MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

CAT NO. MSS5024 **LOT NO.** 4552MS
SIZE: 3 x 1ml **EXPIRY:** 2014-09

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°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 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 1 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 Support, Northern Ireland, tel: +44 (0) 28 9442 2413 or email Technical.Support@randox.com

01 Feb '12 ne

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			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	15.0	12.1	17.9	Siemens Immulite 1000
	ng/ml	18.2	14.6	21.8	
	KIU/l = IU/ml	14.0	11.2	16.8	Wallac Delfia/Delfia Express/AutoDelfia
	ng/ml	16.9	13.6	20.2	
	KIU/l = IU/ml	14.0	12.6	15.4	Siemens Immulite 2000/2500
	ng/ml	16.9	15.2	18.6	
	KIU/l = IU/ml	16.3	13.3	19.3	Siemens Advia Centaur
	ng/ml	19.7	16.1	23.3	
	KIU/l = IU/ml	14.4	12.2	16.6	Beckman DxI800
	ng/ml	17.4	14.8	20.0	
	KIU/l = IU/ml	14.2	12.8	15.6	Brahms Kryptor
	ng/ml	17.2	15.5	18.9	
Free Beta HCG	mU/mL=U/L	8.30	7.22	9.38	Wallac Delfia/Delfia Express/AutoDelfia
	mU/mL=U/L	9.03	7.41	10.7	Siemens Immulite 2000/2500
	mU/mL=U/L	7.68	5.76	9.60	Siemens Immulite 1000
	mU/mL=U/L	6.48	5.83	7.13	Roche Elecsys 2010/1010
	mU/mL=U/L	8.85	7.97	9.73	Brahms Kryptor
Free Estriol	nmol/L	0.929	0.743	1.12	Siemens Immulite 2000/2500
	ng/mL	0.268	0.214	0.320	
	nmol/L	1.20	1.08	1.32	Beckman DxI800
	ng/mL	0.346	0.311	0.380	
Inhibin A	ng/L = pg/ml	114	103	125	Beckman DxI800
PAPP-A	U/L=mIU/ml	0.503	0.440	0.566	Wallac Delfia/Delfia Express/AutoDelfia
	U/L=mIU/ml	1.83	1.50	2.16	Siemens Immulite 1000
	U/L=mIU/ml	1.89	1.59	2.19	Siemens Immulite 2000/2500
Total Beta hCG	mU/ml=IU/l	4838	4354	5322	Abbott Architect I2000/8200
	IU/ml	4.84	4.35	5.33	
	mU/ml=IU/l	4431	3988	4874	Siemens Advia Centaur
	IU/ml	4.43	3.99	4.87	
	mU/ml=IU/l	8520	7328	9712	Siemens Immulite 2000/2500
	IU/ml	8.52	7.33	9.71	
	mU/ml=IU/l	4369	3445	5293	Beckman DxI800
	IU/ml	4.37	3.45	5.29	

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