

BioCLIA Autoimmune Control Set, IAA

Cat.No.	Kit Size
MY00337	2 X 1 mL
MY00388	4 X 1 mL

INTENDED USE

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

SUMMARY AND EXPLANATION

Insulin-dependent diabetes mellitus (IDDM) is an autoimmune disease that pancreatic β cells damaged and the synthesis and secretion of insulin reduced. ¹ Insulin is composed of two peptides, A and B. Peptide A contains 21 amino acids of 11 kinds and peptide B contains 30 amino acids of 15 kinds. Two disulfide bonds formed at A7 (Cys) - B7 (Cys) and A20 (Cys) - B19 (Cys) and made peptides A and B connected. Insulin is a kind of acidic protein, stable in acid or neutral conditions. Recombinant insulin can cause strong cellular and humoral immune response. ^{2,3}

Insulin Autoantibody (IAA) auto-antibodies specific to endogenous insulin of individuals which are not injected exogenous Insulin or the injecting time is less than 7-10 days. They are mainly in IgG types and appeared less in older individuals, and exist for a rather short time in bodies. ^{4,5} IAA is not a diabetes mellitus specific antibody but also positive in insulin autoimmune syndrome ones, thyroid ones or even healthy people. Detection of insulin autoantibody (IAA) gives clinicians a good guidance for diabetes clinical classification, pancreatic β cells damage prediction, screening IDDM in high-risk population and monitoring prognosis. ⁶ In addition to IDDM, individuals with multiple autoimmune or other organ specific autoimmune can be detected as IAA positive when they intake mercaptan drugs such as methimazole or penicillamine.

MATERIALS SUPPLIED

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



Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

	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

Control	N	Negative Control
Control	P	Positive Control

REFERENCE

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5. Fineberg SE, Kawabata TT, Finco-Kent D, Fountaine RJ, Finch GL, Krasner AS. Immunological responses to exogenous insulin. Endocr Rev 2007;28:625-52.
6. Bluestone JA, Herold K, Eisenbarth G. Genetics, pathogenesis and clinical interventions in type [thinsp] 1 diabetes. Nature 2010;464:1293-300.
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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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