Tumor Marker Control **PRODUCT CODE: TMC-300**

LOT# TMCAC1K1 **EXP: 2024/11/30**

INTENDED USE

The Tumor Marker 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 the clinical status. This product is a human-serum based, liquid control, stabilized with preservatives and can be used with all ELISA 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 varied levels of analytes are necessary to insure precision and accuracy in immunoassay systems.

REAGENTS

Monobind's The Tumor Marker Controls are intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 2.0 ml. 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

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 7 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.

Controls should be tightly capped and returned to refrigerator 2 to 8° C as soon as practical after usage. (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 Outdated material should be discarded as a biohazardous component.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	< -20°C
Unopened	Ninety (90) days	2 – 8°C
Opened	Seven (7) days	2 – 8°C

EXPECTED RANGE OF VALUES

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 QA using representative lots of this product, as well as those of Monobind's AccuBind® ELISA and AccuLite® CLIA reagents.

Analyte	A Range	B Range	C Range	Method
CA 125 in U/ml	15.69 ± 5.18	60.31 ± 19.90	117.81 ± 38.88	MB ACCUBIND ELISA
	18.16 ± 5.99	64.25 ± 21.20	126.93 ± 41.89	MB ACCULITE CLIA
CA 19-9 in U/ml	14.89 ± 5.43	52.19 ± 17.22	91.50 ± 30.19	MB ACCUBIND ELISA
	15.01 ± 5.08	46.89 ± 15.47	80.73 ± 26.64	MB ACCULITE CLIA
CA 15-3 in U/ml	15.50 ± 5.12	47.47 ± 15.67	93.09 ± 30.72	MB ACCUBIND ELISA
	14.63 ± 4.83	44.10 ± 19.09	105.29 ± 34.75	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.

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IVD CE 2° 8°

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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
Date of Manufacturer
LOT — Batch Code
Used By (Expiration Day)
Manufacturer
CE — European Conformity
EC REP — Authorized Rep in European Country

DOCUMENT HISTORY

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

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