







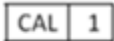






BioCLIA[®] Autoimmune Calibrator Set

IAA

IAA 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 < <i>n</i> > Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator

Set, IAA

Intended Use

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

Catalog Numbers

MY00235 (2 X 1 mL)

MY00286 (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 Calibrator 1** A tube contains 1 mL, ready to use reagent. Calibrator 1 contains human antibodies to IAA in stabilizers and preservatives.

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

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

IAA	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 is added in the 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

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. IAA 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

This product is designed as calibrators for monitoring the performance of the BioCLIA IAA. 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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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.
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Distributor.

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Technical Assistance

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