

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

Cat No. MSS5026 **Lot No.** 5919MS

Size: 3 x 1 ml **Expiry:** 2018-03

INTENDED USE

This product is intended for *in vitro* use, in the quality control of Alpha-fetoprotein, Free Beta hCG, Inhibin A, PAPP-A, Total Beta hCG and Unconjugated Estriol 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 3 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette
Distilled water

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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Range					
Analyte	unit	Target	low	high	methods
Alpha-fetoprotein	KIU/l = IU/ml	121	96.8	145	Siemens Immulite 1000
	ng/ml	146	117	175	
	KIU/l = IU/ml	119	95.2	143	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	144	115	173	
	KIU/l = IU/ml	119	95.2	143	Abbott Architect
	ng/ml	144	115	173	
	KIU/l = IU/ml	118	94.4	142	Siemens Immulite 2000/2500
	ng/ml	143	114	172	
	KIU/l = IU/ml	126	101	151	Siemens Centaur XP/XPT/Classic
	ng/ml	152	122	182	
	KIU/l = IU/ml	119	95.2	143	Beckman Dxl800
	ng/ml	144	115	173	
	KIU/l = IU/ml	97.4	77.9	117	Brahms Kryptor
	ng/ml	118	94.3	142	
	KIU/l = IU/ml	126	101	151	Beckman Access
	ng/ml	152	122	182	
Free Beta hCG	KIU/l = IU/ml	133	106	160	Roche Cobas 6000/8000
	ng/ml	161	128	194	
	KIU/l = IU/ml	131	105	157	Zentech ELISA
	ng/ml	159	127	191	
	KIU/l = IU/ml	131	105	157	Roche Cobas E411
	ng/ml	159	127	191	
Inhibin A	mU/mL=U/L	94.1	70.6	118	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	107	80.3	134	Siemens Immulite 2000/2500
	mU/mL=U/L	101	75.8	126	Siemens Immulite 1000
	mU/mL=U/L	77.9	58.4	97.4	Roche Elecsys 2010/1010
	mU/mL=U/L	94.2	70.7	118	Brahms Kryptor
	mU/mL=U/L	77.0	57.8	96.3	Roche Cobas 6000/8000
PAPP-A	ng/L = pg/ml	432	324	540	Beckman Dxl 600/800
	ng/L = pg/ml	416	312	520	Beckman Access/LXi725
	ng/L = pg/ml	570	428	713	Active Inhibin A ELISA
	U/L=mIU/ml	4.31	3.23	5.39	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	19414	14550	24278	
	U/L=mIU/ml	16.7	12.5	20.9	Siemens Immulite 1000
	ng/ml	75225	56306	94144	
	U/L=mIU/ml	16.1	12.1	20.1	Siemens Immulite 2000/2500
	ng/ml	72522	54504	90540	
	U/L=mIU/ml	0.466	0.350	0.583	Beckman Dxl 600/800
PAPP-A	ng/ml	2099	1577	2621	
	U/L=mIU/ml	4.13	3.10	5.16	Brahms Kryptor
	ng/ml	18604	13964	23244	
	U/L=mIU/ml	6.33	4.75	7.91	Roche Cobas 6000/8000
	ng/ml	28513	21396	35630	

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Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	6.49	4.87	8.11	Roche Cobas E411
	ng/ml	29234	21937	36531	
Total Beta hCG	mU/ml=IU/l	24744	19795	29693	Abbott Architect I2000/8200
	IU/ml	24.7	19.8	29.6	
	mU/ml=IU/l	24355	19484	29226	Siemens Centaur XP/XPT/Classic
	IU/ml	24.4	19.5	29.3	
	mU/ml=IU/l	39963	31970	47956	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	40.0	32.0	48.0	
	mU/ml=IU/l	40110	32088	48132	Siemens Immulite 2000/2500
	IU/ml	40.1	32.1	48.1	
	mU/ml=IU/l	42431	33945	50917	Siemens Immulite 1000
	IU/ml	42.4	33.9	50.9	
	mU/ml=IU/l	28330	22664	33996	Beckman Dxl 600/800
	IU/ml	28.3	22.7	33.9	
	mU/ml=IU/l	25752	20602	30902	Beckman Access/LXi725
	IU/ml	25.8	20.6	31.0	
	mU/ml=IU/l	26555	21244	31866	Roche Cobas 6000/8000
	IU/ml	26.6	21.2	32.0	
	mU/ml=IU/l	25906	20725	31087	Beckman Dxl Total BhCG (5th IS)
	IU/ml	25.9	20.7	31.1	
Unconjugated Estriol	nmol/L	9.52	7.14	11.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	2.75	2.06	3.44	
	nmol/L	4.24	3.18	5.30	Siemens Immulite 2000/2500
	ng/mL	1.22	0.917	1.52	
	nmol/L	3.36	2.52	4.20	Siemens Immulite 1000
	ng/mL	0.969	0.727	1.21	
	nmol/L	4.53	3.40	5.66	Beckman Dxl 600/800
	ng/mL	1.31	0.981	1.64	
	nmol/L	4.47	3.35	5.59	Beckman Access/LXi725
	ng/mL	1.29	0.966	1.61	