

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 8154MS
SIZE 3 x 1ml **EXPIRY:** 2024-11-28
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 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.

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

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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

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Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	82.8	66.2	99.0	Siemens Immulite 1000
	ng/ml	100	80.1	120	
	KIU/l = IU/ml	84.7	67.8	102	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	102	82.0	122	
	KIU/l = IU/ml	82.4	65.9	98.9	Abbott Architect
	ng/ml	100	79.7	120	
	KIU/l = IU/ml	85.1	68.1	102	Siemens Immulite 2000/2500
	ng/ml	103	82.4	124	
	KIU/l = IU/ml	97.3	77.8	117	Siemens Centaur XP/XPT/Classic
	ng/ml	118	94.1	142	
	KIU/l = IU/ml	78.9	63.1	94.7	Beckman Dxl800
	ng/ml	95.5	76.4	115	
	KIU/l = IU/ml	73.9	59.1	88.7	Brahms Kryptor
	ng/ml	89.4	71.5	107	
Free Beta hCG	KIU/l = IU/ml	83.4	66.7	100	Beckman Access
	ng/ml	101	80.7	121	
	KIU/l = IU/ml	96.0	76.8	115	Roche Cobas e601/602
	ng/ml	116	92.9	139	
	KIU/l = IU/ml	92.8	74.2	111	Roche Cobas 4000/E411
	ng/ml	112	89.8	134	
	KIU/l = IU/ml	88.4	70.7	106	Roche Cobas e402/e801
	ng/ml	107	85.5	129	
	KIU/l = IU/ml	92.3	73.8	111	Siemens Atellica IM
	ng/ml	112	89.3	135	
Inhibin A	mU/mL=U/L	139	104	174	Siemens Centaur XP/XPT/Classic
	mU/mL=U/L	99.0	74.3	124	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	112	84.0	140	Siemens Immulite 2000/2500
	mU/mL=U/L	103	77.3	129	Siemens Immulite 1000
	mU/mL=U/L	97.2	72.9	122	Roche Elecsys 2010/1010
	mU/mL=U/L	93.7	70.3	117	Brahms Kryptor
	mU/mL=U/L	87.7	65.8	110	Roche Cobas e601/602
	mU/mL=U/L	87.5	65.6	109	Roche Cobas 4000/E411
	mU/mL=U/L	87.5	65.6	109	Roche Cobas e402/e801
	mU/mL=U/L	105	78.8	131	Siemens Atellica IM
PAPP-A	ng/L = pg/ml	598	449	748	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/L = pg/ml	333	250	416	Beckman Dxl 600/800
	ng/L = pg/ml	518	389	648	Brahms Kryptor
	ng/L = pg/ml	322	242	403	Beckman Access
PAPP-A	U/L=mIU/ml	4.88	3.66	6.10	Siemens Centaur XP/XPT/Classic
	ng/ml	21982	16486	27478	
	U/L=mIU/ml	4.13	3.10	5.16	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	18604	13964	23244	

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	15.3	11.5	19.1	Siemens Immulite 2000/2500
	ng/ml	68919	51802	86036	
	U/L=mIU/ml	0.337	0.253	0.421	Beckman Dxl 600/800
	ng/ml	1518	1140	1896	
	U/L=mIU/ml	5.28	3.96	6.60	Roche Elecsys 2010/1010
	ng/ml	23784	17838	29730	
	U/L=mIU/ml	3.31	2.48	4.14	Brahms Kryptor
	ng/ml	14910	11171	18649	
	U/L=mIU/ml	0.338	0.254	0.423	Beckman Access
	ng/ml	1523	1144	1902	
Total Beta hCG	U/L=mIU/ml	5.47	4.10	6.84	Roche Cobas e601/602
	ng/ml	24640	18468	30812	
	U/L=mIU/ml	5.45	4.09	6.81	Roche Cobas 4000/E411
	ng/ml	24550	18423	30677	
	U/L=mIU/ml	5.36	4.02	6.70	Roche Cobas e402/e801
	ng/ml	24144	18108	30180	
	mU/ml=IU/l	24797	19838	29756	Abbott Architect / Alinity
		IU/ml	24.8	19.8	
	mU/ml=IU/l	22575	18060	27090	Siemens Centaur XP/XPT/Classic
		IU/ml	22.6	18.1	
	mU/ml=IU/l	40746	32597	48895	Siemens Immulite 2000/2500
		IU/ml	40.7	32.6	
	mU/ml=IU/l	49649	39719	59579	Siemens Immulite 1000
		IU/ml	49.6	39.7	
	mU/ml=IU/l	30718	24574	36862	Beckman Dxl 600/800
		IU/ml	30.7	24.6	
	mU/ml=IU/l	30205	24164	36246	Beckman Access
		IU/ml	30.2	24.2	
	mU/ml=IU/l	27994	22395	33593	Roche Cobas 6000/8000
		IU/ml	28.0	22.4	
mU/ml=IU/l	30001	24001	36001	Beckman Access Total BhCG (5th IS)	
	IU/ml	30.0	24.0		36.0
mU/ml=IU/l	31177	24942	37412	Beckman Dxl Total BhCG (5th IS)	
	IU/ml	31.2	24.9		37.5
mU/ml=IU/l	27897	22318	33476	Roche hCG+Beta e801	
	IU/ml	27.9	22.3		33.5
mU/ml=IU/l	21967	17574	26360	Siemens Atellica IM	
	IU/ml	22.0	17.6		26.4
Unconjugated Estriol	nmol/L	38.7	29.0	48.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	11.2	8.36	14.0	
	nmol/L	15.5	11.6	19.4	Siemens Immulite 2000/2500
	ng/mL	4.47	3.35	5.59	
	nmol/L	15.3	11.5	19.1	Siemens Immulite 1000
	ng/mL	4.41	3.32	5.50	
	nmol/L	12.5	9.38	15.6	Beckman Dxl 600/800
	ng/mL	3.61	2.71	4.51	

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Range					
Analyte	unit	Target	low	high	methods
Unconjugated Estriol	nmol/L	6.51	4.88	8.14	Brahms Kryptor
	ng/mL	1.88	1.41	2.35	
	nmol/L	13.2	9.90	16.5	Beckman Access
	ng/mL	3.81	2.86	4.76	