

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

Cat No. MSS5024 **Lot No.** 5805MS
Size: 3 x 1 ml **Expiry:** 2017-10

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.

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. 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)

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Range					
Analyte	unit	Target	low	high	methods
Alpha-fetoprotein	KIU/I = IU/ml	13.9	11.1	16.7	Siemens Immulite 1000
	ng/ml	16.8	13.4	20.2	
	KIU/I = IU/ml	14.5	11.6	17.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	17.5	14.0	21.0	
	KIU/I = IU/ml	13.1	10.5	15.7	Abbott Architect
	ng/ml	15.9	12.7	19.1	
	KIU/I = IU/ml	12.8	10.2	15.4	Siemens Immulite 2000/2500
	ng/ml	15.5	12.3	18.7	
	KIU/I = IU/ml	14.4	11.5	17.3	Siemens Centaur XP/Classic
	ng/ml	17.4	13.9	20.9	
	KIU/I = IU/ml	13.0	10.4	15.6	Roche Elecsys
	ng/ml	15.7	12.6	18.8	
	KIU/I = IU/ml	13.2	10.6	15.8	Beckman Dxl800
	ng/ml	16.0	12.8	19.2	
	KIU/I = IU/ml	12.8	10.2	15.4	Brahms Kryptor
	ng/ml	15.5	12.3	18.7	
Free Beta hCG	KIU/I = IU/ml	13.8	11.0	16.6	Beckman Access
	ng/ml	16.7	13.3	20.1	
	KIU/I = IU/ml	14.5	11.6	17.4	Roche Cobas 6000/8000
	ng/ml	17.5	14.0	21.0	
	KIU/I = IU/ml	14.1	11.3	16.9	Roche Cobas E411
	ng/ml	17.1	13.7	20.5	
Inhibin A	mU/mL=U/L	11.5	8.63	14.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	11.8	8.85	14.8	Siemens Immulite 2000/2500
	mU/mL=U/L	10.7	8.03	13.4	Siemens Immulite 1000
	mU/mL=U/L	11.7	8.78	14.6	Brahms Kryptor
	mU/mL=U/L	9.71	7.28	12.1	Roche Cobas 6000/8000
	mU/mL=U/L	11.9	8.93	14.9	Zentech ELISA
PAPP-A	ng/L = pg/ml	110	82.5	138	Beckman Dxl 600/800
	ng/L = pg/ml	111	83.3	139	Beckman Access/LXi725
	ng/L = pg/ml	118	88.5	148	Active Inhibin A ELISA
	U/L=mIU/ml	0.466	0.350	0.583	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	2099	1577	2621	
	U/L=mIU/ml	1.94	1.46	2.43	Siemens Immulite 1000
	ng/ml	8739	6577	10901	
	U/L=mIU/ml	2.05	1.54	2.56	Siemens Immulite 2000/2500
	ng/ml	9234	6937	11531	
	U/L=mIU/ml	0.056	0.042	0.070	Beckman Dxl 600/800
PAPP-A	ng/ml	252	189	315	
	U/L=mIU/ml	0.537	0.403	0.671	Brahms Kryptor
	ng/ml	2419	1815	3023	
	U/L=mIU/ml	0.786	0.590	0.983	Roche Cobas 6000/8000
	ng/ml	3541	2658	4424	

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mlU/ml	0.800	0.600	1.00	Roche Cobas E411
	ng/ml	3604	2703	4505	
Total Beta hCG	mU/ml=IU/l	4639	3711	5567	Abbott Architect I2000/8200
	IU/ml	4.64	3.71	5.57	
	mU/ml=IU/l	5145	4116	6174	Siemens Centaur XP/Classic
	IU/ml	5.15	4.12	6.18	
	mU/ml=IU/l	8283	6626	9940	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	8.28	6.63	9.93	
	mU/ml=IU/l	9089	7271	10907	Siemens Immulite 2000/2500
	IU/ml	9.09	7.27	10.9	
	mU/ml=IU/l	9182	7346	11018	Siemens Immulite 1000
	IU/ml	9.18	7.35	11.0	
	mU/ml=IU/l	4872	3898	5846	Beckman Dxl 600/800
	IU/ml	4.87	3.90	5.84	
	mU/ml=IU/l	5146	4117	6175	Beckman Access/LXi725
	IU/ml	5.15	4.12	6.18	
	mU/ml=IU/l	5318	4254	6382	Roche Cobas 6000/8000
	IU/ml	5.32	4.25	6.39	
	mU/ml=IU/l	6440	5152	7728	Beckman Access Total BhCG (5th IS)
	IU/ml	6.44	5.15	7.73	
Unconjugated Estriol	nmol/L	2.00	1.50	2.50	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	0.577	0.433	0.721	
	nmol/L	0.760	0.570	0.950	Siemens Immulite 2000/2500
	ng/mL	0.219	0.164	0.274	
	nmol/L	0.794	0.596	0.993	Siemens Immulite 1000
	ng/mL	0.229	0.172	0.286	
	nmol/L	1.10	0.825	1.38	Beckman Access/LXi725
	ng/mL	0.317	0.238	0.396	
	nmol/L	1.12	0.840	1.40	Beckman Dxl 600/800
	ng/mL	0.323	0.242	0.404	