

BioCLIA[®] Autoimmune Control Set

IAA

IAA Assay Controls

Key to Symbols Used



Catalog number



Expiration date



For *in-vitro* Diagnostic Use



Lot number



Store between +2°C and +8°C



Consult Instruction for Use



Manufacturer



Authorized Representative in
European Union



Control 1



Contains Sufficient for $< n >$ Tests



Control 2



Chemical Risk Warning



Biological Risk Warning

BioCLIA® Autoimmune Control Set,

IAA

Intended Use

The BioCLIA Autoimmune Control Set, IAA is intended for the quality control purposes of the BioCLIA IAA performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00337 (2 X 1 mL)

MY00388 (4 X 1 mL)

Summary and Principles of the Procedure

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 1** A tube contains 1 mL, ready to use reagent. Control 1 contains human antibodies to IAA in stabilizers and preservatives (Low).

IAA | Control | Low

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **IAA Control 2** A tube contains 1 mL, ready to use reagent. Control 2 contains human antibodies to IAA in stabilizers and preservatives (High).

IAA | Control | High

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on the 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. 7 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 IAA. 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.

Revision 7

References

1. Seissler J, Hatzigelaki E, Scherbaum W. Modern concepts for the prediction of type 1 diabetes. *Experimental and Clinical Endocrinology & Diabetes* 2001;109:S304-S16.
2. Sonksen P, Sonksen J. Insulin: understanding its action in health and disease. *Br J Anaesth* 2000;85:69-79.
3. Duckworth WC, Bennett RG, Hamel FG. Insulin degradation: progress and potential 1. *Endocr Rev* 1998;19:608-24.
4. Davidson MB, Kumar D, Smith W. Successful treatment of unusual case of brittle diabetes with sulfated beef insulin. *Diabetes Care* 1991;14:1109-10.
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.
7. Richmond JY, McKinney RW. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Public Health Service, 4th Edition; 1999.



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Technical Assistance

For technical assistance, contact your National Distributor.

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