









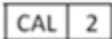




# BioCLIA<sup>®</sup> Autoimmune Calibrator Set

**IA2**

## IA2 Assay Calibrators

### Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Calibrator 1		Contains Sufficient for < n > Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

# BioCLIA® Autoimmune Calibrator Set, IA2

## Intended Use

The BioCLIA Autoimmune Calibrator Set, IA2 is intended for the calibration of the BioCLIA IA2 performed on the BioCLIA® 1200 and BioCLIA® 6500.

## Catalog Numbers

MY00245 (2 x 1 mL)

MY00296 (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.<sup>1</sup> 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.<sup>2</sup>

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).<sup>3</sup>

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.<sup>4</sup>

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.<sup>5</sup>

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.<sup>6</sup>

## Materials supplied

- **IA2 Calibrator 1** A tube contains 1 mL, ready to

use reagent. Calibrator contains human antibodies to IA2 in 0.05 M Tris (pH7.4) Buffer.

IA2	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

IA2	CAL	2
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value information is indicated in the 2D barcode localized 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 calibrators



Proclin 300 added in the IA2 calibrators at

concentration between 0.0015% - 0.6%.

- The product is for *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.
- 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

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator 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.

#### Traceability

BioCLIA Autoimmune Calibrator Set, IA2 can be trace to WHO standard material (NIBSC code: 97/550).

#### Limitations

This product is designed as calibrators for monitoring the performance of the BioCLIA IA2. These calibrators are subjected to the limitations of the assay system. Deviations may indicate problems with one or more components in the test system.

#### References

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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.

17<sup>th</sup> April 2019

Revision 7