

## MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

**CAT. NO.** MSS5024

**LOT NO.** 7794MS

**SIZE:** 3 x 1 ml

**EXPIRY:** 2023-05-28

**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](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 I 3 x 1 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

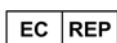
Distilled water

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](mailto:Technical.Services@randox.com).



Randox Teoranta, Meenmore,  
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## MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 7794MS Size: 3 x 1 ml Expiry: 2023-05-28

Analyte	unit	Target	Range		methods	
			low	high		
Alpha-fetoprotein	KIU/l = IU/ml	13.5	10.8	16.2	Siemens Immulite 1000	
	ng/ml	16.3	13.1	19.5		
	KIU/l = IU/ml	13.0	10.4	15.6	Abbott Architect	
	ng/ml	15.7	12.6	18.8		
	KIU/l = IU/ml	13.4	10.7	16.1	Siemens Immulite 2000/2500	
	ng/ml	16.2	12.9	19.5		
	KIU/l = IU/ml	16.3	13.0	19.6	Siemens Centaur XP/XPT/Classic	
	ng/ml	19.7	15.7	23.7		
	KIU/l = IU/ml	13.1	10.5	15.7	Beckman Dxl800	
	ng/ml	15.9	12.7	19.1		
Free Beta hCG	KIU/l = IU/ml	13.9	11.1	16.7	Brahms Kryptor	
	ng/ml	16.8	13.4	20.2		
	KIU/l = IU/ml	13.6	10.9	16.3	Beckman Access	
	ng/ml	16.5	13.2	19.8		
	KIU/l = IU/ml	14.5	11.6	17.4	Roche Cobas 6000/8000	
	ng/ml	17.5	14.0	21.0		
	KIU/l = IU/ml	14.1	11.3	16.9	Roche Cobas E411	
	ng/ml	17.1	13.7	20.5		
	Inhibin A	mU/mL=U/L	30.6	23.0	38.3	Siemens Immulite 2000/2500
		mU/mL=U/L	25.9	19.4	32.4	Siemens Immulite 1000
mU/mL=U/L		22.7	17.0	28.4	Brahms Kryptor	
mU/mL=U/L		22.3	16.7	27.9	Roche Cobas 6000/8000	
mU/mL=U/L		23.0	17.3	28.8	Roche Cobas 4000/E411	
PAPP-A	ng/L = pg/ml	105	78.8	131	Beckman Dxl 600/800	
	ng/L = pg/ml	105	78.8	131	Beckman Access/LXi725	
Total Beta hCG	U/L=mIU/ml	1.43	1.07	1.79	Siemens Immulite 1000	
	ng/ml	6441	4820	8062		
	U/L=mIU/ml	1.57	1.18	1.96	Siemens Immulite 2000/2500	
	ng/ml	7072	5315	8829		
	U/L=mIU/ml	0.033	0.025	0.041	Beckman Dxl 600/800	
	ng/ml	149	113	185		
	U/L=mIU/ml	0.392	0.294	0.490	Brahms Kryptor	
	ng/ml	1766	1324	2208		
Total Beta hCG	U/L=mIU/ml	0.603	0.452	0.754	Roche Cobas 6000/8000	
	ng/ml	2716	2036	3396		
	U/L=mIU/ml	0.590	0.443	0.738	Roche Cobas E411	
	ng/ml	2658	1995	3321		
	mU/ml=IU/l	3155	2524	3786	Abbott Architect I2000/8200	
	IU/ml	3.16	2.52	3.80		
	mU/ml=IU/l	2910	2328	3492	Siemens Centaur XP/XPT/Classic	
	IU/ml	2.91	2.33	3.49		
Total Beta hCG	mU/ml=IU/l	6876	5501	8251	Siemens Immulite 2000/2500	
	IU/ml	6.88	5.50	8.26		

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Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	7604	6083	9125	Siemens Immulite 1000
	IU/ml	7.60	6.08	9.12	
	mU/ml=IU/l	4164	3331	4997	Beckman Dxl 600/800
	IU/ml	4.16	3.33	4.99	
	mU/ml=IU/l	4257	3406	5108	Beckman Access/LXi725
	IU/ml	4.26	3.41	5.11	
	mU/ml=IU/l	4095	3276	4914	Roche Cobas 6000/8000
	IU/ml	4.10	3.28	4.92	
	mU/ml=IU/l	4272	3418	5126	Beckman Access Total BhCG (5th IS)
	IU/ml	4.27	3.42	5.12	
Unconjugated Estriol	nmol/L	2.21	1.66	2.76	Siemens Immulite 2000/2500
	ng/mL	0.637	0.479	0.795	
	nmol/L	2.28	1.71	2.85	Siemens Immulite 1000
	ng/mL	0.658	0.493	0.823	
	nmol/L	2.00	1.50	2.50	Beckman Dxl 600/800
	ng/mL	0.577	0.433	0.721	
	nmol/L	0.624	0.468	0.780	Brahms Kryptor
	ng/mL	0.180	0.135	0.225	
	nmol/L	2.13	1.60	2.66	Beckman Access/LXi725
	ng/mL	0.614	0.461	0.767	

**ADDITIONAL VALUES FOR  
MATERNAL CONTROL - LEVEL I  
(MATERNAL CONTROL I)  
Cat No. MSS5024  
Lot No. 7794MS**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	14.5	11.6 - 17.4	AutoDELFI A (A/B096-101)
	ng/ml	17.5	14.0 - 21.0	
	KIU/l = IU/ml	14.8	11.8 - 17.8	DELFI A Xpress (6001-0010 / 6001-001C)
	ng/ml	17.9	14.3 - 21.5	
Free Beta hCG	mU/ml = U/l	23.9	17.9 - 29.9	AutoDELFI A (A/B097-101)
	mU/ml = U/l	29.6	22.2 - 37.0	DELFI A Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	176	132 - 220	AutoDELFI A (B064-102)
PAPP-A	U/l = mIU/ml	0.420	0.315 - 0.525	AutoDELFI A (A/B098-201)
	ng/ml	1892	1419 - 2365	
	U/l = mIU/ml	0.399	0.299 - 0.499	DELFI A Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	1797	1348 - 2246	
Unconjugated Estriol	nmol/l	5.26	3.95 - 6.57	AutoDELFI A (B095-101 / B095-101U)
	ng/ml	1.52	1.14 - 1.90	
	nmol/l	3.98	2.99 - 4.97	DELFI A Xpress (6005-0010 / 6005-001C)
	ng/ml	1.15	0.863 - 1.44	

EC REP

Randox Teoranta, Meenmore,  
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F94 TV06, Ireland

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COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml ng/ml	16.4 19.8	13.1 - 19.7 15.8 - 23.8	Siemens Atellica IM

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