BioCLIA® Autoimmune Calibrator Set

DGP IgG

DGP IgG Assay Calibrators

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
CAL 1	Calibrator 1		
CAL 2	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator Set, DGP IgG

Intended Use

The BioCLIA Autoimmune Calibrator Set, DGP IgG is intended for the calibration of the BioCLIA DGP IgG performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00243 (2 X 1 mL)

My00294 (4 X 1 mL)

Summary and Explanation

Anti-deamidated gliadin peptide 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 coeliac 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. The IgG antibody is similar to AGA IgA, but is found at higher levels in patients with the IgA-less phenotype. It is also associated with coeliac disease and non-celiac gluten sensitivity. [5-7]

AGAs were one of the first serological markers for coeliac 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. [8]

Materials supplied

- **DGP IgG Calibrator 1** A tube contains 1mL, ready to use reagent. Control contains human antibodies to DGP IgG in stabilizers and preservatives. Preservatives: 0.0015% < Proclin 300 < 0.6%. DGP-G | CAL | 1
- **DGP IgG Calibrator 2** A tube contains 1mL, ready to use reagent. Control contains human antibodies to DGP IgG in stabilizers and preservatives. Preservatives: 0.0015% < Proclin 300 < 0.6%. DGP-G | CAL | 2

Target value information is indicated in the 2D barcode localized 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. [9] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:

 Human serum is added in the calibrators.

 Proclin 300 is added in the calibrators at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any calibrators beyond their expiration dates. Do not mix calibrators from different lots unless specified.
- Instructions must be carefully followed for using and storing of calibrators. Any modification in procedure may interfere with the results. Calibrators and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Calibrators contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with calibrators happens, rinse immediately the contact surface with plenty of water and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator 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.

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. DGP IgG 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

This product is designed as calibrators for monitoring the performance of the BioCLIA DGP IgG. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

References

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4. Hadjivassiliou M, Gibson A, Davies-Jones GA, et al. Does cryptic gluten sensitivity play a part in neurological illness? Lancet. 1996, 347 (8998): 369.
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8. 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.
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Technical Assistance

For technical assistance, contact your National Distributor.

17th April 2019

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