THYROXINE BINDING GLOBULIN (TBG) CONTROL - TRI LEVEL

LOT# TBGAC1B0

Product Code: TBG-300
Exp: 02-2025

INTENDED USE

The TBG 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 TBG levels. This product is human serum based, liquid and stabilized with preservatives and can be used with all RIA, EIA, ELISA or FIA, CLIA methods.

SUMMARY AND EXPLANATION

The use of quality control materials 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 verify precision and accuracy in immunoassay systems.

REAGENTS

Monobind Inc.'s TBG controls are intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 1.0 ml(2 A, 2 B and 2 C Level). The analyte activities are established in this form 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) Store the unused portions at 2-8°C after each use.

STORAGE, STABILITY AND DISPOSAL

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 (see below). Outdated material should be discarded as biohazardous component.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

EXPECTED RANGE OF VALUES FOR TBG Qsure Controls MASTER LOT :TBGAC1B0				
	A	B	C	
Analyte	Range	Range	Range	Method
TBG in µg/ml	4.25 ± 1.54	13.40 ± 4.42	35.83 ± 11.82	MB ACCUBIND ELISA

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 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 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.

Revision:1 **Date:2022-01-20** **Product Code: TBG-300**

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 2° 8° CE

EC REP **CEpartner4U,** Esdoornlaan 13
3951 DBMaarn, The Neatherlands
www.cepartner4u.eu

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	2° 8° — Temperature Limitation Storage Condition (2-8° C)	Consult Instructions for Use
REF — Catalogue Number	Σ — Contains Sufficient Test for Σ	LOT — Batch Code
Used By (Expiration Day)	Date of Manufacturer	Manufacturer
EC REP — Authorized Rep in European Country	CE — European Conformity	

DOCUMENT HISTORY

PREPARED BY: _____ DEPT: QC VERIFIED BY: AShatola DEPT: QA

APPROVED BY: _____ DEPT: Administration EFFECTIVE DATE: 2022-JAN-20

REVISION: 1 DCO: 1533