

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 7946MS
SIZE: 3 x 1ml **EXPIRY:** 2023-10-28
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 94451070 or email Technical.Services@randox.com.

EC	REP
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Randox Teoranta, Meenmore,
 Dungloe, Donegal,
 F94 TV06, Ireland

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Cat. No. MSS5026 Lot. No. 7946MS Size 3 x 1ml Expiry 2023-10-28

Range						
Analyte	unit	Target	low	high	methods	
Alphafoetoprotein	KIU/l = IU/ml	87.2	69.8	105	Siemens Immulite 1000	
	ng/ml	106	84.5	128		
	KIU/l = IU/ml	86.0	68.8	103	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	104	83.2	125		
	KIU/l = IU/ml	86.2	69.0	103	Abbott Architect	
	ng/ml	104	83.5	125		
	KIU/l = IU/ml	85.8	68.6	103	Siemens Immulite 2000/2500	
	ng/ml	104	83.0	125		
	KIU/l = IU/ml	97.4	77.9	117	Siemens Centaur XP/XPT/Classic	
	ng/ml	118	94.3	142		
	KIU/l = IU/ml	83.7	67.0	100	Beckman Dxl800	
	ng/ml	101	81.1	121		
	KIU/l = IU/ml	78.8	63.0	94.6	Brahms Kryptor	
	ng/ml	95.3	76.2	114		
Free Beta hCG	KIU/l = IU/ml	87.2	69.8	105	Beckman Access	
	ng/ml	106	84.5	128		
	KIU/l = IU/ml	97.4	77.9	117	Roche Cobas e601/602	
	ng/ml	118	94.3	142		
	KIU/l = IU/ml	99.4	79.5	119	Roche Cobas 4000/E411	
	ng/ml	120	96.2	144		
	KIU/l = IU/ml	96.3	77.0	116	Roche Cobas e801	
	ng/ml	117	93.2	141		
	Free Beta hCG	mU/mL=U/L	157	118	196	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	176	132	220	Siemens Immulite 2000/2500
		mU/mL=U/L	157	118	196	Siemens Immulite 1000
		mU/mL=U/L	135	101	169	Brahms Kryptor
		mU/mL=U/L	134	101	168	Roche Cobas e601/602
		mU/mL=U/L	136	102	170	Roche Cobas 4000/E411
mU/mL=U/L		133	100	166	Roche Cobas e801	
Inhibin A	ng/L = pg/ml	324	243	405	Beckman Dxl 600/800	
	ng/L = pg/ml	537	403	671	Brahms Kryptor	
	ng/L = pg/ml	326	245	408	Beckman Access	
PAPP-A	U/L=mIU/ml	3.79	2.84	4.74	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	17072	12793	21351		
	U/L=mIU/ml	14.0	10.5	17.5	Siemens Immulite 2000/2500	
	ng/ml	63063	47297	78829		
	U/L=mIU/ml	0.297	0.223	0.371	Beckman Dxl 600/800	
	ng/ml	1338	1005	1671		
	U/L=mIU/ml	3.20	2.40	4.00	Brahms Kryptor	
ng/ml	14414	10811	18017			
PAPP-A	U/L=mIU/ml	0.305	0.229	0.381	Beckman Access	
	ng/ml	1374	1032	1716		

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	5.01	3.76	6.26	Roche Cobas e601/602
	ng/ml	22568	16937	28199	
	U/L=mIU/ml	4.93	3.70	6.16	Roche Cobas 4000/E411
	ng/ml	22207	16667	27747	
PAPP-A	U/L=mIU/ml	4.79	3.59	5.99	Roche Cobas e801
	ng/ml	21577	16171	26983	
Total Beta hCG	mU/ml=IU/l	18705	14964	22446	Abbott Architect / Alinity
	IU/ml	18.7	15.0	22.4	
	mU/ml=IU/l	16529	13223	19835	Siemens Centaur XP/XPT/Classic
	IU/ml	16.5	13.2	19.8	
	mU/ml=IU/l	39719	31775	47663	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	39.7	31.8	47.6	
	mU/ml=IU/l	37280	29824	44736	Siemens Immulite 2000/2500
	IU/ml	37.3	29.8	44.8	
	mU/ml=IU/l	37187	29750	44624	Siemens Immulite 1000
	IU/ml	37.2	29.8	44.6	
	mU/ml=IU/l	23695	18956	28434	Beckman Dxl 600/800
	IU/ml	23.7	19.0	28.4	
	mU/ml=IU/l	23906	19125	28687	Beckman Access
	IU/ml	23.9	19.1	28.7	
	mU/ml=IU/l	22728	18182	27274	Roche Cobas 6000/8000
	IU/ml	22.7	18.2	27.2	
mU/ml=IU/l	23171	18537	27805	Beckman Access Total BhCG (5th IS)	
IU/ml	23.2	18.5	27.9		
mU/ml=IU/l	23954	19163	28745	Beckman Dxl Total BhCG (5th IS)	
IU/ml	24.0	19.2	28.8		
mU/ml=IU/l	22830	18264	27396	Roche hCG+Beta e801	
IU/ml	22.8	18.3	27.3		
Unconjugated Estriol	nmol/L	33.6	25.2	42.0	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	9.69	7.27	12.1	
	nmol/L	14.8	11.1	18.5	Siemens Immulite 2000/2500
	ng/mL	4.27	3.20	5.34	
	nmol/L	14.5	10.9	18.1	Siemens Immulite 1000
	ng/mL	4.18	3.14	5.22	
	nmol/L	12.2	9.15	15.3	Beckman Dxl 600/800
	ng/mL	3.52	2.64	4.40	
nmol/L	6.96	5.22	8.70	Brahms Kryptor	
ng/mL	2.01	1.51	2.51		
nmol/L	12.5	9.38	15.6	Beckman Access	
ng/mL	3.61	2.71	4.51		

**ADDITIONAL VALUES FOR
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Lot No. 7946MS
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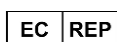
COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	86.7	69.4 - 104	AutoDELFI A (A/B096-101)
	ng/ml	105	84.0 - 126	
	KIU/l = IU/ml	82.8	66.2 - 99.4	DELFI A Xpress (6001-0010 / 6001-001C)
	ng/ml	100	80.0 - 120	
Free Beta hCG	mU/ml = U/l	140	105 - 175	AutoDELFI A (A/B097-101)
	mU/ml = U/l	168	126 - 210	DELFI A Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	571	428 - 714	AutoDELFI A (B064-102)
PAPP-A	U/l = mIU/ml	4.00	3.00 – 5.00	AutoDELFI A (A/B098-201)
	ng/ml	18018	13514 - 22522	
	U/l = mIU/ml	3.51	2.63 – 4.39	DELFI A Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	15811	11858 - 19764	
Unconjugated Estriol	nmol/l	36.7	27.5 – 45.9	AutoDELFI A (B095-101 / B095-101U)
	ng/ml	10.6	7.95 – 13.3	
	nmol/l	28.9	21.7 – 36.1	DELFI A Xpress (6005-0010 / 6005-001C)
	ng/ml	8.33	6.25 – 10.4	

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COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	95.2	66.6 - 124	Snibe Maglumi
	ng/ml	115	80.6 - 150	
Free Beta hCG	mU/ml = U/l	207	145 - 269	Snibe Maglumi



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