






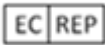
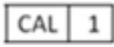






BioCLIA[®] Autoimmune Calibrator Set

ICA

ICA 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, ICA

Intended Use

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

Catalog Numbers

MY00246 (2 x 1 mL)

MY00297 (4 x 1 mL)

Summary and Principles of the Procedure

Insulin - dependent diabetes mellitus (IDDM), Type 1, is caused by the autoimmune destruction of the beta cells of the pancreas.^{1, 2} This selective autoimmune pathogenesis causes complete elimination of insulin secretion. The immunological evidence was demonstrated by the presence of specific islet cell autoantibodies in IDDM sera.³ At least three autoantibodies have been identified against antigenic components of the islet cells in Type 1 diabetics. These autoantibodies are directed specifically to islet cell antigenic components, glutamic acid decarboxylase and insulin.⁴

Islet Cell Autoantibodies are present in 70% of patients with a recent onset of IDDM compared with 0.1 - 0.5% of the control non-diabetic population.⁵ ICA are also detected in first degree relatives of IDDM patients. These individuals comprise the segment of human population who are at a high risk of developing IDDM. Several studies reported that the ICA-positive first degree relatives of IDDM patients subsequently developed diabetes.⁶ Other studies also suggested that the presence of serum ICA and IAA is an indicator of the enhanced likelihood to develop IDDM.⁷ Therefore, serological detection of ICA may be a powerful tool for early diagnosis of IDDM. The significance of these autoantibodies as markers of IDDM is also illustrated by their presence in nondiabetic individuals who ultimately develop IDDM. The screening of high-risk populations, for all of the three autoantibodies (ICA, IAA and ICA) will help to either prevent or to slow down the onset of the disease. A high-risk (asymptomatic) population, positive for two or more autoantibodies, is vulnerable for developing IDDM, usually in the next 5-7 years.⁸

Materials supplied

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

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

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

ICA	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.⁹ 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 ICA 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, ICA 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 ICA. 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

1. Cooke A. An overview on possible mechanisms of destruction of the insulin-producing beta cell. *Curr Top Microbiol Immunol* 1989;164:125-42.
2. Harrison L, Campbell I, Colman P, Chosich N, Kay T, Tait B, et al. Type 1 diabetes: immunology and immunotherapy. *Adv Endocrinol Metab* 1990;1:35-94.
3. Bottazzo G, Florin-Christensen A, Doniach D. Islet-cell antibodies in diabetes mellitus with autoimmune polyendocrine deficiencies. *The Lancet* 1974;304:1279-83.
4. Colman PG, Nayak RC, Campbell IL, Eisenbarth GS. Binding of cytoplasmic islet cell antibodies is blocked by human pancreatic glycolipid extracts. *Diabetes* 1988;37:645-52.
5. Riley W, Maclaren N. Islet-cell antibodies are seldom transient. *The Lancet* 1984;323:1351-52.
6. Soeldner JS, Tuttleman M, Srikanta S, Ganda OP, Eisenbarth GS. Insulin-dependent diabetes mellitus and autoimmunity: islet-cell autoantibodies, insulin autoantibodies, and beta-cell failure. *N Engl J Med* 1985;313:893-4.
7. Eisenbarth GS, Connelly J, Soeldner JS. The "natural" history of type I diabetes. *Diabetes Metab Rev* 1987;3:873-91.
8. Dean BM, Becker F, McNally JM, Tarn AC, Schwartz G, Gale EA, Bottazzo GF. Insulin autoantibodies in the pre-diabetic period: correlation with islet cell antibodies and development of diabetes. *Diabetologia* 1986;29:339-42.
9. 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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