MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 7944MS
SIZE: 3 x 1 ml **EXPIRY:** 2023-10-28
GTIN: 05055273207392

INTENDED USE
This product is intended for *in vitro* use in the quality control of Alpha-fetoprotein, 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.

Dispose of all biological materials according to local or national guidelines. Safety Data Sheets are available on www.randox.com.

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 94451070 or email Technical.Services@randox.com.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	54.2	43.4	65.0	Siemens Immulite 1000
	ng/ml	65.6	52.5	78.7	
	KIU/l = IU/ml	52.0	41.6	62.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	62.9	50.3	75.5	
	KIU/l = IU/ml	51.9	41.5	62.3	Abbott Architect
	ng/ml	62.8	50.2	75.4	
	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	58.2	46.6	69.8	Siemens Centaur XP/XPT/Classic
	ng/ml	70.4	56.4	84.4	
	KIU/l = IU/ml	50.7	40.6	60.8	Beckman DxI800
	ng/ml	61.3	49.1	73.5	
	KIU/l = IU/ml	48.4	38.7	58.1	Brahms Kryptor
	ng/ml	58.6	46.8	70.4	
	KIU/l = IU/ml	52.2	41.8	62.6	Beckman Access
	ng/ml	63.2	50.6	75.8	
	KIU/l = IU/ml	57.7	46.2	69.2	Roche Cobas e601/602
	ng/ml	69.8	55.9	83.7	
	KIU/l = IU/ml	57.8	46.2	69.4	Roche Cobas 4000/E411
	ng/ml	69.9	55.9	83.9	
	KIU/l = IU/ml	56.5	45.2	67.8	Roche Cobas e801
	ng/ml	68.4	54.7	82.1	
Free Beta hCG	mU/mL=U/L	78.7	59.0	98.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	86.3	64.7	108	Siemens Immulite 2000/2500
	mU/mL=U/L	77.4	58.1	96.8	Siemens Immulite 1000
	mU/mL=U/L	64.4	48.3	80.5	Brahms Kryptor
	mU/mL=U/L	63.7	47.8	79.6	Roche Cobas e601/602
	mU/mL=U/L	64.6	48.5	80.8	Roche Cobas 4000/E411
	mU/mL=U/L	62.8	47.1	78.5	Roche Cobas e801
Inhibin A	ng/L = pg/ml	175	131	219	Beckman DxI 600/800
	ng/L = pg/ml	265	199	331	Brahms Kryptor
	ng/L = pg/ml	171	128	214	Beckman Access
PAPP-A	U/L=mIU/ml	1.81	1.36	2.26	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	8153	6126	10180	
	U/L=mIU/ml	6.65	4.99	8.31	Siemens Immulite 1000
	ng/ml	29955	22477	37433	
	U/L=mIU/ml	6.96	5.22	8.70	Siemens Immulite 2000/2500
	ng/ml	31351	23513	39189	
	U/L=mIU/ml	0.150	0.113	0.188	Beckman DxI 600/800
	ng/ml	676	509	843	
	U/L=mIU/ml	1.63	1.22	2.04	Brahms Kryptor
	ng/ml	7342	5495	9189	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
PAPP-A	U/L=mIU/ml	0.150	0.113	0.188	Beckman Access
	ng/ml	676	509	843	
	U/L=mIU/ml	2.45	1.84	3.06	Roche Cobas e601/602
	ng/ml	11036	8288	13784	
	U/L=mIU/ml	2.41	1.81	3.01	Roche Cobas 4000/E411
	ng/ml	10856	8153	13559	
	U/L=mIU/ml	2.42	1.82	3.03	Roche Cobas e801
	ng/ml	10901	8198	13604	
Total Beta hCG	mU/ml=IU/l	9456	7565	11347	Abbott Architect / Alinity
	IU/ml	9.46	7.57	11.4	
	mU/ml=IU/l	19621	15697	23545	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	19.6	15.7	23.5	
	mU/ml=IU/l	17785	14228	21342	Siemens Immulite 2000/2500
	IU/ml	17.8	14.2	21.4	
	mU/ml=IU/l	19231	15385	23077	Siemens Immulite 1000
	IU/ml	19.2	15.4	23.0	
	mU/ml=IU/l	11804	9443	14165	Beckman DxI 600/800
	IU/ml	11.8	9.44	14.2	
	mU/ml=IU/l	11182	8946	13418	Beckman Access
	IU/ml	11.2	8.95	13.5	
	mU/ml=IU/l	10690	8552	12828	Roche Cobas 6000/8000
	IU/ml	10.7	8.55	12.9	
	mU/ml=IU/l	11451	9161	13741	Beckman Access Total BhCG (5th IS)
	IU/ml	11.5	9.16	13.8	
	mU/ml=IU/l	11499	9199	13799	Beckman DxI Total BhCG (5th IS)
	IU/ml	11.5	9.20	13.8	
Unconjugated Estriol	nmol/L	18.8	14.1	23.5	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	5.42	4.07	6.77	
	nmol/L	8.51	6.38	10.6	Siemens Immulite 2000/2500
	ng/mL	2.45	1.84	3.06	
	nmol/L	9.07	6.80	11.3	Siemens Immulite 1000
	ng/mL	2.62	1.96	3.28	
	nmol/L	7.15	5.36	8.94	Beckman DxI 600/800
	ng/mL	2.06	1.55	2.57	
	nmol/L	3.47	2.60	4.34	Brahms Kryptor
	ng/mL	1.00	0.750	1.25	
	nmol/L	7.60	5.70	9.50	Beckman Access
	ng/mL	2.19	1.64	2.74	

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