

BioCLIA Autoimmune Control Set, DGP IgA

Cat.No.	Kit Size
MY00344	2 X 1 mL
MY00395	4 X 1 mL

INTENDED USE

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

SUMMARY AND EXPLANATION

Anti-DGP IgA antibodies (anti-DGP antibodies) are produced in response to gliadin, a prolamin found in wheat. DGP IgA is found in about 80% of patients with celiac disease.^{1,2} It is directed against the alpha/beta and gamma (α , β , γ) gliadins.³ It is also found in a number of patients who are not enteropathic. Some of these patients may have neuropathies that respond favorably to a gluten elimination diet. This is referred to as gluten-sensitive idiopathic neuropathy.⁴ Clinically these antibodies and IgG antibodies to gliadin are abbreviated as AGA.

AGAs were one of the first serological markers for celiac disease. Problematic with AGA is the typical sensitivity and specificity was about 85%. Gliadin peptides which are synthesized as the deamidated form have much higher sensitivity and specificity, creating 2 serological tests for CD that approach biopsy diagnostic in performance.⁵

MATERIALS SUPPLIED

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

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

- DGP IgA Control P** Barcode labeled tubes with buffer containing human IgA antibodies to DGP 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

1. 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.
2. 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.
3. 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.
4. 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

1. Volta U, Cassani F, De FR, Lenzi M, Primignani M, Agape D, et al. Antibodies to gliadin in adult coeliac disease and dermatitis herpetiformis. Digestion 1984;30:263-70.
2. Volta U, Lenzi M, Lazzari R, Cassani F, Collina A, Bianchi FB, Pisi E. Antibodies to

gliadin detected by immunofluorescence and a micro-ELISA method: markers of active childhood and adult coeliac disease. Gut 1985;26:667-71.

3. Bateman E, Ferry B, Hall A, Misbah S, Anderson R, Kelleher P. IgA antibodies of coeliac disease patients recognise a dominant T cell epitope of A-gliadin. Gut 2004;53:1274-78.
4. Hadjivassiliou M, Gibson A, Davies-Jones G, Lobo A, Stephenson T, Milford-Ward A. Does cryptic gluten sensitivity play a part in neurological illness? The Lancet 1996;347:369-71.
5. Agardh D. Antibodies against synthetic deamidated gliadin peptides and tissue transglutaminase for the identification of childhood celiac disease. Clinical Gastroenterology & Hepatology the Official Clinical Practice Journal of the American Gastroenterological Association 2007;5:1276-81.
6. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.



HOB Biotech Group Corp., Ltd.
C6 Building, No. 218 Xinghu Road, Suzhou Industrial Park,
Suzhou, Jiangsu, 215123, China

CONTACT INFORMATION:

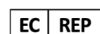
TEL (+86)512-69561996

Fax (+86)512-62956652

WEBSITE: www.hob-biotech.com

CUSTOMER SERVICE: HOB Biotech Group Co., Ltd

CUSTOMER SERVICE: TEL (+86)4008601202



EUROPE REPRESENTATIVE: Emergo Europe

ADDRESS/LOCATION:

Prinsessegracht 20, 2514 AP The Hague, The Netherlands



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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