













BioCLIA[®] Autoimmune Calibrator Set

Anti-TG

Anti-TG 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
			Contains Sufficient for $< n >$ Tests
	Calibrator 1-6		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Calibrator Set, Anti-TG

Intended Use

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

Catalog Numbers

MY00237 (6 x 1 mL)

MY00288 (12 x 1 mL)

Summary and Explanation

Thyroglobulin (Tg) is a large heterologous glycoprotein (660 kDa) exists in thyroid follicular cell, play an important role in the biosynthesis of thyroid hormone, T3 and T4.¹ In thyroid follicular cells, thyroid peroxidase catalyzes iodide reaction of tyrosyl group in Tg, and iodinated Tg will be kept in follicle colloid as a saver for T3 and T4. When the thyroid gland is stimulated, Tg will degrade and consequently the thyroid hormone, T3 and T4 release into blood.^{2,3}

The detection of anti-Tg antibodies is an effective method for diagnosis of autoimmune thyroid disease. Anti-Tg antibodies levels increase in 80-100% lymphoma thyroiditis or chronic thyroiditis cases, 10-20% subacute thyroiditis patients and 60-70% patients with hyperthyroidism.⁴ It also related to patients with Addison's disease or Insulin-Dependent Thyroid disease (IDDM). Due to the heterogeneity of Tg, anti-Tg antibodies are also positive in elder patients with other diseases or people with normal thyroid function.^{3,4,5}

Materials supplied

- **Anti-TG Calibrator 1-6** Six/Twelve tubes containing 1 mL, ready to use reagent. Calibrator contains anti-TG antibodies in 0.05 M Tris (pH7.4) buffer.

Anti-TG	CAL	1-6
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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. 5 Avoid contact 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 Anti-TG 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, Anti-TG can be trace to China National Standard Anti-Thyroglobulin Antibodies (Anti-TG), CNS Code: 150556.

Limitations

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

References

1. Boron WF, Boulpaep EL. Medical Physiology: A Cellular and Molecular Approach. 2003.
2. Shimojo N, Saito K, Kohno Y, Sasaki N, Tarutani O, Nakajima H. Antigenic determinants on thyroglobulin: comparison of the reactivities of different thyroglobulin preparations with serum antibodies and T cells of patients with chronic thyroiditis. J Clin Endocrinol Metab 1988;66:689-95.
3. Feldtrasmussen U. Analytical and clinical performance goals for testing autoantibodies to thyroperoxidase, thyroglobulin, and

thyrotropin receptor. Clin Chem 1996;42:160-3.

4. Burek CL, Rose NR. Thyroglobulin Autoantibodies. Autoantibodies 1996;24:810-15.

5. 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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