

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

Cat No. MSS5024 **Lot No.** 5916MS
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, 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.

30 Oct '15 ne

%

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 5916MS Size: 3 x 1 ml Expiry: 2018-03

Range					
Analyte	unit	Target	low	high	methods
Alpha-fetoprotein	KIU/l = IU/ml	15.8	12.6	19.0	Siemens Immulite 1000
	ng/ml	19.1	15.2	23.0	
	KIU/l = IU/ml	17.2	13.8	20.6	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	20.8	16.7	24.9	
	KIU/l = IU/ml	15.6	12.5	18.7	Abbott Architect
	ng/ml	18.9	15.1	22.7	
	KIU/l = IU/ml	15.2	12.2	18.2	Siemens Immulite 2000/2500
	ng/ml	18.4	14.8	22.0	
	KIU/l = IU/ml	17.8	14.2	21.4	Siemens Centaur XP/XPT/Classic
	ng/ml	21.5	17.2	25.8	
	KIU/l = IU/ml	15.6	12.5	18.7	Beckman Dxl800
	ng/ml	18.9	15.1	22.7	
	KIU/l = IU/ml	15.1	12.1	18.1	Brahms Kryptor
	ng/ml	18.3	14.6	22.0	
	KIU/l = IU/ml	17.8	14.2	21.4	Beckman Access
	ng/ml	21.5	17.2	25.8	
Free Beta hCG	KIU/l = IU/ml	17.4	13.9	20.9	Roche Cobas 6000/8000
	ng/ml	21.1	16.8	25.4	
	KIU/l = IU/ml	17.1	13.7	20.5	Roche Cobas E411
	ng/ml	20.7	16.6	24.8	
	mU/mL=U/L	15.4	11.6	19.3	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	17.5	13.1	21.9	Siemens Immulite 2000/2500
	mU/mL=U/L	14.9	11.2	18.6	Siemens Immulite 1000
Inhibin A	mU/mL=U/L	13.3	9.98	16.6	Roche Elecsys 2010/1010
	mU/mL=U/L	16.0	12.0	20.0	Brahms Kryptor
	mU/mL=U/L	13.1	9.83	16.4	Roche Cobas 6000/8000
	mU/mL=U/L	16.1	12.1	20.1	Zentech ELISA
	ng/L = pg/ml	105	78.8	131	Beckman Dxl 600/800
	ng/L = pg/ml	109	81.8	136	Beckman Access/LXi725
	ng/L = pg/ml	198	149	248	Active Inhibin A ELISA
PAPP-A	U/L=mIU/ml	0.464	0.348	0.580	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	2090	1568	2612	
	U/L=mIU/ml	1.66	1.25	2.08	Siemens Immulite 1000
	ng/ml	7477	5631	9323	
	U/L=mIU/ml	1.89	1.42	2.36	Siemens Immulite 2000/2500
	ng/ml	8514	6396	10632	
	U/L=mIU/ml	0.050	0.038	0.063	Beckman Dxl 600/800
	ng/ml	225	171	279	
	U/L=mIU/ml	0.782	0.587	0.978	Roche Elecsys 2010/1010
	ng/ml	3523	2644	4402	
	U/L=mIU/ml	0.501	0.376	0.626	Brahms Kryptor
	ng/ml	2257	1694	2820	

%

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 5916MS Size: 3 x 1 ml Expiry: 2018-03

Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mlU/ml	0.740	0.555	0.925	Roche Cobas 6000/8000
	ng/ml	3333	2500	4166	
	U/L=mlU/ml	0.747	0.560	0.934	Roche Cobas E411
	ng/ml	3365	2523	4207	
Total Beta hCG	mU/ml=IU/l	3752	3002	4502	Abbott Architect I2000/8200
	IU/ml	3.75	3.00	4.50	
	mU/ml=IU/l	3648	2918	4378	Siemens Centaur XP/XPT/Classic
	IU/ml	3.65	2.92	4.38	
	mU/ml=IU/l	7198	5758	8638	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	7.20	5.76	8.64	
	mU/ml=IU/l	7584	6067	9101	Siemens Immulite 2000/2500
	IU/ml	7.58	6.07	9.09	
	mU/ml=IU/l	7816	6253	9379	Siemens Immulite 1000
	IU/ml	7.82	6.25	9.39	
	mU/ml=IU/l	4287	3430	5144	Beckman Dxl 600/800
	IU/ml	4.29	3.43	5.15	
	mU/ml=IU/l	4361	3489	5233	Beckman Access/LXi725
	IU/ml	4.36	3.49	5.23	
	mU/ml=IU/l	4312	3450	5174	Roche Cobas 6000/8000
	IU/ml	4.31	3.45	5.17	
	mU/ml=IU/l	4712	3770	5654	Beckman Dxl Total BhCG (5th IS)
	IU/ml	4.71	3.77	5.65	
Unconjugated Estriol	nmol/L	2.15	1.61	2.69	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	0.620	0.464	0.776	
	nmol/L	0.870	0.653	1.09	Siemens Immulite 2000/2500
	ng/mL	0.251	0.188	0.314	
	nmol/L	1.22	0.915	1.53	Beckman Dxl 600/800
	ng/mL	0.352	0.264	0.440	
	nmol/L	1.09	0.818	1.36	Beckman Access/LXi725
	ng/mL	0.314	0.236	0.392	