

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026

LOT NO. 7340MS

SIZE: 3 x 1ml

EXPIRY: 2021-10-28

GTIN: 05055273207408

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 3 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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Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	KIU/l = IU/ml	157	126	188	Siemens Immulite 1000
	ng/ml	190	152	228	
	KIU/l = IU/ml	142	114	170	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	172	138	206	
	KIU/l = IU/ml	139	111	167	Abbott Architect
	ng/ml	168	134	202	
	KIU/l = IU/ml	147	118	176	Siemens Immulite 2000/2500
	ng/ml	178	143	213	
	KIU/l = IU/ml	158	126	190	Siemens Centaur XP/XPT/Classic
	ng/ml	191	152	230	
	KIU/l = IU/ml	136	109	163	Beckman Dxl800
	ng/ml	165	132	198	
	KIU/l = IU/ml	128	102	154	Brahms Kryptor
	ng/ml	155	123	187	
Free Beta hCG	KIU/l = IU/ml	142	114	170	Beckman Access
	ng/ml	172	138	206	
	KIU/l = IU/ml	160	128	192	Roche Cobas 6000/8000
	ng/ml	194	155	233	
	KIU/l = IU/ml	157	126	188	Roche Cobas E411
	ng/ml	190	152	228	
Inhibin A	mU/mL=U/L	191	143	239	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	238	179	298	Siemens Immulite 2000/2500
	mU/mL=U/L	217	163	271	Siemens Immulite 1000
	mU/mL=U/L	221	166	276	Brahms Kryptor
	mU/mL=U/L	194	146	243	Roche Cobas 6000/8000
	mU/mL=U/L	193	145	241	Roche Cobas 4000/E411
PAPP-A	ng/L = pg/ml	658	494	823	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/L = pg/ml	412	309	515	Beckman Dxl 600/800
	ng/L = pg/ml	399	299	499	Beckman Access/LXi725
	ng/L = pg/ml	440	330	550	Active Inhibin A ELISA
PAPP-A	U/L=mlU/ml	4.82	3.62	6.03	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	21712	16306	27118	
	U/L=mlU/ml	14.3	10.7	17.9	Siemens Immulite 1000
	ng/ml	64414	48198	80630	
	U/L=mlU/ml	14.8	11.1	18.5	Siemens Immulite 2000/2500
	ng/ml	66667	50000	83334	
	U/L=mlU/ml	0.352	0.264	0.440	Beckman Dxl 600/800
	ng/ml	1586	1189	1983	
	U/L=mlU/ml	4.46	3.35	5.58	Brahms Kryptor
	ng/ml	20090	15090	25090	
PAPP-A	U/L=mlU/ml	6.12	4.59	7.65	Roche Cobas 6000/8000
	ng/ml	27568	20676	34460	

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	5.89	4.42	7.36	Roche Cobas E411
	ng/ml	26532	19910	33154	
Total Beta hCG	mU/ml=IU/l	29460	23568	35352	Abbott Architect I2000/8200
	IU/ml	29.5	23.6	35.4	
	mU/ml=IU/l	47746	38197	57295	Biomerieux Vidas/Mini Vidas
	IU/ml	47.7	38.2	57.2	
	mU/ml=IU/l	28273	22618	33928	Siemens Centaur XP/XPT/Classic
	IU/ml	28.3	22.6	34.0	
	mU/ml=IU/l	49313	39450	59176	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	49.3	39.5	59.1	
	mU/ml=IU/l	46072	36858	55286	Siemens Immulite 2000/2500
	IU/ml	46.1	36.9	55.3	
	mU/ml=IU/l	51392	41114	61670	Siemens Immulite 1000
	IU/ml	51.4	41.1	61.7	
	mU/ml=IU/l	35155	28124	42186	Beckman Dxl 600/800
	IU/ml	35.2	28.1	42.3	
	mU/ml=IU/l	35354	28283	42425	Beckman Access/LXi725
	IU/ml	35.4	28.3	42.5	
	mU/ml=IU/l	32259	25807	38711	Roche Cobas 6000/8000
	IU/ml	32.3	25.8	38.8	
	mU/ml=IU/l	35713	28570	42856	Beckman Access Total BhCG (5th IS)
	IU/ml	35.7	28.6	42.8	
mU/ml=IU/l	36814	29451	44177	Beckman Dxl Total BhCG (5th IS)	
IU/ml	36.8	29.5	44.1		
Unconjugated Estriol	nmol/L	49.7	37.3	62.1	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	14.3	10.8	17.8	
	nmol/L	19.9	14.9	24.9	Siemens Immulite 2000/2500
	ng/mL	5.74	4.30	7.18	
	nmol/L	20.1	15.1	25.1	Siemens Immulite 1000
	ng/mL	5.80	4.35	7.25	
	nmol/L	21.8	16.4	27.3	Beckman Dxl 600/800
	ng/mL	6.29	4.73	7.85	
	nmol/L	14.7	11.0	18.4	Brahms Kryptor
	ng/mL	4.24	3.17	5.31	
	nmol/L	21.8	16.4	27.3	Beckman Access/LXi725
	ng/mL	6.29	4.73	7.85	