RANDOX 2797 CE

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

CAT. NO. MSS5024 **LOT NO.** 8434MS
SIZE: 3 x 1 ml **EXPIRY:** 2025-05-28
GTIN: 05055273207385

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.

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 1 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Distilled water
Volumetric pipette

VALUE ASSIGNMENT
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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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Dungloe, Donegal,
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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	12.5	10.0	15.0	Siemens Immulite 1000
	ng/ml	15.1	12.1	18.1	
	KIU/l = IU/ml	14.8	11.8	17.8	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	17.9	14.3	21.5	
	KIU/l = IU/ml	12.9	10.3	15.5	Abbott Architect
	ng/ml	15.6	12.5	18.7	
	KIU/l = IU/ml	13.1	10.5	15.7	Siemens Immulite 2000/2500
	ng/ml	15.9	12.7	19.1	
	KIU/l = IU/ml	16.0	12.8	19.2	Siemens Centaur XP/XPT/Classic
	ng/ml	19.4	15.5	23.3	
	KIU/l = IU/ml	12.7	10.2	15.2	Beckman DxI800
	ng/ml	15.4	12.3	18.5	
	KIU/l = IU/ml	13.5	10.8	16.2	Brahms Kryptor
	ng/ml	16.3	13.1	19.5	
	KIU/l = IU/ml	13.7	11.0	16.4	Beckman Access
	ng/ml	16.6	13.3	19.9	
	KIU/l = IU/ml	14.4	11.5	17.3	Roche Cobas e601/602
	ng/ml	17.4	13.9	20.9	
	KIU/l = IU/ml	14.7	11.8	17.6	Roche Cobas 4000/E411
	ng/ml	17.8	14.3	21.3	
	KIU/l = IU/ml	13.6	10.9	16.3	Roche Cobas e402/e801
	ng/ml	16.5	13.2	19.8	
Free Beta hCG	mU/mL=U/L	14.6	11.0	18.3	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	16.9	12.7	21.1	Siemens Immulite 2000/2500
	mU/mL=U/L	16.6	12.5	20.8	Siemens Immulite 1000
	mU/mL=U/L	13.2	9.90	16.5	Roche Elecsys 2010/1010
	mU/mL=U/L	15.4	11.6	19.3	Brahms Kryptor
	mU/mL=U/L	14.0	10.5	17.5	Roche Cobas e601/602
	mU/mL=U/L	14.2	10.7	17.8	Roche Cobas 4000/E411
	mU/mL=U/L	13.9	10.4	17.4	Roche Cobas e402/e801
Inhibin A	ng/L = pg/ml	162	122	203	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/L = pg/ml	90.6	68.0	113	Beckman DxI 600/800
	ng/L = pg/ml	127	95.3	159	Brahms Kryptor
	ng/L = pg/ml	87.9	65.9	110	Beckman Access
PAPP-A	U/L=mIU/ml	0.586	0.440	0.733	Siemens Centaur XP/XPT/Classic
	ng/ml	2640	1982	3298	
	U/L=mIU/ml	0.430	0.323	0.538	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	1937	1455	2419	
	U/L=mIU/ml	1.47	1.10	1.84	Siemens Immulite 1000
	ng/ml	6622	4955	8289	
	U/L=mIU/ml	1.58	1.19	1.98	Siemens Immulite 2000/2500
	ng/ml	7117	5360	8874	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
PAPP-A	U/L=mIU/ml	0.036	0.027	0.045	Beckman Dxl 600/800
	ng/ml	162	122	202	
	U/L=mIU/ml	0.416	0.312	0.520	Brahms Kryptor
	ng/ml	1874	1405	2343	
	U/L=mIU/ml	0.036	0.027	0.045	Beckman Access
	ng/ml	162	122	202	
	U/L=mIU/ml	0.647	0.485	0.809	Roche Cobas e601/602
	ng/ml	2914	2185	3643	
	U/L=mIU/ml	0.630	0.473	0.788	Roche Cobas 4000/E411
	ng/ml	2838	2131	3545	
	U/L=mIU/ml	0.622	0.467	0.778	Roche Cobas e402/e801
	ng/ml	2802	2104	3500	
Total Beta hCG	mU/ml=IU/l	3559	2847	4271	Abbott Architect / Alinity
	IU/ml	3.56	2.85	4.27	
	mU/ml=IU/l	3423	2738	4108	Siemens Centaur XP/XPT/Classic
	IU/ml	3.42	2.74	4.10	
	mU/ml=IU/l	8234	6587	9881	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	8.23	6.59	9.87	
	mU/ml=IU/l	6395	5116	7674	Siemens Immulite 2000/2500
	IU/ml	6.40	5.12	7.68	
	mU/ml=IU/l	7038	5630	8446	Siemens Immulite 1000
	IU/ml	7.04	5.63	8.45	
	mU/ml=IU/l	5109	4087	6131	Beckman Dxl 600/800
	IU/ml	5.11	4.09	6.13	
	mU/ml=IU/l	4825	3860	5790	Beckman Access
	IU/ml	4.83	3.86	5.80	
	mU/ml=IU/l	4165	3332	4998	Roche Cobas 6000/8000
	IU/ml	4.17	3.33	5.01	
	mU/ml=IU/l	4845	3876	5814	Beckman Access Total BhCG (5th IS)
	IU/ml	4.85	3.88	5.82	
	mU/ml=IU/l	5074	4059	6089	Beckman Dxl Total BhCG (5th IS)
	IU/ml	5.07	4.06	6.08	
	mU/ml=IU/l	4014	3211	4817	Roche hCG+Beta e801
	IU/ml	4.01	3.21	4.81	
	mU/ml=IU/l	3644	2915	4373	Siemens Atellica IM
	IU/ml	3.64	2.92	4.36	
Unconjugated Estriol	nmol/L	4.60	3.45	5.75	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	1.33	0.995	1.67	
	nmol/L	1.87	1.40	2.34	Siemens Immulite 2000/2500
	ng/mL	0.539	0.404	0.674	
	nmol/L	2.02	1.52	2.53	Siemens Immulite 1000
	ng/mL	0.583	0.438	0.728	
	nmol/L	2.03	1.52	2.54	Beckman Dxl 600/800
	ng/mL	0.585	0.438	0.732	
	nmol/L	0.480	0.360	0.600	Brahms Kryptor
	ng/mL	0.138	0.104	0.172	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Unconjugated Estriol	nmol/L	2.04	1.53	2.55	Beckman Access
	ng/mL	0.588	0.441	0.735	

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