

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

| | | | |
|-----------------|----------------|----------------|------------|
| CAT. NO. | MSS5025 | LOT NO. | 6471MS |
| SIZE: | 3 x 1ml | EXPIRY: | 2019-10-28 |
| GTIN: | 05055273207392 | | |

INTENDED USE

This product is intended for in-vitro use in the quality control of Alphafoetoprotein, Free Beta HCG, Free Estriol, Human Chorionic Gonadotrophin, 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.

For IN VITRO diagnostic use only.

STORAGE AND STABILITY

OPENED: Store refrigerated (2 to 8°C). Reconstituted serum is stable for 7 days at 2 to 8°C if kept capped in original container and free from contamination. 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 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 1ml 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 2 3 x 1ml

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 94451070 or email Technical.Services@randox.com

31 Mar 17 pl

**MATERNAL CONTROL !'LEVEL 2'fA5 H9 F B5 @7 CBHF C @&L**

Cat. No. MSS5025 Lot. No. 6471MS Size 3 x 1ml Expiry 2019-10-28

| Analyte | unit | Target | Range | | methods | |
|-------------------|---------------|-----------|-------|------------------|--|--|
| | | | low | high | | |
| Alphafoetoprotein | KIU/l = IU/ml | 59.6 | 47.7 | 71.5 | Siemens Immulite 1000 | |
| | ng/ml | 72.1 | 57.7 | 86.5 | | |
| | KIU/l = IU/ml | 60.7 | 48.6 | 72.8 | Perkin Elmer Delfia/Delfia Xpress/AutoDelfia | |
| | ng/ml | 73.4 | 58.8 | 88.0 | | |
| | KIU/l = IU/ml | 59.3 | 47.4 | 71.2 | Abbott Architect | |
| | ng/ml | 71.8 | 57.4 | 86.2 | | |
| | KIU/l = IU/ml | 58.6 | 46.9 | 70.3 | Siemens Immulite 2000/2500 | |
| | ng/ml | 70.9 | 56.7 | 85.1 | | |
| | KIU/l = IU/ml | 61.9 | 49.5 | 74.3 | Siemens Centaur XP/XPT/Classic | |
| | ng/ml | 74.9 | 59.9 | 89.9 | | |
| | KIU/l = IU/ml | 57.6 | 46.1 | 69.1 | Beckman Dxl800 | |
| | ng/ml | 69.7 | 55.8 | 83.6 | | |
| Free Beta hCG | KIU/l = IU/ml | 53.2 | 42.6 | 63.8 | Brahms Kryptor | |
| | ng/ml | 64.4 | 51.5 | 77.3 | | |
| | KIU/l = IU/ml | 66.1 | 52.9 | 79.3 | Beckman Access | |
| | ng/ml | 80.0 | 64.0 | 96.0 | | |
| | KIU/l = IU/ml | 65.3 | 52.2 | 78.4 | Roche Cobas 6000/8000 | |
| | ng/ml | 79.0 | 63.2 | 94.8 | | |
| | KIU/l = IU/ml | 64.7 | 51.8 | 77.6 | Roche Cobas E411 | |
| | ng/ml | 78.3 | 62.7 | 93.9 | | |
| | Inhibin A | mU/mL=U/L | 35.0 | 26.3 | 43.8 | Perkin Elmer Delfia/Delfia Xpress/AutoDelfia |
| | | mU/mL=U/L | 40.5 | 30.4 | 50.6 | Siemens Immulite 2000/2500 |
| mU/mL=U/L | | 39.3 | 29.5 | 49.1 | Siemens Immulite 1000 | |
| mU/mL=U/L | | 37.2 | 27.9 | 46.5 | Brahms Kryptor | |
| mU/mL=U/L | | 29.9 | 22.4 | 37.4 | Roche Cobas 6000/8000 | |
| PAPP-A | ng/L = pg/ml | 235 | 176 | 294 | Beckman Dxl 600/800 | |
| | ng/L = pg/ml | 232 | 174 | 290 | Beckman Access/LXi725 | |
| | ng/L = pg/ml | 324 | 243 | 405 | Active Inhibin A ELISA | |
| PAPP-A | U/L=mlU/ml | 1.95 | 1.46 | 2.44 | Perkin Elmer Delfia/Delfia Xpress/AutoDelfia | |
| | ng/ml | 8784 | 6577 | 10991 | | |
| | U/L=mlU/ml | 6.86 | 5.15 | 8.58 | Siemens Immulite 1000 | |
| | ng/ml | 30901 | 23198 | 38604 | | |
| | U/L=mlU/ml | 6.68 | 5.01 | 8.35 | Siemens Immulite 2000/2500 | |
| | ng/ml | 30090 | 22568 | 37612 | | |
| | U/L=mlU/ml | 0.200 | 0.150 | 0.250 | Beckman Dxl 600/800 | |
| | ng/ml | 901 | 676 | 1126 | | |
| | U/L=mlU/ml | 2.02 | 1.52 | 2.53 | Brahms Kryptor | |
| | ng/ml | 9099 | 6847 | 11351 | | |
| | U/L=mlU/ml | 2.82 | 2.12 | 3.53 | Roche Cobas 6000/8000 | |
| | ng/ml | 12703 | 9550 | 15856 | | |
| U/L=mlU/ml | 2.77 | 2.08 | 3.46 | Roche Cobas E411 | | |
| ng/ml | 12477 | 9369 | 15585 | | | |



