MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

Cat No. MSS5026 **Lot No.** 5810MS
Size: 3 x 1 ml **Expiry:** 2017-10

INTENDED USE

This product is intended for *in vitro* use in the quality control of Alpha-fetoprotein, Free Beta hCG, Free Estriol, Human Chorionic Gonadrophin, 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 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**
Alphafoetoprotein	KIU/l = IU/ml	102	81.6	122	Siemens Immulite 1000
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	97.6	78.1	117	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	118	94.5	142	
	KIU/l = IU/ml	98.2	78.6	118	Abbott Architect
	ng/ml	119	95.1	143	
	KIU/l = IU/ml	100	80.0	120	Siemens Immulite 2000/2500
	ng/ml	121	96.8	145	
	KIU/l = IU/ml	104	83.2	125	Siemens Centaur XP/Classic
	ng/ml	126	101	151	
	KIU/l = IU/ml	97.6	78.1	117	Beckman DxI800
	ng/ml	118	94.5	142	
	KIU/l = IU/ml	81.2	65.0	97.4	Brahms Kryptor
	ng/ml	98.3	78.7	118	
	KIU/l = IU/ml	103	82.4	124	Beckman Access
	ng/ml	125	100	150	
	KIU/l = IU/ml	107	85.6	128	Roche Cobas 6000/8000
	ng/ml	129	104	154	
	KIU/l = IU/ml	107	85.6	128	Roche Cobas E411
	ng/ml	129	104	154	
Free Beta hCG	mU/mL=U/L	65.5	49.1	81.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	68.7	51.5	85.9	Siemens Immulite 2000/2500
	mU/mL=U/L	66.3	49.7	82.9	Siemens Immulite 1000
	mU/mL=U/L	59.5	44.6	74.4	Roche Elecsys 2010/1010
	mU/mL=U/L	66.5	49.9	83.1	Brahms Kryptor
	mU/mL=U/L	54.2	40.7	67.8	Roche Cobas 6000/8000
Inhibin A	ng/L = pg/ml	426	320	533	Beckman DxI 600/800
	ng/L = pg/ml	421	316	526	Beckman Access/LXi725
	ng/L = pg/ml	452	339	565	Active Inhibin A ELISA
PAPP-A	U/L=mIU/ml	4.53	3.40	5.66	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	20405	15315	25495	
	U/L=mIU/ml	18.9	14.2	23.6	Siemens Immulite 1000
	ng/ml	85135	63964	106306	
	U/L=mIU/ml	18.7	14.0	23.4	Siemens Immulite 2000/2500
	ng/ml	84234	63063	105405	
	U/L=mIU/ml	0.510	0.383	0.638	Beckman DxI 600/800
	ng/ml	2297	1725	2869	
	U/L=mIU/ml	7.24	5.43	9.05	Roche Elecsys 2010/1010
	ng/ml	32613	24459	40767	
	U/L=mIU/ml	4.44	3.33	5.55	Brahms Kryptor
	ng/ml	20000	15000	25000	
	U/L=mIU/ml	7.22	5.42	9.03	Roche Cobas 6000/8000
	ng/ml	32522	24414	40630	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
PAPP-A	U/L=mIU/ml	7.13	5.35	8.91	Roche Cobas E411
	ng/ml	32117	24099	40135	
Total Beta hCG	mU/ml=IU/l	28041	22433	33649	Abbott Architect I2000/8200
	IU/ml	28.0	22.4	33.6	
	mU/ml=IU/l	27144	21715	32573	Siemens Centaur XP/Classic
	IU/ml	27.1	21.7	32.5	
	mU/ml=IU/l	46717	37374	56060	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	46.7	37.4	56.0	
	mU/ml=IU/l	46183	36946	55420	Siemens Immulite 2000/2500
	IU/ml	46.2	36.9	55.5	
	mU/ml=IU/l	49812	39850	59774	Siemens Immulite 1000
	IU/ml	49.8	39.9	59.7	
	mU/ml=IU/l	29010	23208	34812	Beckman DxI 600/800
	IU/ml	29.0	23.2	34.8	
	mU/ml=IU/l	30948	24758	37138	Beckman Access/LXi725
	IU/ml	30.9	24.8	37.0	
	mU/ml=IU/l	28800	23040	34560	Roche Cobas 6000/8000
	IU/ml	28.8	23.0	34.6	
Unconjugated Estriol	nmol/L	7.66	5.75	9.58	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	2.21	1.66	2.76	
	nmol/L	3.58	2.69	4.48	Siemens Immulite 2000/2500
	ng/mL	1.03	0.776	1.28	
	nmol/L	3.33	2.50	4.16	Siemens Immulite 1000
	ng/mL	0.960	0.721	1.20	
	nmol/L	3.91	2.93	4.89	Beckman Access/LXi725
	ng/mL	1.13	0.845	1.42	
	nmol/L	4.70	3.53	5.88	Zentech ELISA
	ng/mL	1.36	1.02	1.70	
	nmol/L	3.69	2.77	4.61	Beckman DxI 600/800
	ng/mL	1.06	0.800	1.33	