

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 8153MS
SIZE 3 x 1 ml **EXPIRY:** 2024-11-28
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 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 2 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 94451070 or email Technical.Services@randox.com.

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Analyte	unit	Target	Range		methods	
			low	high		
Alphafoetoprotein	KIU/l = IU/ml	51.0	40.8	61.2	Siemens Immulite 1000	
	ng/ml	61.7	49.4	74.0		
	KIU/l = IU/ml	51.3	41.0	61.6	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	62.1	49.6	74.6		
	KIU/l = IU/ml	48.5	38.8	58.2	Abbott Architect	
	ng/ml	58.7	46.9	70.5		
	KIU/l = IU/ml	51.1	40.9	61.3	Siemens Immulite 2000/2500	
	ng/ml	61.8	49.5	74.1		
	KIU/l = IU/ml	58.8	47.0	70.6	Siemens Centaur XP/XPT/Classic	
	ng/ml	71.1	56.9	85.3		
	KIU/l = IU/ml	47.0	37.6	56.4	Beckman Dxl800	
	ng/ml	56.9	45.5	68.3		
	KIU/l = IU/ml	44.9	35.9	53.9	Brahms Kryptor	
	ng/ml	54.3	43.4	65.2		
Free Beta hCG	KIU/l = IU/ml	49.1	39.3	58.9	Beckman Access	
	ng/ml	59.4	47.6	71.2		
	KIU/l = IU/ml	57.0	45.6	68.4	Roche Cobas e601/602	
	ng/ml	69.0	55.2	82.8		
	KIU/l = IU/ml	54.4	43.5	65.3	Roche Cobas 4000/E411	
	ng/ml	65.8	52.6	79.0		
	KIU/l = IU/ml	52.9	42.3	63.5	Roche Cobas e402/e801	
	ng/ml	64.0	51.2	76.8		
	KIU/l = IU/ml	58.0	46.4	69.6	Siemens Atellica IM	
	ng/ml	70.2	56.1	84.3		
	Inhibin A	mU/mL=U/L	60.2	45.2	75.3	Siemens Centaur XP/XPT/Classic
		mU/mL=U/L	49.9	37.4	62.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	56.1	42.1	70.1	Siemens Immulite 2000/2500
		mU/mL=U/L	56.5	42.4	70.6	Siemens Immulite 1000
mU/mL=U/L		47.6	35.7	59.5	Brahms Kryptor	
mU/mL=U/L		43.9	32.9	54.9	Roche Cobas e601/602	
mU/mL=U/L		43.6	32.7	54.5	Roche Cobas 4000/E411	
mU/mL=U/L		43.2	32.4	54.0	Roche Cobas e402/e801	
PAPP-A	ng/L = pg/ml	341	256	426	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	188	141	235	Beckman Dxl 600/800	
	ng/L = pg/ml	269	202	336	Brahms Kryptor	
	ng/L = pg/ml	184	138	230	Beckman Access	
PAPP-A	U/L=mIU/ml	2.75	2.06	3.44	Siemens Centaur XP/XPT/Classic	
	ng/ml	12387	9279	15495		
	U/L=mIU/ml	2.05	1.54	2.56	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	9234	6937	11531		
PAPP-A	U/L=mIU/ml	8.48	6.36	10.6	Siemens Immulite 1000	
	ng/ml	38198	28649	47747		

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mlIU/ml	7.89	5.92	9.86	Siemens Immulite 2000/2500
	ng/ml	35541	26667	44415	
	U/L=mlIU/ml	0.181	0.136	0.226	Beckman Dxl 600/800
	ng/ml	815	613	1017	
	U/L=mlIU/ml	1.71	1.28	2.14	Brahms Kryptor
	ng/ml	7703	5766	9640	
	U/L=mlIU/ml	0.185	0.139	0.231	Beckman Access
	ng/ml	833	626	1040	
	U/L=mlIU/ml	2.82	2.12	3.53	Roche Cobas e601/602
	ng/ml	12703	9550	15856	
	U/L=mlIU/ml	2.80	2.10	3.50	Roche Cobas 4000/E411
	ng/ml	12613	9459	15767	
	U/L=mlIU/ml	2.71	2.03	3.39	Roche Cobas e402/e801
	ng/ml	12207	9144	15270	
Total Beta hCG	mU/ml=IU/l	12298	9838	14758	Abbott Architect / Alinity
	IU/ml	12.3	9.84	14.8	
	mU/ml=IU/l	11256	9005	13507	Siemens Centaur XP/XPT/Classic
	IU/ml	11.3	9.01	13.6	
	mU/ml=IU/l	25750	20600	30900	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	25.8	20.6	31.0	
	mU/ml=IU/l	21785	17428	26142	Siemens Immulite 2000/2500
	IU/ml	21.8	17.4	26.2	
	mU/ml=IU/l	24958	19966	29950	Siemens Immulite 1000
	IU/ml	25.0	20.0	30.0	
	mU/ml=IU/l	16037	12830	19244	Beckman Dxl 600/800
	IU/ml	16.0	12.8	19.2	
	mU/ml=IU/l	15561	12449	18673	Beckman Access
	IU/ml	15.6	12.4	18.8	
	mU/ml=IU/l	13691	10953	16429	Roche Cobas 6000/8000
	IU/ml	13.7	11.0	16.4	
	mU/ml=IU/l	15219	12175	18263	Beckman Access Total BhCG (5th IS)
	IU/ml	15.2	12.2	18.2	
	mU/ml=IU/l	16560	13248	19872	Beckman Dxl Total BhCG (5th IS)
	IU/ml	16.6	13.2	20.0	
	mU/ml=IU/l	13362	10690	16034	Roche hCG+Beta e801
	IU/ml	13.4	10.7	16.1	
mU/ml=IU/l	11064	8851	13277	Siemens Atellica IM	
IU/ml	11.1	8.85	13.4		
Unconjugated Estriol	nmol/L	21.8	16.4	27.3	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	6.29	4.73	7.85	
	nmol/L	9.54	7.16	11.9	Siemens Immulite 2000/2500
	ng/mL	2.75	2.06	3.44	
	nmol/L	9.65	7.24	12.1	Siemens Immulite 1000
	ng/mL	2.78	2.09	3.47	
	nmol/L	7.90	5.93	9.88	Beckman Dxl 600/800
	ng/mL	2.28	1.71	2.85	

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Analyte	unit	Target	Range		methods
			low	high	
Unconjugated Estriol	nmol/L	4.01	3.01	5.01	Brahms Kryptor
	ng/mL	1.16	0.868	1.45	
	nmol/L	8.19	6.14	10.2	Beckman Access
	ng/mL	2.36	1.77	2.95	