



THYROGLOBULIN CONTROL – TRI LEVEL
LOT# TG (A-C) 1H6

PRODUCT CODE: TG-300
EXP: 08-2019

INTENDED USE

The Thyroglobulin Controls are intended for in vitro diagnostic use only 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 a 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 < -20 °C

STORAGE, STABILITY AND DISPOSAL

This control is provided liquid and ready to use. This product will be stable until the expiration date when stored unopened at < -20 °C. Once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2 to 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 Outdated material should be discarded as a biohazardous component.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 | Printed on vial | < -20 °C |
| Opened | Thirty (30) days | 2 – 8°C |

EXPECTED VALUES

The expected ranges are given below:

| Analyte | Low Control (A) | | Normal Control (B) | | High Control (C) | | Method |
|---------|-----------------|-----------|--------------------|------------|------------------|-------------|----------------|
| | Mean | Range | Mean | Range | Mean | Range | |
| Tg | 1.6 | 0.5-2.7 | 13 | 11-15 | 60 | 50-70 | Access™ |
| | 3.4 | 2.28-4.52 | 11.77 | 7.88-15.65 | 39.75 | 26.63-52.86 | AccuBind ELISA |
| | 2.83 | 1.90-3.77 | 10.38 | 6.95-13.80 | 38.32 | 25.68-50.97 | AccuLite CLIA |

Access™ is a trademark of Beckman-Coulter, Inc.

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.

Effective Date: 2016-SEP-01 Rev. 0
MPTG300

Product Code: TG-300

For Orders and Inquiries, please contact



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

Please visit our website to learn more about our other interesting products and services.



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

| DOCUMENT HISTORY | | | |
|---------------------------------|----------------------|-----------------------------|----------|
| PREPARED BY: <i>[Signature]</i> | DEPT: QC | VERIFIED BY: <i>Ashatka</i> | DEPT: QA |
| APPROVED BY: <i>[Signature]</i> | DEPT: Administration | EFFECTIVE DATE: 2016-SEP-01 | |
| REVISION: 0 | | DCO: N/A | |