

## MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

**CAT. NO.** MSS5026

**LOT NO.** 6738MS

**SIZE:** 3 x 1 ml

**EXPIRY:** 2020-05-28

**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](http://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 94451070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

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Analyte	unit	Target	Range		methods	
			low	high		
Alpha-fetoprotein	KIU/l = IU/ml	103	82.4	124	Siemens Immulite 1000	
	ng/ml	125	100	150		
	KIU/l = IU/ml	98.5	78.8	118	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	119	95.3	143		
	KIU/l = IU/ml	92.2	73.8	111	Abbott Architect	
	ng/ml	112	89.3	135		
	KIU/l = IU/ml	99.1	79.3	119	Siemens Immulite 2000/2500	
	ng/ml	120	96.0	144		
	KIU/l = IU/ml	114	91.2	137	Siemens Centaur XP/XPT/Classic	
	ng/ml	138	110	166		
	KIU/l = IU/ml	97.2	77.8	117	Beckman Dxl800	
	ng/ml	118	94.1	142		
Free Beta hCG	KIU/l = IU/ml	84.1	67.3	101	Brahms Kryptor	
	ng/ml	102	81.4	123		
	KIU/l = IU/ml	102	81.6	122	Beckman Access	
	ng/ml	123	98.7	147		
	KIU/l = IU/ml	109	87.2	131	Roche Cobas 6000/8000	
	ng/ml	132	106	158		
	KIU/l = IU/ml	108	86.4	130	Roche Cobas E411	
	ng/ml	131	105	157		
	Free Beta hCG	mU/mL=U/L	185	139	231	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	214	161	268	Siemens Immulite 2000/2500
		mU/mL=U/L	189	142	236	Siemens Immulite 1000
		mU/mL=U/L	207	155	259	Brahms Kryptor
mU/mL=U/L		174	131	218	Roche Cobas 6000/8000	
mU/mL=U/L		180	135	225	Roche Cobas 4000/E411	
Inhibin A	ng/L = pg/ml	714	536	893	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	429	322	536	Beckman Dxl 600/800	
	ng/L = pg/ml	424	318	530	Beckman Access/LXi725	
	ng/L = pg/ml	426	320	533	Active Inhibin A ELISA	
PAPP-A	U/L=mIU/ml	3.90	2.93	4.88	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	17568	13198	21938		
	U/L=mIU/ml	13.0	9.75	16.3	Siemens Immulite 1000	
	ng/ml	58559	43919	73199		
	U/L=mIU/ml	13.2	9.90	16.5	Siemens Immulite 2000/2500	
	ng/ml	59459	44595	74323		
	U/L=mIU/ml	0.345	0.259	0.431	Beckman Dxl 600/800	
	ng/ml	1554	1167	1941		
PAPP-A	U/L=mIU/ml	3.86	2.90	4.83	Brahms Kryptor	
	ng/ml	17387	13063	21711		
	U/L=mIU/ml	5.36	4.02	6.70	Roche Cobas 6000/8000	
	ng/ml	24144	18108	30180		

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			low	high	
PAPP-A	U/L=mIU/ml	5.26	3.95	6.58	Roche Cobas E411
	ng/ml	23694	17793	29595	
Total Beta hCG	mU/ml=IU/l	34898	27918	41878	Abbott Architect I2000/8200
	IU/ml	34.9	27.9	41.9	
	mU/ml=IU/l	32624	26099	39149	Siemens Centaur XP/XPT/Classic
	IU/ml	32.6	26.1	39.1	
	mU/ml=IU/l	46417	37134	55700	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	46.4	37.1	55.7	
	mU/ml=IU/l	47094	37675	56513	Siemens Immulite 2000/2500
	IU/ml	47.1	37.7	56.5	
	mU/ml=IU/l	52970	42376	63564	Siemens Immulite 1000
	IU/ml	53.0	42.4	63.6	
	mU/ml=IU/l	44064	35251	52877	Beckman Dxl 600/800
	IU/ml	44.1	35.3	52.9	
	mU/ml=IU/l	46385	37108	55662	Beckman Access/LXi725
	IU/ml	46.4	37.1	55.7	
	mU/ml=IU/l	36410	29128	43692	Roche Cobas 6000/8000
	IU/ml	36.4	29.1	43.7	
	mU/ml=IU/l	44315	35452	53178	Beckman Access Total BhCG (5th IS)
	IU/ml	44.3	35.5	53.1	
mU/ml=IU/l	44242	35394	53090	Beckman Dxl Total BhCG (5th IS)	
IU/ml	44.2	35.4	53.0		
Unconjugated Estriol	nmol/L	40.7	30.5	50.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	11.7	8.80	14.6	
	nmol/L	15.4	11.6	19.3	Siemens Immulite 2000/2500
	ng/mL	4.44	3.35	5.53	
	nmol/L	16.0	12.0	20.0	Siemens Immulite 1000
	ng/mL	4.61	3.46	5.76	
	nmol/L	16.8	12.6	21.0	Beckman Dxl 600/800
	ng/mL	4.85	3.63	6.07	
nmol/L	16.3	12.2	20.4	Beckman Access/LXi725	
ng/mL	4.70	3.52	5.88		
nmol/L	17.7	13.3	22.1	IBL ELISA	
ng/mL	5.10	3.84	6.36		