivity is only 54% which is lower than the aCL. Besides, concentration of anti- β -2 glycoprotein I antibodies is related to the severity of thrombosis in systemic lupus erythematosus (SLE) patients. ⁶

MATERIALS SUPPLIED

- **β 2 Glycoprotein 1 IgM Control N** Barcode labeled tubes with buffer containing human IgM antibodies to β 2 Glycoprotein 1 in stabilizers and preservatives. Ready to use, 1 mL.

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

- **β 2 Glycoprotein 1 IgM Control P** Barcode labeled tubes with buffer containing human IgM antibodies to β 2 Glycoprotein 1 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 <n> Tests
	Biological Risk		GHS07 Warning

	Negative Control
	Positive Control

REFERENCE

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- Galli M, Bevers E, Comfurius P, Barbui T, Zwaal R. Effect of antiphospholipid antibodies on procoagulant activity of activated platelets and platelet - derived microvesicles. British journal of haematology 1993;83:466-72.
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- Tsutsumi A, Matsuura E, Ichikawa K, Fujisaku A, Mukai M, Kobayashi S, Koike T. Antibodies to β 2-glycoprotein I and clinical manifestations in patients with systemic lupus erythematosus. Arthritis & Rheumatism 1996;39:1466-74.
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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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