**BioCLIA Autoimmune Calibrator Set, DGP IgA**

| Cat.No. | Kit Size |
|---|---|
| MY00242 | 2 X 1 mL |
| MY00293 | 4 X 1 mL |

**INTENDED USE**

The BioCLIA Autoimmune Calibrator Set, DGP IgA is intended for the calibration 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 Calibrator 1** Barcode labeled tubes with buffer containing human IgA antibodies to DGP in stabilizers and preservatives. Ready to use, 1 mL.

| CAL | 1 |
|---|---|

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **DGP IgA Calibrator 2** Barcode labeled tubes with buffer containing human IgA antibodies to DGP in stabilizers and preservatives. Ready to use, 1 mL.

| CAL | 2 |
|---|---|

Preservatives: 0.0015% < Proclin 300 < 0.6%.

The Calibrator Code contains calibrators' information is provided in each kit.

**WARNINGS AND PRECAUTIONS**

- For professional *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.
- 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 calibrators.

- 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 gloves and clothing.

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

- Store the kit at 2-8 °C.
- The shelf life of the unopened kit is 12 months from day of production.
- Vial opened calibrators could be used for 28 successive days, exposure no more than 2 hours each time when kept uncapped and is good for up to 20 calibrations, 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.

***Assay Calibration***

The BioCLIA Autoimmune Reagent Kit utilizes a predefined lot specific Master Curve which is uploaded into the instrument via the barcode

provided in the main reagent kit. The Calibrator Code contains calibrator information is then scanned. Based on the results of running two calibrators, the instrument specific Working Calibration Curve is generated and is used to calculate the concentration from the RLU obtained for each patient.

For each new lot of reagent, please calibrate prior to the first time use, and every 28 days thereafter. The software will not allow the lot to be used if the above requirements are not meet.

***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 calibrators are designed for calibration of the same lot of BioCLIA Autoimmune Reagent Kit.
- The calibrators can be kept uncapped onboard the instrument up to 2 hours for each time of usage. And a total up to 20 calibrations are suggested, for any longer period of time, the reagent should be discarded, otherwise may result in improper calibration of the assay and which can give improper results.

**SYMBOLS**

| | | | |
|---|---|---|---|
| REF | Catalog Number | | Use-by date |
| IVD | In Vitro diagnostic medical device | LOT | Lot Number |
| +2°C +8°C | Store between +2°C and +8°C | | Consult Instruction for Use |
| | Manufacturer | EC REP | Authorized Representative in the European Community |
| CE | CE Marking | Σ | Contains Sufficient for<n>Tests |
| | Biological Risk | | GHS07 Warning |

| | |
|---|---|
| CAL 1 | Calibrator 1 |
| CAL 2 | Calibrator 2 |

**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.
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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.
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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.


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**The eIFU is available on Website:**
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**TECHNICAL ASSISTANCE**

For technical assistance, contact your National Distributor.

Date of issue: 17th March 2019

Date of revision: 20th December 2021

Change Control Number: CN21129E

Version: A/1 (EN)