

THYROXINE BINDING GLOBULIN (TBG) CONTROL - TRULEVE

LOT# TBGAC1L6

Product Code: TBG-300 Exp: 12-2021

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, 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 Low (A), 2 Mid (B) and 2 High (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 Outdated material should be discarded as biohazardous component.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

EXI ESTED WHITEE OF WALDES						
EXPECTED RANGE OF VALUES FOR THYROXINE BINDING GLOBULIN (TBG) CONTROL						
LOT: TBGAC1L6						
	Low (A)	Mid (B)	High (C)			
Analyte	Range	Range	Range	Method		
TBG in µg/ml	4.83 ± 1.59	17.33 ± 5.72	40.26 ± 13.28	MB ACCUBIND ELISA		
TBG in µg/ml	4.79 ± 1.59	16.86 ± 5.56	46.27 ± 15.27	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/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 non-reactive for HIV 182, 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.

For Orders and Inquires, please contact

Solossary of Symbols
(Ex 900/ISO 1522)

For Orders and Inquires, please contact

Solossary of Symbols
(Ex 900/ISO 1522)

IND

In Vitro

Lake Forest, CA 92630 USA

Tel: +1 949.951.2665
Fax: +1 949.951.3539

Mail: info@monobind.com
Fax: www.monobind.com
Fax: www.monobind.com
Fax: www.monobind.com
Fax: www.monobind.com
Cepartner4U, Esdoornlaan 13
3951 DBMaarn, The Neatherlands
www.copartner4u.ou

Manufacturer

Manufacturer

Manufacturer

Manufacturer

Manufacturer

Manufacturer

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

PREPARED BY: DOCUMENT HISTORY
DEPT: QC VERIFIED BY: AShark DEPT: QA

APPROVED BY: Prolight DEPT: Administration EFFECTIVE DATE: 2016-DEC-09

REVISION: 0 DCO: N/A

EC REP