THYROGLOBULIN (TG) CONTROL - TRI LEVEL **PRODUCT CODE: TG-300**
LOT# TGAC1H3 **EXP: 2026-08-01**

INTENDED USE

The Thyroglobulin Controls are intended for use as an assayed quality control material to monitor the consistency of performance of laboratory test procedures associated with determination and monitoring of thyroglobulin levels. This product is human-serum based, liquid control, stabilized with preservatives and can be used with all RIA, EIA, ELISA, CLIA, and 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. Controls that contain varied levels of analytes are necessary to insure precision and accuracy in immunoassay systems.

REAGENTS

Monobind's thyroglobulin controls are intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 3.0 ml (2 of each level). The analyte activities are adjusted to concentrations in the low, middle and high range in order to monitor the efficacy of the procedure in use.

INSTRUCTIONS FOR USE

1) Bring the vials to room temperature before use.
2) Carefully unscrew and remove cap.
3) Aliquot the materials in 0.5 ml aliquots in cryo vials and store at ≤ -20ºC.

STORAGE, STABILITY AND DISPOSAL

The control is provided liquid and ready to use. This product will be stable until the expiration date when stored unopened at **< - 20.** Once the control is opened, all analytes will be 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.

Long term room temperature storage is not supported. Unused controls should be tightly capped and frozen within two (2) hours. Once thawed, do not refreeze the control; discard remaining material. It is recommended that customers aliquot control into separate containers before freezing to allow for usage on different days. Outdated material should be discarded as a biohazardous component.

STORAGE	STABILITY	TEMPERATURE
Unopened	Three (3) years	≤ -20ºC
Opened	Thirty (30) days	2-8°C

ASSIGNMENT OF VALUES & EXPECTED RANGE OF VALUES

EXPECTED RANGE OF VALUES FOR Thyroglobulin Controls - Tri-level Set
MASTER LOT TGAC1H3

Analyte	A Range	B Range	C Range	Method
Tg in ng/ml	2.44 ± 0.80	11.60 ± 3.83	57.59 ± 19.0	MB ACCUBIND ELISA
	1.78 ± 0.59	10.03 ± 3.31	52.75 ± 17.41	MB ACCULITE CLIA

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by Monobind QC using representative lots of this product, as well as those of Monobind's AccuBind® ELISA and AccuLite® CLIA reagents.

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 manufacturer's stated 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 negative and 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 Inquires, please contact
Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630 USA
Tel: +1 949.951.2665 Mail: info@monobind.com
Fax: +1 949.951.3539 Fax: www.monobind.com
IVD CE
EC REP CEpartner4U, Esdoornlaan 13
3951 DBMaarn, The Netherlands
www.cepartner4u.eu

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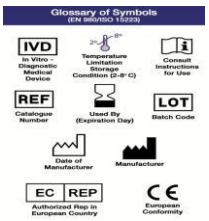

DOCUMENT HISTORY

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