

IMPORTANT NOTICE

MSS5024

7460MS

The reconstituted stability for Maternal Control Level 1 lot 7460MS for Free Beta hCG is **2 days**
when stored at **+2°C to +8°C**.

Free Beta hCG is stable for 7 days when frozen once at -18°C to -24°C.

Authorised by: Gareth Little
Serum QC Manager
Date: 10 September 2019

Ref: CCS5842

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

CAT. NO. MSS5024

LOT NO. 7460MS

SIZE: 3 x 1 ml

EXPIRY: 2022-04-28

GTIN: 05055273207385

INTENDED USE

This product is intended for *in vitro* use, in the quality control of Alpha-fetoprotein, Free Beta hCG, Free Estriol, Human Chorionic Gonadotropin, Inhibin A and PAPP-A methods on clinical chemistry systems.

SAFETY PRECAUTIONS AND WARNINGS

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV1 & HIV2) antibody, Hepatitis B surface antigen (HbsAg) and the Hepatitis C virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting disease.

Dispose of all biological materials according to local or national guidelines. Safety Data Sheets are available on www.randox.com.

For IN VITRO diagnostic use only.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination. The reconstituted stability for Free Beta hCG is 2 days when stored at +2°C to +8°C, and 7 days when frozen once at -18°C to -24°C.

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

PREPARATION FOR USE

Open the vial carefully, avoiding any loss of the material and reconstitute with 1 ml of distilled water. Replace the rubber stopper; close the vial and leave to stand for 30 minutes before use. Ensure that all traces of dry material are dissolved by swirling gently.

MATERIALS PROVIDED

Maternal Control - Level I 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Distilled water

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Maternal Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 7460MS Size: 3 x 1 ml Expiry: 2022-04-28

| Analyte | unit | Target | Range | | methods | |
|-------------------|---------------|-----------|-------|-------|--|----------------------------|
| | | | low | high | | |
| Alpha-fetoprotein | KIU/l = IU/ml | 14.1 | 11.3 | 16.9 | Siemens Immulite 1000 | |
| | ng/ml | 17.1 | 13.7 | 20.5 | | |
| | KIU/l = IU/ml | 13.5 | 10.8 | 16.2 | Abbott Architect | |
| | ng/ml | 16.3 | 13.1 | 19.5 | | |
| | KIU/l = IU/ml | 14.1 | 11.3 | 16.9 | Siemens Immulite 2000/2500 | |
| | ng/ml | 17.1 | 13.7 | 20.5 | | |
| | KIU/l = IU/ml | 16.3 | 13.0 | 19.6 | Siemens Centaur XP/XPT/Classic | |
| | ng/ml | 19.7 | 15.7 | 23.7 | | |
| | KIU/l = IU/ml | 13.6 | 10.9 | 16.3 | Beckman Dxl800 | |
| | ng/ml | 16.5 | 13.2 | 19.8 | | |
| | KIU/l = IU/ml | 14.3 | 11.4 | 17.2 | Brahms Kryptor | |
| | ng/ml | 17.3 | 13.8 | 20.8 | | |
| | KIU/l = IU/ml | 14.2 | 11.4 | 17.0 | Beckman Access | |
| | ng/ml | 17.2 | 13.8 | 20.6 | | |
| Free Beta hCG | KIU/l = IU/ml | 15.6 | 12.5 | 18.7 | Roche Cobas 6000/8000 | |
| | ng/ml | 18.9 | 15.1 | 22.7 | | |
| | KIU/l = IU/ml | 15.4 | 12.3 | 18.5 | Roche Cobas E411 | |
| | ng/ml | 18.6 | 14.9 | 22.3 | | |
| | KIU/l = IU/ml | 15.2 | 12.2 | 18.2 | AutoDELFI A (A/B096-101) | |
| | ng/ml | 18.4 | 14.8 | 22.0 | | |
| | KIU/l = IU/ml | 14.4 | 11.5 | 17.3 | DELFI A Xpress (6001-0010 / 6001-001C) | |
| | ng/ml | 17.4 | 13.9 | 20.9 | | |
| | Free Beta hCG | mU/mL=U/L | 24.0 | 18.0 | 30.0 | Siemens Immulite 2000/2500 |
| | | mU/mL=U/L | 24.9 | 18.7 | 31.1 | Siemens Immulite 1000 |
| | | mU/mL=U/L | 20.5 | 15.4 | 25.6 | Brahms Kryptor |
| | | mU/mL=U/L | 15.2 | 11.4 | 19.0 | Roche Cobas 6000/8000 |
| mU/mL=U/L | | 14.6 | 11.0 | 18.3 | Roche Cobas 4000/E411 | |
| mU/mL=U/L | | 19.3 | 14.5 | 24.1 | AutoDELFI A (A/B097-101) | |
| mU/mL=U/L | | 29.4 | 22.1 | 36.8 | DELFI A Xpress (6002-0010 / 6002-001C) | |
| Inhibin A | ng/L = pg/ml | 107 | 80.3 | 134 | Beckman Dxl 600/800 | |
| | ng/L = pg/ml | 138 | 104 | 173 | Brahms Kryptor | |
| | ng/L = pg/ml | 108 | 81.0 | 135 | Beckman Access/LXi725 | |
| | ng/L = pg/ml | 170 | 128 | 213 | AutoDELFI A (B064-102) | |
| PAPP-A | U/L=mIU/ml | 1.52 | 1.14 | 1.90 | Siemens Immulite 1000 | |
| | ng/ml | 6847 | 5135 | 8559 | | |
| | U/L=mIU/ml | 1.64 | 1.23 | 2.05 | Siemens Immulite 2000/2500 | |
| | ng/ml | 7387 | 5541 | 9233 | | |
| | U/L=mIU/ml | 0.038 | 0.029 | 0.048 | Beckman Dxl 600/800 | |
| | ng/ml | 171 | 131 | 211 | | |
| | U/L=mIU/ml | 0.481 | 0.361 | 0.601 | Brahms Kryptor | |
| | ng/ml | 2167 | 1626 | 2708 | | |
| | U/L=mIU/ml | 0.701 | 0.526 | 0.876 | Roche Cobas 6000/8000 | |
| | ng/ml | 3158 | 2369 | 3947 | | |

