

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 7798MS
SIZE: 3 x 1ml **EXPIRY:** 2023-05-28
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.

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

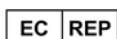
MATERIALS REQUIRED BUT NOT PROVIDED

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.



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Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	KIU/l = IU/ml	102	81.6	122	Siemens Immulite 1000
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	98.4	78.7	118	Abbott Architect
	ng/ml	119	95.2	143	
	KIU/l = IU/ml	102	81.6	122	Siemens Immulite 2000/2500
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	116	92.8	139	Siemens Centaur XP/XPT/Classic
	ng/ml	140	112	168	
	KIU/l = IU/ml	96.9	77.5	116	Beckman Dxl800
	ng/ml	117	93.8	140	
	KIU/l = IU/ml	90.4	72.3	108	Brahms Kryptor
	ng/ml	109	87.5	131	
Free Beta hCG	KIU/l = IU/ml	97.9	78.3	117	Beckman Access
	ng/ml	118	94.7	141	
	KIU/l = IU/ml	111	88.8	133	Roche Cobas 6000/8000
	ng/ml	134	107	161	
	KIU/l = IU/ml	108	86.4	130	Roche Cobas E411
	ng/ml	131	105	157	
	mU/mL=U/L	220	165	275	Siemens Immulite 2000/2500
	mU/mL=U/L	217	163	271	Siemens Immulite 1000
	mU/mL=U/L	180	135	225	Brahms Kryptor
	mU/mL=U/L	158	119	198	Roche Cobas 6000/8000
mU/mL=U/L	166	125	208	Roche Cobas 4000/E411	
Inhibin A	ng/L = pg/ml	403	302	504	Beckman Dxl 600/800
	ng/L = pg/ml	578	434	723	Brahms Kryptor
	ng/L = pg/ml	385	289	481	Beckman Access/LXi725
PAPP-A	U/L=mlU/ml	13.3	9.98	16.6	Siemens Immulite 1000
	ng/ml	59910	44955	74865	
	U/L=mlU/ml	14.3	10.7	17.9	Siemens Immulite 2000/2500
	ng/ml	64414	48198	80630	
	U/L=mlU/ml	0.304	0.228	0.380	Beckman Dxl 600/800
	ng/ml	1369	1027	1711	
	U/L=mlU/ml	4.96	3.72	6.20	Roche Elecsys 2010/1010
	ng/ml	22342	16757	27927	
	U/L=mlU/ml	3.04	2.28	3.80	Brahms Kryptor
	ng/ml	13694	10270	17118	
	U/L=mlU/ml	4.87	3.65	6.09	Roche Cobas 6000/8000
	ng/ml	21937	16441	27433	
U/L=mlU/ml	4.83	3.62	6.04	Roche Cobas E411	
ng/ml	21757	16306	27208		
Total Beta hCG	mU/ml=IU/l	23527	18822	28232	Abbott Architect I2000/8200
	IU/ml	23.5	18.8	28.2	

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Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	19733	15786	23680	Siemens Centaur XP/XPT/Classic
	IU/ml	19.7	15.8	23.6	
	mU/ml=IU/l	41837	33470	50204	Siemens Immulite 2000/2500
	IU/ml	41.8	33.5	50.1	
	mU/ml=IU/l	42625	34100	51150	Siemens Immulite 1000
	IU/ml	42.6	34.1	51.1	
	mU/ml=IU/l	30103	24082	36124	Beckman Dxl 600/800
	IU/ml	30.1	24.1	36.1	
	mU/ml=IU/l	28321	22657	33985	Beckman Access/LXi725
	IU/ml	28.3	22.7	33.9	
	mU/ml=IU/l	29193	23354	35032	Roche Cobas 6000/8000
	IU/ml	29.2	23.4	35.0	
	mU/ml=IU/l	29325	23460	35190	Beckman Access Total BhCG (5th IS)
	IU/ml	29.3	23.5	35.1	
mU/ml=IU/l	30382	24306	36458	Beckman Dxl Total BhCG (5th IS)	
IU/ml	30.4	24.3	36.5		
Unconjugated Estriol	nmol/L	15.7	11.8	19.6	Siemens Immulite 2000/2500
	ng/mL	4.53	3.40	5.66	
	nmol/L	16.8	12.6	21.0	Siemens Immulite 1000
	ng/mL	4.85	3.63	6.07	
	nmol/L	12.5	9.38	15.6	Beckman Dxl 600/800
	ng/mL	3.61	2.71	4.51	
	nmol/L	7.04	5.28	8.80	Brahms Kryptor
	ng/mL	2.03	1.52	2.54	
	nmol/L	12.8	9.60	16.0	Beckman Access/LXi725
	ng/mL	3.69	2.77	4.61	

**ADDITIONAL VALUES FOR
MATERNAL CONTROL - LEVEL 3
(MATERNAL CONTROL 3)**

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Lot No. 7798MS

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COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml ng/ml	117 142	93.6 - 140 114 - 170	Siemens Atellica IM

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COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	99.2	79.4 - 119	AutoDELFIA (A/B096-101)
	ng/ml	120	96.0 - 144	
	KIU/l = IU/ml	101	80.8 - 121	DELFIA Xpress (6001-0010 / 6001-001C)
	ng/ml	122	97.6 - 146	
Free Beta hCG	mU/ml = U/l	163	122 - 204	AutoDELFIA (A/B097-101)
	mU/ml = U/l	> 200	-	DELFIA Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	652	489 - 815	AutoDELFIA (B064-102)
PAPP-A	U/l = mIU/ml	3.92	2.94 - 4.90	AutoDELFIA (A/B098-201)
	ng/ml	17658	13244 - 22072	
	U/l = mIU/ml	3.63	27.2 - 4.54	DELFIA Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	16351	12263 - 20439	
Unconjugated Estriol	nmol/l	36.4	27.3 - 45.5	AutoDELFIA (B095-101 / B095-101U)
	ng/ml	10.5	7.88 - 13.1	
	nmol/l	28.1	21.1 - 35.1	DELFIA Xpress (6005-0010 / 6005-001C)
	ng/ml	8.10	6.08 - 10.1	

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