MATERNAL CONTROL - TRI LEVEL **PRODUCT CODE: MC-300**

Alpha-Fetoprotein (AFP), β-Human Chorionic Gonadotropin (hCG), Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG), Unconjugated Estriol (uE3)

LOT# MCAC1D2 **EXP:2025/04/20**

INTENDED USE

The Maternal 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 fertility status. This product is a human-serum based, lyophilized 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 high levels of hormones are necessary to ensure precision, linearity, and accuracy in high activity specimens.

REAGENTS

Monobind's Maternal Controls are intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 5.0 ml, lyophilized. The analyte activities are adjusted to exact high concentrations in order to monitor the efficacy of the procedure in use. **For Free β-hCG-XR, a 1:10 dilution is recommended, whereas hCG should be diluted 1:1000.**

INSTRUCTIONS FOR USE

Bring the vials to room temperature before use.

1) Carefully unscrew and remove cap.
2) Add five (5) ml of distilled or deionized water to each vial to reconstitute. Close the cap tightly and let the contents mix thoroughly for 30 minutes.
3) Aliquot the unused materials in 0.5 ml aliquots in cryo vials and store at -20°C.

STORAGE, STABILITY AND DISPOSAL

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, 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.

Reconstituted 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 Outdated material should be discarded as a biohazardous component.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
Reconstituted, Opened	Seven (7) days	2 – 8°C
Reconstituted, Opened	Ninety (90) days	< -10°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	B	C	
	Assigned Value Range	Assigned Value Range	Assigned Value Range	Method

hCG in IU/ml	42.44 ± 14.01	93.10 ± 30.72	152.40 ± 50.29	MB ACCUBIND ELISA
	40 ± 13.20	104 ± 34.32	151.70 ± 50.06	MB ACCULITE CLIA
AFP in IU/ml	11.46 ± 3.78	36.70 ± 12.11	90.53 ± 29.87	MB ACCUBIND ELISA
	11.61 ± 3.83	33.98 ± 11.21	90.09 ± 29.73	MB ACCULITE CLIA
fβhCG in IU/ml	0.15 ± 0.05	0.33 ± 0.11	0.55 ± 0.18	MB ACCUBIND ELISA
	0.19 ± 0.06	0.37 ± 0.12	0.55 ± 0.18	MB ACCULITE CLIA
uE3 in nmol/L	2.18 ± 0.72	8.68 ± 2.86	24.06 ± 7.94	MB ACCUBIND ELISA
	2.09 ± 0.69	9.22 ± 3.04	26.26 ± 8.66	MB ACCULITE CLIA

Conversion to Test Values

Analyte	Control Unit	Equivalent Test Value
AFP	IU/ml	Divide by 1.09 = ng/ml
hCG	IU/ml	Multiply by 1,000 = mIU/ml
fβ-hCG	IU/ml	Multiply by 1,000 = mIU/ml = ng/ml
uE3	nmol/L	Divide by 3.467 = ng/ml

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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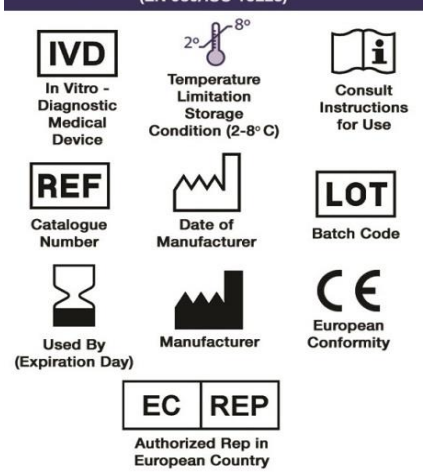
Glossary of Symbols
(EN 980/ISO 15223)



DOCUMENT HISTORY

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