

# ANTI-THYROID AUTOIMMUNE CONTROL

Dual-Component TgAb/TPOAb  
PRODUCT CODE: AIT-101

LOT# AIT- K05

EXP: 11-10

Revision: 1

Date: 04-12-06

## INTENDED USE

The Thyroid Autoimmune Controls are intended for *in vitro diagnostic use only* and are designed 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 FIA 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. Two (2) levels of control are provided for monitoring the procedure(s) used.

## 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 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 After opening, any unused material is stable for 30 days when stored at 2-8°C. Any outdated material should be discarded as biohazardous component.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).

	Positive Control		Expected	
	(TgAb) Mean	Expected(TPOAb) Range	Mean	Range
Access™	1511	1270 - 1753	N/A	N/A
Monobind ELISA	1586	1250 - 1922	332	
	266 - 398			
Monobind CLIA	1564	1230 - 1942	330	
	264 - 396			

	Negative Control		Expected	
	(TgAb) Mean	Expected(TPOAb) Range	Mean	Range
Access™	< 2.2	< 2.2	N/A	N/A
Monobind ELISA	24	< 508.68.6	< 15	
Monobind CLIA	24	< 508.67.5	< 14	

Access is a trademark of Beckman-Coulter, Inc.

Each laboratory should establish their own ranges for the product used. A trend log should be maintained for batch-to-batch consistency of the test. Large variations from the established mean may result from (a) improper technique, (b) improper dilutions from the stated manufacturer's procedure or (c) modifications of the test system by the manufacturer.

## WARNING AND PRECAUTIONS

All products that contain human serum have been found to be non reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA licensed viral 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.

## FOR IN VITRO DIAGNOSTIC USE

For Orders and Inquiries, please contact



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