



ANTI THYROID AUTOIMMUNE CONTROL – TWO LEVEL

PRODUCT CODE: AIT-101

**Dual-Component TgAb/TPOAb
LOT# AIT- 1E6**

EXP: 05-2021

INTENDED USE

The Thyroid Autoimmune Controls are intended for *in vitro diagnostic use* only as an assayed quality control material to monitor the consistency of performance of Anti-Thyroglobulin and Anti-Thyroid Peroxidase procedures. Monobind Inc.'s controls are human serum-based, ready-to-use liquid controls stabilized with preservatives and can be used with all RIA, EIA, ELISA or CLIA methods.

SUMMARY AND EXPLANATION

The use of quality control material to assist in the assessment of precision in the clinical laboratory is an integral part of laboratory practices. Controls that contained two (2) levels of control are necessary to ensure precision and accuracy in immunoassay systems.

REAGENTS

Monobind Inc.'s Thyroid Autoimmune Controls are intended to be used in the exact manner as patient samples. The controls are packaged as 6 vials of 1.0 ml (3 vials of each level). The antibody activities are adjusted to two distinct concentrations [normal (negative) and elevated (positive)] in order to monitor the efficacy of the procedure in use. Follow the manufacturer's instructions for patient dilution to dilute the controls using the diluent supplied with the test.

INSTRUCTIONS FOR USE

1. Bring the vials to room temperature before use.
2. Carefully unscrew and remove cap.
3. Open only one set (normal and elevated) at a time. Dilute according to instructions in the procedure used.
4. Store the unused portions at 2-8°C after each use.

STORAGE AND STABILITY

The controls will be stable until the expiration date at 2-8°C when unopened. The expiration date is printed on each vial as well as on the outside container. After opening, any unused material is stable for 30 days when stored at 2-8°C. Any outdated material should be discarded as biohazardous component.

EXPECTED VALUES

These controls have been assayed by leading manufacturers of autoimmune test systems. Values are expressed in IU/ml (WHO: 65/93 for TgAb and 66/387 for TPOAb).

Analyte	Positive Controls		Negative Controls		Method
	Mean	Range	Mean	Range	
TgAb	1284.19	860.41-1707.97	< 20	-	MB ACCUBIND ELISA
	1247.87	836.07-1659.67	<20	-	MB ACCULITE CLIA
TPOAb	336.28	225.31-447.25	<5	-	MB ACCUBIND ELISA
	323.40	216.68-430.12	<5	-	MB ACCULITE CLIA

Individual laboratory means should fall within the corresponding acceptable range; however laboratory means may vary from the listed values during the life of this control. Therefore, each laboratory should establish its own means and acceptable ranges for the product used, using Monobind's assignment only as guide. A trend log should be maintained for batch to batch consistency of the test. Variations over time and between laboratories may be caused by a) differences in laboratory personnel, b) improper technique, c) instrumentation and reagents, d) improper dilutions from the stated manufacturer's procedure, and/ or e) modifications in the manufacturer's test procedure.

Refer to <http://www.monobind.com/site/qc-documents.html> for any updated insert information.

WARNING AND PRECAUTIONS

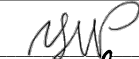

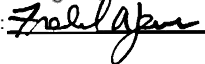
FOR IN VITRO DIAGNOSTIC USE

All products that contain human serum have been found to be non-reactive for HIV 1&2, HIV-Ag, HBsAg, HCV and RPR by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

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For Orders and Inquiries, please contact



Tel: +1 949.951.2665 Email: info@monobind.com
Fax: +1 949.951.3539 Web: www.monobind.com

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EC REP CEpartner4U, Esdoornlaan 13, 3951DB Maarn, The Netherlands www.cepartner4u.eu