






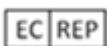







BioCLIA[®] Autoimmune Control Set

β2 Glycoprotein 1 IgG

β2 Glycoprotein 1 IgG Assay Controls

Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Control 1		Contains Sufficient for $< n >$ Tests
	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Control Set, β 2 Glycoprotein 1 IgG

Intended Use

The BioCLIA Autoimmune Control Set, β 2 Glycoprotein 1 IgG is intended for the quality control purposes of the BioCLIA β 2 Glycoprotein 1 IgG performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00329 (2 X 1 mL)

MY00380 (4 X 1 mL)

Summary and Principles of the Procedure

β -2 glycoprotein I (or called apolipoprotein H) antigens are plasma proteins exist 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 that 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, anti- β -2 glycoprotein I antibodies concentration is related to the severity of thrombosis in systemic lupus erythematosus (SLE) patients.⁶

Materials supplied

- **β 2 Glycoprotein 1 IgG Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains human antibodies to β 2 Glycoprotein 1 in stabilizers and preservatives (Low).

β 2GP1-G | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

β 2GP1-G | 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 β 2 Glycoprotein 1 IgG. 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. Schousboe I, Rasmussen M. Synchronized inhibition of the phospholipid mediated autoactivation of factor XII in plasma by beta 2-glycoprotein I and anti-beta 2-glycoprotein I. Thrombosis and haemostasis 1995;73:798-804.
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6. 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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Technical Assistance

For technical assistance, contact your National Distributor.

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Revision 9



EUROPE REPRESENTATIVE: Emergo Europe