BioCLIA® Autoimmune Control Set

DGP IgA

DGP IgA 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, DGP IgA

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® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00344 (2 X 1 mL)

My00395 (4 X 1 mL)

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

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **DGP IgA Control 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to DGP IgA in stabilizers and preservatives (High). DGP-A | 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. [6] 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 DGP IgA. 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

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.

IVD

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Technical Assistance
For technical assistance, contact your National Distributor.

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