QSure™ Quality Control Sera

Ensure your assay results. Simple to use. Cost effective.

Monobind's QSure® Multi-Ligand Control is human-serum based and designed to assist clinical laboratories with immunoassay precision. It contains a broad spectrum of an analytes (30+) with established value ranges for Monobind's AccuBind® ELISA and AccuLite® CLIA tests and can be used as commercial control for other manufacturers' methods.

- Robust menu (30+ anlaytes)
- Tri-Level (A-C: Low, Middle and High)
- 3 years at <8°C
    - 7 day open-vial stability at 2-8°C
    - 90 days open-vial stability at <-10°C
- Reconstitute and use like patient samples
- Extend use & reduce contamination
    - Aliquot into 0.5ml vials & freeze
    - Thaw per use (do not refreeze, discard remaining material)
- Product contains two vials of each A-C with 3ml fill volume (6 x 3ml)

Item# ML-300B

Analytes

AFP	Ferritin	PSA, Free
Aldosterone	FSH	SHBG
ANST	Folate	T3, Total
CEA	hCG	T3, Free
Cortisol	hGH	T3U
C-Peptide	IgE	T4, Total
DHEA	Insulin	T4, Free
DHEA-S	LH	Testosterone
DIG	PRL	Testosterone, Free
Estradiol (E2)	Progesterone	TSH
Estriol (uE3)	17OHP	Vit B12
Estrone (E1)	PSA	Vit D

Contact us today to learn more
www.monobind.com :: sales@monobind.com

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

LOT# AITPN1D4 **EXP:2029/04/25**

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	1450.86	972.08-1929.64	<50	-	MB ACCUBIND ELISA
	1359.90	911.13-1808.67	<50	-	MB ACCULITE CLIA
Anti-TPO in IU/ml	360.43	241.48-479.37	<20	-	MB ACCUBIND ELISA
	363.0	243.21-482.79	<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.

Revision: 0 **Date: 2024-04-25** **Product Code: AIT-101**

For Orders and Inquires, please contact

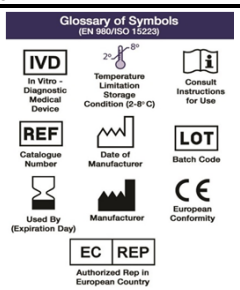
Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630 USA

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.



PREPARED BY:		DEPT: QC	DOCUMENT HISTORY VERIFIED BY:	AShatola	DEPT: QA
APPROVED BY:		DEPT: Administration	EFFECTIVE DATE: 2024-APRIL-25		
REVISION: 0			DCO: N/A		

Monobind Inc.
The World Resource for Diagnostic Products

100 North Pointe Drive
Lake Forest, California 92630 USA
Phone: 949-951-2665 Ex208 Fax: 949-951-3539

CERTIFICATE OF ANALYSIS

QUALITY CONTROL RELEASE

Product: QSure® Tumor Marker Control
Item #: TMC-300
Lot #: TMCAC1D4
Expiration Date: 2027-04-03

Bleed testing: Each unit of plasma used in this pool was tested per below by FDA approved reagent tests.

Test	Specification	Results
HIV-I/II	Non-Reactive @ Donor Level	Non-Reactive @ Donor Level
HIV-Ag	Non-Reactive @ Donor Level	Non-Reactive @ Donor Level
HBsAg	Non-Reactive @ Donor Level	Non-Reactive @ Donor Level
HCV	Non-Reactive @ Donor Level	Non-Reactive @ Donor Level
RPR	Non-Reactive @ Donor Level	Non-Reactive @ Donor Level

Performance testing: Each level of product tested per below.

Level A

Test	Specification	Results	Actions
pH @ 25C (pH Meter)	6.75 - 8.15	7.7	Pass
Optical Density @ 700nm (Beckman Spectrophotometer)	< 2.0	0.012nm	Pass

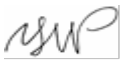
Level B

Test	Specification	Results	Actions
pH @ 25C (pH Meter)	7.00 -7.70	7.52	Pass
Optical Density @ 700nm (Beckman Spectrophotometer)	< 2.0	0.078nm	Pass

Level C

Test	Specification	Results	Actions
pH @ 25C (pH Meter)	7.00 -7.70	7.48	Pass
Optical Density @ 700nm (Beckman Spectrophotometer)	< 2.0	0.049nm	Pass

QC Ref: QCR- TMC-300-24-00 **Date: 2024-04-03**

QC Approval: 

Janet M Varona
Quality Control Supervisor

Monobind Inc.
100 North Pointe Drive
Lake Forest, California 92630 USA