

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

CAT. NO. MSS5024 **LOT NO.** 7942MS
SIZE: 3 x 1 ml **EXPIRY:** 2023-10-28
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

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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MATERNAL CONTROL LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot. No. 7942MS Size 3 x 1ml Expiry 2023-10-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	11.5	9.20	13.8	Siemens Immulite 1000
	ng/ml	13.9	11.1	16.7	
	KIU/l = IU/ml	12.4	9.92	14.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	15.0	12.0	18.0	
	KIU/l = IU/ml	11.6	9.28	13.9	Abbott Architect
	ng/ml	14.0	11.2	16.8	
	KIU/l = IU/ml	11.2	8.96	13.4	Siemens Immulite 2000/2500
	ng/ml	13.6	10.8	16.4	
	KIU/l = IU/ml	11.3	9.04	13.6	Beckman Dxl800
	ng/ml	13.7	10.9	16.5	
	KIU/l = IU/ml	12.2	9.76	14.6	Brahms Kryptor
	ng/ml	14.8	11.8	17.8	
KIU/l = IU/ml	12.2	9.76	14.6	Beckman Access	
ng/ml	14.8	11.8	17.8		
KIU/l = IU/ml	12.6	10.1	15.1	Roche Cobas e601/602	
ng/ml	15.2	12.2	18.2		
KIU/l = IU/ml	12.0	9.60	14.4	Roche Cobas 4000/E411	
ng/ml	14.5	11.6	17.4		
KIU/l = IU/ml	12.3	9.84	14.8	Roche Cobas e801	
ng/ml	14.9	11.9	17.9		
Free Beta hCG	mU/mL=U/L	27.2	20.4	34.0	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	30.0	22.5	37.5	Siemens Immulite 2000/2500
	mU/mL=U/L	26.7	20.0	33.4	Siemens Immulite 1000
	mU/mL=U/L	23.0	17.3	28.8	Brahms Kryptor
	mU/mL=U/L	22.4	16.8	28.0	Roche Cobas e601/602
	mU/mL=U/L	22.4	16.8	28.0	Roche Cobas 4000/E411
	mU/mL=U/L	21.5	16.1	26.9	Roche Cobas e801
Inhibin A	ng/L = pg/ml	88.8	66.6	111	Beckman Dxl 600/800
	ng/L = pg/ml	124	93.0	155	Brahms Kryptor
	ng/L = pg/ml	86.6	65.0	108	Beckman Access
PAPP-A	U/L=mIU/ml	0.410	0.308	0.513	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	1847	1387	2307	
	U/L=mIU/ml	1.38	1.04	1.73	Siemens Immulite 1000
	ng/ml	6216	4685	7747	
	U/L=mIU/ml	1.49	1.12	1.86	Siemens Immulite 2000/2500
	ng/ml	6712	5045	8379	
	U/L=mIU/ml	0.030	0.023	0.038	Beckman Dxl 600/800
	ng/ml	135	104	166	
	U/L=mIU/ml	0.390	0.293	0.488	Brahms Kryptor
ng/ml	1757	1320	2194		
U/L=mIU/ml	0.030	0.023	0.038	Beckman Access	
ng/ml	135	104	166		

MATERNAL CONTROL LEVEL 1 (MATERNAL CONTROL 1)

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Analyte	unit	Target	Range		methods	
			low	high		
PAPP-A	U/L=mIU/ml	0.610	0.458	0.763	Roche Cobas e601/602	
	ng/ml	2748	2063	3433		
	U/L=mIU/ml	0.600	0.450	0.750	Roche Cobas 4000/E411	
	ng/ml	2703	2027	3379		
	U/L=mIU/ml	0.570	0.428	0.713	Roche Cobas e801	
	ng/ml	2568	1928	3208		
Total Beta hCG	mU/ml=IU/l	3056	2445	3667	Abbott Architect / Alinity	
	IU/ml	3.06	2.45	3.67		
	mU/ml=IU/l	6471	5177	7765	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	IU/ml	6.47	5.18	7.76		
	mU/ml=IU/l	6790	5432	8148	Siemens Immulite 2000/2500	
	IU/ml	6.79	5.43	8.15		
	mU/ml=IU/l	7254	5803	8705	Siemens Immulite 1000	
	IU/ml	7.25	5.80	8.70		
	mU/ml=IU/l	4108	3286	4930	Beckman Dxl 600/800	
	IU/ml	4.11	3.29	4.93		
	mU/ml=IU/l	4193	3354	5032	Beckman Access	
	IU/ml	4.19	3.35	5.03		
	mU/ml=IU/l	3963	3170	4756	Roche Cobas 6000/8000	
	IU/ml	3.96	3.17	4.75		
Unconjugated Estriol	mU/ml=IU/l	4074	3259	4889	Beckman Access Total BhCG (5th IS)	
	IU/ml	4.07	3.26	4.88		
	mU/ml=IU/l	4054	3243	4865	Beckman Dxl Total BhCG (5th IS)	
	IU/ml	4.05	3.24	4.86		
	mU/ml=IU/l	3865	3092	4638	Roche hCG+Beta e801	
	IU/ml	3.87	3.09	4.65		
		nmol/L	4.62	3.47	5.78	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		ng/mL	1.33	1.00	1.66	
		nmol/L	1.84	1.38	2.30	Siemens Immulite 2000/2500
		ng/mL	0.531	0.398	0.664	
		nmol/L	1.77	1.33	2.21	Siemens Immulite 1000
		ng/mL	0.510	0.384	0.636	
		nmol/L	1.96	1.47	2.45	Beckman Dxl 600/800
		ng/mL	0.565	0.424	0.706	
	nmol/L	0.450	0.338	0.563	Brahms Kryptor	
	ng/mL	0.130	0.097	0.163		
	nmol/L	2.20	1.65	2.75	Beckman Access	
	ng/mL	0.634	0.476	0.792		