

MATERNAL CONTROL – TRI LEVEL

Alpha-Fetoprotein (AFP), Chorionic Gonadotropin (hCG), Free Beta Chorionic Gonadotropin Subunit (Free β hCG), and Estriol (E3)
PRODUCT CODE: MC-300

LOT# CMJ04/5/6 (Low, Mid, High) EXP: 12-09

Revision: 1 Date: 04-13-06

INTENDED USE

The Human Maternal Control is 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 fertility status. This product is human serum based, ready to use liquid control, stabilized with preservatives and can be used with all RIA, EIA, ELISA or FIA 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 insure precision, linearity and accuracy of dilutions in high activity specimens.

REAGENTS

Monobind Inc's Maternal Panel Control is intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 5.0 ml. The analyte activities are adjusted to exact high concentrations 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 (<-20°C storage) 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 Outdated material should be discarded as biohazardous component.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 | Printed on vial | < -20°C |
| Unopened | Ninety (90) days | 2 – 8°C |
| Opened | Thirty (30) days | 2 – 8°C |

EXPECTED VALUES

The expected ranges for each analyte are given below;

| Analyte | A Assigned Value Range | B Assigned Value Range | C Assigned Value Range |
|---------------------------|------------------------------|------------------------------|------------------------------|
| AFP in U/ mL | 12.5 10.0 – 15.0 | 45.0 38.0 – 52.0 | 85.0 75.0 – 95.0 |
| hCG in U/ mL | 40.0 35.0 – 45.0 | 85.0 75.0 – 95.0 | 130.0 110.0 – 150.0 |
| Free β hCG in U/ mL | 0.71 0.57 – 0.85 | 1.51 1.21 – 1.81 | 2.05 1.64 – 2.46 |
| E3 in nmol / L | 0.8 0.6 – 1.0 | 2.5 2.0 – 3.0 | 4.5 4.0 – 5.0 |

*The values were obtained on Monobind ELISA and confirmed with WALLAC Auto Delphia

Each laboratory should establish their own ranges for the product used. A trend log should be maintained for batch to batch consistency of the test. Large variations from the established mean may result from (a) improper technique, (b) improper dilutions from the stated manufacturer's procedure or (c) modifications of the test system by the manufacturer.

WARNING AND PRECAUTIONS

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.

FOR IN VITRO DIAGNOSTIC USE ONLY

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