BioCLIA Autoimmune Control Set, IA2

Cat.No.	Kit Size
MY00347	2 X 1 mL
MY00398	4 X 1 mL

INTENDED USE

The BioCLIA Autoimmune Control Set, IA2 is intended for the quality control purposes of the BioCLIA IA2 performed on the BioCLIA 6500 and BioCLIA 500. For professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Type 1 diabetes, also known as insulin-dependent diabetes mellitus (IDDM), results from a chronic autoimmune destruction of the insulin-secreting pancreatic beta cells, probably initiated by exposure of genetically susceptible host to an environmental agent. [1] Autoimmune destruction of beta cells is thought to be completely asymptomatic until 80 - 90% of the cells are lost. This process may take years to complete and may occur at any time. [2]

During the preclinical phase, this autoimmune process is marked by circulating autoantibodies to beta cell antigens. These autoantibodies are present years before the onset of type 1 diabetes and prior to clinical symptoms. Early studies utilized the immunofluorescence test for islet-cell antibodies (ICA), which has been difficult to standardize and is now replaced by a combination of several radioimmunoassays for antibodies against specific beta cell antigens, such is insulin (IAA), glutamic acid decarboxylase (IA2) and tyrosine phosphatase ICA 512 (IA2). [3]

IA2, a member of the protein tyrosine phosphatases family is localized in the dense granules of pancreatic beta cells and the second defined recombinant islet cell antigen. IA2 shares sequence identity with the islet cell antigen 512. The higher frequency of antibodies to IA2 is explained by the presence of autoantibodies directed to the COOH terminus of IA2 which is lacking in the ICA512 molecule. [4]

IA2 autoantibodies are present in the majority of individuals with new-onset type 1 diabetes and in individuals in the pre-diabetic phase of the disease. The appearance of autoantibodies to IA2 seems to be correlated with the rapid progression to overt type 1 diabetes. [5]

The combination of tests for IA265 and IA2 autoantibodies is highly relevant for risk assessment of type 1 diabetes in children and adolescence. The screening for IA265 and IA2 autoantibodies detect more than 90 % of subjects at risk for type 1 diabetes and may, therefore, possess the potential to replace ICA technique. [6]

MATERIALS SUPPLIED

- **IA2 Control N** Barcode labeled tubes with buffer containing human antibodies to IA2 in stabilizers and preservatives. Ready to use, 1 mL.

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **IA2 Control P** Barcode labeled tubes with buffer containing human antibodies to IA2 in stabilizers and preservatives. Ready to use, 1 mL.

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

Control N	Negative Control
Control P	Positive Control

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

REFERENCE

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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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