MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

Cat No. MSS5025 **Lot No.** 5918MS
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 2 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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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alpha-fetoprotein	KIU/l = IU/ml	63.7	51.0	76.4	Siemens Immulite 1000
	ng/ml	77.1	61.7	92.5	
	KIU/l = IU/ml	63.1	50.5	75.7	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	76.4	61.1	91.7	
	KIU/l = IU/ml	61.1	48.9	73.3	Abbott Architect
	ng/ml	73.9	59.2	88.6	
	KIU/l = IU/ml	61.7	49.4	74.0	Siemens Immulite 2000/2500
	ng/ml	74.7	59.8	89.6	
	KIU/l = IU/ml	65.7	52.6	78.8	Siemens Centaur XP/XPT/Classic
	ng/ml	79.5	63.6	95.4	
	KIU/l = IU/ml	61.2	49.0	73.4	Beckman DxI800
	ng/ml	74.1	59.3	88.9	
	KIU/l = IU/ml	51.7	41.4	62.0	Brahms Kryptor
	ng/ml	62.6	50.1	75.1	
	KIU/l = IU/ml	65.7	52.6	78.8	Beckman Access
	ng/ml	79.5	63.6	95.4	
	KIU/l = IU/ml	68.4	54.7	82.1	Roche Cobas 6000/8000
	ng/ml	82.8	66.2	99.4	
	KIU/l = IU/ml	67.3	53.8	80.8	Zentech ELISA
	ng/ml	81.4	65.1	97.7	
	KIU/l = IU/ml	70.3	56.2	84.4	Roche Cobas E411
	ng/ml	85.1	68.0	102	
Free Beta hCG	mU/mL=U/L	43.1	32.3	53.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	50.3	37.7	62.9	Siemens Immulite 2000/2500
	mU/mL=U/L	49.2	36.9	61.5	Siemens Immulite 1000
	mU/mL=U/L	45.1	33.8	56.4	Brahms Kryptor
	mU/mL=U/L	36.0	27.0	45.0	Roche Cobas 6000/8000
	mU/mL=U/L	35.4	26.6	44.3	Zentech ELISA
Inhibin A	ng/L = pg/ml	216	162	270	Beckman DxI 600/800
	ng/L = pg/ml	220	165	275	Beckman Access/LXi725
	ng/L = pg/ml	245	184	306	Active Inhibin A ELISA
PAPP-A	U/L=mIU/ml	2.23	1.67	2.79	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	10045	7523	12567	
	U/L=mIU/ml	8.97	6.73	11.2	Siemens Immulite 1000
	ng/ml	40405	30315	50495	
	U/L=mIU/ml	9.11	6.83	11.4	Siemens Immulite 2000/2500
	ng/ml	41036	30766	51306	
	U/L=mIU/ml	0.260	0.195	0.325	Beckman DxI 600/800
	ng/ml	1171	878	1464	
	U/L=mIU/ml	3.54	2.66	4.43	Roche Elecsys 2010/1010
	ng/ml	15946	11982	19910	
	U/L=mIU/ml	2.34	1.76	2.93	Brahms Kryptor
	ng/ml	10541	7928	13154	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
PAPP-A	U/L=mIU/ml	3.27	2.45	4.09	Roche Cobas 6000/8000
	ng/ml	14730	11036	18424	
	U/L=mIU/ml	3.25	2.44	4.06	Roche Cobas E411
	ng/ml	14640	10991	18289	
Total Beta hCG	mU/ml=IU/l	11388	9110	13676	Abbott Architect I2000/8200
	IU/ml	11.4	9.11	13.7	
	mU/ml=IU/l	10141	8113	12169	Siemens Centaur XP/XPT/Classic
	IU/ml	10.1	8.12	12.1	
	mU/ml=IU/l	20912	16730	25094	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	20.9	16.7	25.1	
	mU/ml=IU/l	19237	15390	23084	Siemens Immulite 2000/2500
	IU/ml	19.2	15.4	23.0	
	mU/ml=IU/l	21543	17234	25852	Siemens Immulite 1000
	IU/ml	21.5	17.2	25.8	
	mU/ml=IU/l	12453	9962	14944	Beckman DxI 600/800
	IU/ml	12.5	9.96	15.0	
	mU/ml=IU/l	12035	9628	14442	Beckman Access/LXi725
	IU/ml	12.0	9.63	14.4	
	mU/ml=IU/l	11767	9414	14120	Roche Cobas 6000/8000
	IU/ml	11.8	9.41	14.2	
	mU/ml=IU/l	14172	11338	17006	Beckman Access Total BhCG (5th IS)
	IU/ml	14.2	11.3	17.1	
	mU/ml=IU/l	13545	10836	16254	Beckman DxI Total BhCG (5th IS)
	IU/ml	13.5	10.8	16.2	
Unconjugated Estriol	nmol/L	4.28	3.21	5.35	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	1.23	0.926	1.53	
	nmol/L	1.93	1.45	2.41	Siemens Immulite 2000/2500
	ng/mL	0.557	0.418	0.696	
	nmol/L	2.22	1.67	2.78	Beckman DxI 600/800
	ng/mL	0.640	0.482	0.798	
	nmol/L	2.08	1.56	2.60	Beckman Access/LXi725
	ng/mL	0.600	0.450	0.750	
	nmol/L	4.19	3.14	5.24	Zentech ELISA
	ng/mL	1.21	0.906	1.51	

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