

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

CAT. NO. MSS5024 **LOT NO.** 8373MS
SIZE: 3 x 1 ml **EXPIRY:** 2025-10-28
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.

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

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.

EC	REP
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MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot. No. 8373MS Size 3 x 1 ml Expiry 2025-10-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	15.2	12.2	18.2	Siemens Immulite 1000
	ng/ml	18.4	14.8	22.0	
	KIU/l = IU/ml	14.1	11.3	16.9	Abbott Architect
	ng/ml	17.1	13.7	20.5	
	KIU/l = IU/ml	14.0	11.2	16.8	Siemens Immulite 2000/2500
	ng/ml	16.9	13.6	20.2	
	KIU/l = IU/ml	16.0	12.8	19.2	Siemens Centaur XP/XPT/Classic
	ng/ml	19.4	15.5	23.3	
	KIU/l = IU/ml	13.7	11.0	16.4	Beckman Dxl800
	ng/ml	16.6	13.3	19.9	
	KIU/l = IU/ml	14.8	11.8	17.8	Brahms Kryptor
	ng/ml	17.9	14.3	21.5	
	KIU/l = IU/ml	14.5	11.6	17.4	Beckman Access
	ng/ml	17.5	14.0	21.0	
	KIU/l = IU/ml	15.7	12.6	18.8	Roche Cobas e601/602
	ng/ml	19.0	15.2	22.8	
KIU/l = IU/ml	14.9	11.9	17.9	Roche Cobas 4000/E411	
ng/ml	18.0	14.4	21.6		
KIU/l = IU/ml	15.6	12.5	18.7	Roche Cobas e402/e801	
ng/ml	18.9	15.1	22.7		
KIU/l = IU/ml	15.2	12.2	18.2	DELFLIA/AutoDELFLIA	
ng/ml	18.4	14.8	22.0		
KIU/l = IU/ml	15.4	12.3	18.5	DELFLIA Xpress	
ng/ml	18.6	14.9	22.4		
KIU/l = IU/ml	15.0	10.5	19.5	SNIBE Maglumi Analysers	
ng/ml	18.2	12.7	23.7		
Free Beta hCG	mU/mL=U/L	33.1	24.8	41.4	Siemens Immulite 2000/2500
	mU/mL=U/L	38.3	28.7	47.9	Brahms Kryptor
	mU/mL=U/L	31.1	23.3	38.9	Roche Cobas e601/602
	mU/mL=U/L	31.6	23.7	39.5	Roche Cobas 4000/E411
	mU/mL=U/L	30.5	22.9	38.1	Roche Cobas e402/e801
	mU/mL=U/L	31.5	23.6	39.4	DELFLIA/AutoDELFLIA
	mU/mL=U/L	35.8	26.9	44.8	DELFLIA Xpress
	mU/mL=U/L	57.7	40.4	75.0	SNIBE Maglumi Analysers
Inhibin A	ng/L = pg/ml	91.3	68.5	114	Beckman Dxl 600/800
	ng/L = pg/ml	125	93.8	156	Brahms Kryptor
	ng/L = pg/ml	91.1	68.3	114	Beckman Access
	ng/L = pg/ml	164	123	205	Auto Delphia
PAPP-A	U/L=mIU/ml	0.500	0.375	0.625	Siemens Centaur XP/XPT/Classic
	ng/ml	2252	1689	2815	
	U/L=mIU/ml	1.54	1.16	1.93	Siemens Immulite 2000/2500
	ng/ml	6937	5225	8649	

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

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Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	0.040	0.030	0.050	Beckman Dxl 600/800
	ng/ml	180	135	225	
	U/L=mIU/ml	0.390	0.293	0.488	Brahms Kryptor
	ng/ml	1757	1320	2194	
	U/L=mIU/ml	0.040	0.030	0.050	Beckman Access
	ng/ml	180	135	225	
	U/L=mIU/ml	0.640	0.480	0.800	Roche Cobas e601/602
	ng/ml	2883	2162	3604	
	U/L=mIU/ml	0.630	0.473	0.788	Roche Cobas 4000/E411
	ng/ml	2838	2131	3545	
U/L=mIU/ml	0.610	0.458	0.763	Roche Cobas e402/e801	
ng/ml	2748	2063	3433		
U/L=mIU/ml	0.404	0.300	0.510	DELFLIA/AutoDELFLIA	
ng/ml	1820	1351	2297		
U/L=mIU/ml	0.402	0.300	0.500	DELFLIA Xpress	
ng/ml	1811	1351	2252		
U/L=mIU/ml	0.450	0.312	0.579	SNIBE Maglumi Analysers	
ng/ml	2027	1419	2635		
Total Beta hCG	mU/ml=IU/l	1863	1490	2236	Abbott Architect / Alinity
	IU/ml	1.86	1.49	2.23	
	mU/ml=IU/l	8986	8035	9937	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	8.99	8.04	9.94	
	mU/ml=IU/l	7410	5928	8892	Siemens Immulite 2000/2500
	IU/ml	7.41	5.93	8.89	
	mU/ml=IU/l	7610	6088	9132	Siemens Immulite 1000
	IU/ml	7.61	6.09	9.13	
	mU/ml=IU/l	2510	2008	3012	Beckman Access
	IU/ml	2.51	2.01	3.01	
mU/ml=IU/l	3018	2414	3622	Roche Cobas 6000/8000	
IU/ml	3.02	2.41	3.63		
mU/ml=IU/l	2498	1998	2998	Beckman Access Total BhCG (5th IS)	
IU/ml	2.50	2.00	3.00		
mU/ml=IU/l	2995	2396	3594	Roche hCG+Beta e801	
IU/ml	3.00	2.40	3.60		
Unconjugated Estriol	nmol/L	1.86	1.40	2.33	Siemens Immulite 2000/2500
	ng/mL	0.536	0.404	0.668	
	nmol/L	2.10	1.58	2.63	Beckman Dxl 600/800
	ng/mL	0.606	0.456	0.756	
	nmol/L	0.560	0.420	0.700	Brahms Kryptor
	ng/mL	0.162	0.121	0.203	
	nmol/L	2.19	1.64	2.74	Beckman Access
	ng/mL	0.632	0.473	0.791	
	nmol/L	5.38	4.04	6.73	DELFLIA/AutoDELFLIA
	ng/mL	1.55	1.17	1.94	
nmol/L	4.18	3.14	5.23	DELFLIA Xpress	
ng/mL	1.21	0.910	1.51		

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Range					
Analyte	unit	Target	low	high	methods
Unconjugated Estriol	nmol/L	2.26	1.58	2.94	SNIBE Maglumi Analysers
	ng/mL	0.650	0.460	0.850	