ANTI-TG & ANTI-TPO CONTROL - POSITIVE & NEGATIVE **PRODUCT CODE: AIT-101**

LOT# AITPN1G9 **EXP: 07-2024**

INTENDED USE

The Anti-Tg and Anti-TPO 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. This product is a human-serum based, liquid control, stabilized with preservatives and can be used with all ELISA, RIA, and 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 contain two (2) levels of analytes are necessary to ensure precision and accuracy in immunoassay systems.

REAGENTS

Monobind Inc.'s Anti-TG/TPO Controls are intended to be used in the exact manner as patient samples. The control is 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, STABILITY AND DISPOSAL

This product will be stable until the expiration date when stored unopened at 2-8 °C. Once the control is opened, any unused material is stable for 30 days when stored tightly capped at 2-8 °C. To avoid contamination, it is recommended labs aliquot required quantities into vials before each use. Any outdated material should be discarded as biohazardous component.

STORAGE	STABILITY	TEMPERATURE
Unopened	Five (5) years	2 – 8°C
Opened	Thirty (30) days	2 – 8°C

EXPECTED RANGE OF 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		
	Mean	Range	Range		Method
Anti-Tg in IU/ml	1571.7	1053.041-2090.36	<50	-	MB ACCUBIND ELISA
	1570.25	1052.07-2088.43	<50	-	MB ACCULITE CLIA
Anti-TPO in IU/ml	325.87	218.33-433.40	<20	-	MB ACCUBIND ELISA
	324.08	217.13-431.03	<20	-	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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Please visit our website to learn more about our products and services.

Glossary of Symbols (EN 980/ISO 15223)

IVD — In Vitro - Diagnostic Medical Device
Temperature Limitation Storage Condition (2-8°C)
Consult Instructions for Use
REF — Catalogue Number
Date of Manufacture
LOT — Batch Code
Used By (Expiration Day)
Manufacturer
European Conformity
EC REP — Authorized Rep in European Country

DOCUMENT HISTORY

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