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Cat. No. MSS5025 Lot. No. 6471MS Size 3 x 1ml Expiry 2019-10-28

| Analyte | unit | Target | Range | | methods | |
|----------------------|----------------------|--------|-------|-----------------------|--|--|
| | | | low | high | | |
| Total Beta hCG | mU/ml=IU/l | 14608 | 11686 | 17530 | Abbott Architect I2000/8200 | |
| | IU/ml | 14.6 | 11.7 | 17.5 | | |
| | mU/ml=IU/l | 13770 | 11016 | 16524 | Siemens Centaur XP/XPT/Classic | |
| | IU/ml | 13.8 | 11.0 | 16.6 | | |
| | mU/ml=IU/l | 26091 | 20873 | 31309 | Perkin Elmer Delfia/Delfia Xpress/AutoDelfia | |
| | IU/ml | 26.1 | 20.9 | 31.3 | | |
| | mU/ml=IU/l | 24128 | 19302 | 28954 | Siemens Immulite 2000/2500 | |
| | IU/ml | 24.1 | 19.3 | 28.9 | | |
| | mU/ml=IU/l | 26776 | 21421 | 32131 | Siemens Immulite 1000 | |
| | IU/ml | 26.8 | 21.4 | 32.2 | | |
| | mU/ml=IU/l | 16653 | 13322 | 19984 | Beckman Dxl 600/800 | |
| | IU/ml | 16.7 | 13.3 | 20.1 | | |
| | mU/ml=IU/l | 18000 | 14400 | 21600 | Beckman Access/LXi725 | |
| | IU/ml | 18.0 | 14.4 | 21.6 | | |
| Unconjugated Estriol | mU/ml=IU/l | 16752 | 13402 | 20102 | Roche Cobas 6000/8000 | |
| | IU/ml | 16.8 | 13.4 | 20.2 | | |
| | mU/ml=IU/l | 18709 | 14967 | 22451 | Beckman Access Total BhCG (5th IS) | |
| | IU/ml | 18.7 | 15.0 | 22.4 | | |
| | mU/ml=IU/l | 18077 | 14462 | 21692 | Beckman Dxl Total BhCG (5th IS) | |
| | IU/ml | 18.1 | 14.5 | 21.7 | | |
| | Unconjugated Estriol | nmol/L | 25.1 | 18.8 | 31.4 | Perkin Elmer Delfia/Delfia Xpress/AutoDelfia |
| | | ng/mL | 7.24 | 5.42 | 9.06 | |
| | | nmol/L | 9.94 | 7.46 | 12.4 | Siemens Immulite 2000/2500 |
| | | ng/mL | 2.87 | 2.15 | 3.59 | |
| | | nmol/L | 9.61 | 7.21 | 12.0 | Siemens Immulite 1000 |
| | | ng/mL | 2.77 | 2.08 | 3.46 | |
| | | nmol/L | 11.3 | 8.48 | 14.1 | Beckman Dxl 600/800 |
| | | ng/mL | 3.26 | 2.45 | 4.07 | |
| nmol/L | | 8.03 | 6.02 | 10.0 | Brahms Kryptor | |
| ng/mL | | 2.32 | 1.74 | 2.90 | | |
| nmol/L | 11.3 | 8.48 | 14.1 | Beckman Access/LXi725 | | |
| ng/mL | 3.26 | 2.45 | 4.07 | | | |