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 7460MS Size: 3 x 1 ml Expiry: 2022-04-28

| Analyte | unit | Target | Range | | methods |
|----------------------|------------|--------|-------|---|---|
| | | | low | high | |
| PAPP-A | U/L=mlU/ml | 0.704 | 0.528 | 0.880 | Roche Cobas E411 |
| | ng/ml | 3171 | 2378 | 3964 | |
| | U/L=mlU/ml | 0.517 | 0.390 | 0.650 | AutoDELFLIA (A/B098-201) |
| | ng/ml | 2329 | 1757 | 2928 | |
| | U/L=mlU/ml | 0.481 | 0.360 | 0.600 | DELFLIA Xpress (6003-0020 / 6003-002C / |
| | ng/ml | 2167 | 1622 | 2703 | 6003-0050 / 6003-005C) |
| Total Beta hCG | mU/ml=IU/l | 2583 | 2066 | 3100 | Abbott Architect I2000/8200 |
| | IU/ml | 2.58 | 2.07 | 3.09 | |
| | mU/ml=IU/l | 576 | 461 | 691 | Siemens Centaur XP/XPT/Classic |
| | IU/ml | 0.576 | 0.461 | 0.691 | |
| | mU/ml=IU/l | 8529 | 6823 | 10000 | Siemens Immulite 2000/2500 |
| | IU/ml | 8.53 | 6.82 | 10.2 | |
| | mU/ml=IU/l | 10000 | 8000 | 10000 | Siemens Immulite 1000 |
| | IU/ml | 10.0 | 8.00 | 12.0 | |
| | mU/ml=IU/l | 3300 | 2640 | 3960 | Beckman Dxl 600/800 |
| | IU/ml | 3.30 | 2.64 | 3.96 | |
| | mU/ml=IU/l | 3331 | 2665 | 3997 | Beckman Access/LXi725 |
| | IU/ml | 3.33 | 2.67 | 3.99 | |
| | mU/ml=IU/l | 4395 | 3516 | 5274 | Roche Cobas 6000/8000 |
| | IU/ml | 4.40 | 3.52 | 5.28 | |
| | mU/ml=IU/l | 3275 | 2620 | 3930 | Beckman Access Total BhCG (5th IS) |
| | IU/ml | 3.28 | 2.62 | 3.94 | |
| | mU/ml=IU/l | 3064 | 2451 | 3677 | Beckman Dxl Total BhCG (5th IS) |
| | IU/ml | 3.06 | 2.45 | 3.67 | |
| mU/ml=IU/l | 8284 | 6627 | 9941 | Perkin Elmer DELFLIA / DELFLIA Xpress / AutoDELFLIA | |
| IU/ml | 8.28 | 6.63 | 9.94 | | |
| Unconjugated Estriol | nmol/L | 2.01 | 1.51 | 2.51 | Siemens Immulite 2000/2500 |
| | ng/mL | 0.580 | 0.435 | 0.725 | |
| | nmol/L | 1.77 | 1.33 | 2.21 | Siemens Immulite 1000 |
| | ng/mL | 0.510 | 0.384 | 0.636 | |
| | nmol/L | 2.29 | 1.72 | 2.86 | Beckman Dxl 600/800 |
| | ng/mL | 0.660 | 0.496 | 0.824 | |
| | nmol/L | 1.10 | 0.825 | 1.38 | Brahms Kryptor |
| | ng/mL | 0.317 | 0.238 | 0.396 | |
| | nmol/L | 2.33 | 1.75 | 2.91 | Beckman Access/LXi725 |
| | ng/mL | 0.672 | 0.505 | 0.839 | |
| | nmol/L | 5.97 | 4.48 | 7.46 | AutoDELFLIA (B095-101/B095-101U) |
| | ng/mL | 1.72 | 1.29 | 2.15 | |
| nmol/L | 4.83 | 3.62 | 6.04 | DELFLIA Xpress (6005-0010 / 6005-001C) | |
| ng/mL | 1.39 | 1.04 | 1.74 | | |