

BioCLIA[®] Autoimmune Control Set

IA2

IA2 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, IA2

Intended Use

The BioCLIA Autoimmune Control Set, IA2 is intended for the quality control purposes of the BioCLIA IA2 performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00347 (2 x 1 mL)

MY00398 (4 x 1 mL)

Summary and Principles of the Procedure

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 as 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 1** A tube contains 1 mL, ready to use reagent. Control contains human antibodies to IA2 in 0.05 M Tris (pH7.4) Buffer.

IA2	Control	L
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **IA2 Control 2** A tube contains 1 mL, ready to use reagent. Control contains human antibodies to IA2 in 0.05 M Tris (pH7.4) Buffer.

IA2	Control	H
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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 added in the IA2 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 IA2. 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.

References

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3. Batstra MR, Aanstoot HJ, Herbrink P. Prediction and diagnosis of type 1 diabetes using beta-cell autoantibodies. Clinical Laboratory 2001;47:497-507.
4. Seissler J, Hatziagelaki E, Scherbaum WA. Modern concepts for the prediction of type 1 diabetes. Experimental and clinical endocrinology & diabetes : official journal, German Society of Endocrinology [and] German Diabetes Association 2001;109 Suppl 2:S304-16.
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6. Winter WE, Harris N, Schatz D. Immunological markers in the

diagnosis and prediction of autoimmune type 1a diabetes. Clin Diabetes 2002;20:183-91.

7. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.



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Technical Assistance

For technical assistance, contact your National Distributor.

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