

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

Cat No. MSS5025 **Lot No.** 5807MS

Size: 3 x 1 ml **Expiry:** 2017-10

INTENDED USE

This product is intended for *in vitro* use in the quality control of Alphafetoprotein, 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 2 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

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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Range					
Analyte	unit	Target	low	high	methods
Alphafetoprotein	KIU/l = IU/ml	53.5	42.8	64.2	Siemens Immulite 1000
	ng/ml	64.7	51.8	77.6	
	KIU/l = IU/ml	53.0	42.4	63.6	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	64.1	51.3	76.9	
	KIU/l = IU/ml	51.6	41.3	61.9	Abbott Architect
	ng/ml	62.4	50.0	74.8	
	KIU/l = IU/ml	52.7	42.2	63.2	Siemens Immulite 2000/2500
	ng/ml	63.8	51.1	76.5	
	KIU/l = IU/ml	57.3	45.8	68.8	Siemens Centaur XP/Classic
	ng/ml	69.3	55.4	83.2	
	KIU/l = IU/ml	49.9	39.9	59.9	Beckman Dxl800
	ng/ml	60.4	48.3	72.5	
	KIU/l = IU/ml	48.0	37.2	58.8	Brahms Kryptor
	ng/ml	58.1	45.0	71.2	
	KIU/l = IU/ml	53.8	43.0	64.6	Beckman Access
	ng/ml	65.1	52.0	78.2	
Free Beta hCG	KIU/l = IU/ml	56.6	45.3	67.9	Roche Cobas 6000/8000
	ng/ml	68.5	54.8	82.2	
	KIU/l = IU/ml	40.1	28.1	52.1	Zentech ELISA
	ng/ml	48.5	34.0	63.0	
	KIU/l = IU/ml	58.6	46.9	70.3	Roche Cobas E411
	ng/ml	70.9	56.7	85.1	
Inhibin A	mU/mL=U/L	31.5	23.6	39.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	32.7	24.5	40.9	Siemens Immulite 2000/2500
	mU/mL=U/L	28.2	21.2	35.3	Siemens Immulite 1000
	mU/mL=U/L	26.4	19.8	33.0	Roche Elecsys 2010/1010
	mU/mL=U/L	31.9	23.9	39.9	Brahms Kryptor
	mU/mL=U/L	25.2	18.9	31.5	Roche Cobas 6000/8000
	mU/mL=U/L	27.1	20.3	33.9	Zentech ELISA
PAPP-A	ng/L = pg/ml	234	176	293	Beckman Dxl 600/800
	ng/L = pg/ml	233	175	291	Beckman Access/LXi725
	U/L=mIU/ml	2.37	1.78	2.96	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	10676	8018	13334	
	U/L=mIU/ml	9.57	7.18	12.0	Siemens Immulite 1000
	ng/ml	43108	32342	53874	
	U/L=mIU/ml	9.69	7.27	12.1	Siemens Immulite 2000/2500
	ng/ml	43649	32748	54550	
	U/L=mIU/ml	0.260	0.195	0.325	Beckman Dxl 600/800
	ng/ml	1171	878	1464	
	U/L=mIU/ml	3.48	2.61	4.35	Roche Elecsys 2010/1010
	ng/ml	15676	11757	19595	
	U/L=mIU/ml	2.42	1.82	3.03	Brahms Kryptor
	ng/ml	10901	8198	13604	

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Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	3.51	2.63	4.39	Roche Cobas 6000/8000
	ng/ml	15811	11847	19775	
	U/L=mIU/ml	3.53	2.65	4.41	Roche Cobas E411
	ng/ml	15901	11937	19865	
Total Beta hCG	mU/ml=IU/l	13236	10589	15883	Abbott Architect I2000/8200
	IU/ml	13.2	10.6	15.9	
	mU/ml=IU/l	13273	10618	15928	Siemens Centaur XP/Classic
	IU/ml	13.3	10.6	16.0	
	mU/ml=IU/l	22998	18398	27598	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	23.0	18.4	27.6	
	mU/ml=IU/l	22871	18297	27445	Siemens Immulite 2000/2500
	IU/ml	22.9	18.3	27.5	
	mU/ml=IU/l	24019	19215	28823	Siemens Immulite 1000
	IU/ml	24.0	19.2	28.8	
	mU/ml=IU/l	13037	10430	15644	Beckman Dxl 600/800
	IU/ml	13.0	10.4	15.6	
Unconjugated Estriol	mU/ml=IU/l	12854	10283	15425	Roche Cobas 6000/8000
	IU/ml	12.8	10.3	15.3	
	nmol/L	3.67	2.75	4.59	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	1.06	0.793	1.33	
	nmol/L	1.64	1.16	2.12	Siemens Immulite 2000/2500
	ng/mL	0.473	0.335	0.610	
	nmol/L	1.81	1.36	2.26	Siemens Immulite 1000
	ng/mL	0.522	0.392	0.652	
	nmol/L	1.95	1.46	2.44	Beckman Access/LXi725
	ng/mL	0.562	0.421	0.703	