

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 8374MS
SIZE: 3 x 1 ml **EXPIRY:** 2025-10-28
GTIN: 05055273207392

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 2 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 94451070 or email Technical.Services@randox.com.

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Cat. No. MSS5025 Lot. No. 8374MS Size 3 x 1ml Expiry 2025-10-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	57.2	45.8	68.6	Siemens Immulite 1000
	ng/ml	69.2	55.4	83.0	
	KIU/l = IU/ml	54.6	43.7	65.5	Abbott Architect
	ng/ml	66.1	52.9	79.3	
	KIU/l = IU/ml	56.0	44.8	67.2	Siemens Immulite 2000/2500
	ng/ml	67.8	54.2	81.4	
	KIU/l = IU/ml	62.7	50.2	75.2	Siemens Centaur XP/XPT/Classic
	ng/ml	75.9	60.7	91.1	
	KIU/l = IU/ml	54.1	43.3	64.9	Beckman Dxl800
	ng/ml	65.5	52.4	78.6	
	KIU/l = IU/ml	51.6	41.3	61.9	Brahms Kryptor
	ng/ml	62.4	50.0	74.8	
	KIU/l = IU/ml	54.0	43.2	64.8	Beckman Access
	ng/ml	65.3	52.3	78.3	
	KIU/l = IU/ml	63.3	50.6	76.0	Roche Cobas e601/602
	ng/ml	76.6	61.2	92.0	
KIU/l = IU/ml	60.6	48.5	72.7	Roche Cobas 4000/E411	
ng/ml	73.3	58.7	87.9		
KIU/l = IU/ml	61.5	49.2	73.8	Roche Cobas e402/e801	
ng/ml	74.4	59.5	89.3		
KIU/l = IU/ml	56.5	45.2	67.8	DELFI/AutoDELFI/A	
ng/ml	68.4	54.7	82.0		
KIU/l = IU/ml	56.8	45.4	68.2	DELFI/A Xpress	
ng/ml	68.7	54.9	82.5		
KIU/l = IU/ml	62.3	43.6	81.0	SNIBE Maglumi Analysers	
ng/ml	75.4	52.8	98.0		
Free Beta hCG	mU/mL=U/L	109	81.8	136	Siemens Immulite 2000/2500
	mU/mL=U/L	130	97.5	163	Brahms Kryptor
	mU/mL=U/L	101	75.8	126	Roche Cobas e601/602
	mU/mL=U/L	104	78.0	130	Roche Cobas 4000/E411
	mU/mL=U/L	102	76.5	128	Roche Cobas e402/e801
	mU/mL=U/L	105	78.8	131	DELFI/AutoDELFI/A
	mU/mL=U/L	118	88.5	148	DELFI/A Xpress
	mU/mL=U/L	205	144	267	SNIBE Maglumi Analysers
Inhibin A	ng/L = pg/ml	186	140	233	Beckman Dxl 600/800
	ng/L = pg/ml	285	214	356	Brahms Kryptor
	ng/L = pg/ml	186	140	233	Beckman Access
	ng/L = pg/ml	340	255	425	AutoDELFI/A
PAPP-A	U/L=mIU/ml	2.29	1.72	2.86	Siemens Centaur XP/XPT/Classic
	ng/ml	10315	7748	12883	
	U/L=mIU/ml	7.64	5.73	9.55	Siemens Immulite 2000/2500
	ng/ml	34414	25811	43018	

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Range						
Analyte	unit	Target	low	high	methods	
PAPP-A	U/L=mIU/ml	0.180	0.135	0.225	Beckman Dxl 600/800	
	ng/ml	811	608	1014		
	U/L=mIU/ml	1.72	1.29	2.15	Brahms Kryptor	
	ng/ml	7748	5811	9685		
	U/L=mIU/ml	0.180	0.135	0.225	Beckman Access	
	ng/ml	811	608	1014		
	U/L=mIU/ml	2.70	2.03	3.38	Roche Cobas e601/602	
	ng/ml	12162	9144	15225		
	U/L=mIU/ml	2.69	2.02	3.36	Roche Cobas 4000/E411	
	ng/ml	12117	9099	15135		
	U/L=mIU/ml	2.62	1.97	3.28	Roche Cobas e402/e801	
	ng/ml	11802	8874	14775		
Total Beta hCG	U/L=mIU/ml	1.96	1.47	2.45	DELFLIA/AutoDELFLIA	
	ng/ml	8829	6622	11036		
	U/L=mIU/ml	1.88	1.41	2.35	DELFLIA Xpress	
	ng/ml	8468	6351	10586		
	U/L=mIU/ml	1.74	1.22	2.26	SNIBE Maglumi Analysers	
	ng/ml	7838	5487	10189		
	Total Beta hCG	mU/ml=IU/l	6223	4978	7468	Abbott Architect / Alinity
		IU/ml	6.22	4.98	7.46	
		mU/ml=IU/l	26490	21192	31788	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		IU/ml	26.5	21.2	31.8	
		mU/ml=IU/l	21363	17090	25636	Siemens Immulite 2000/2500
		IU/ml	21.4	17.1	25.6	
mU/ml=IU/l		2221.1	17769	26653	Siemens Immulite 1000	
IU/ml		22.2	17.8	26.7		
mU/ml=IU/l		8286	6629	9943	Beckman Dxl 600/800	
IU/ml		8.29	6.63	9.95		
mU/ml=IU/l		7735	6188	9282	Beckman Access	
IU/ml		7.74	6.19	9.29		
mU/ml=IU/l		8986	7189	10783	Roche Cobas 6000/8000	
IU/ml		8.99	7.19	10.8		
mU/ml=IU/l		7667	6134	9200	Beckman Access Total BhCG (5th IS)	
IU/ml		7.67	6.13	9.21		
mU/ml=IU/l		8405	6724	10086	Beckman Dxl Total BhCG (5th IS)	
IU/ml		8.41	6.72	10.1		
mU/ml=IU/l	9139	7311	10967	Roche hCG+Beta e801		
IU/ml	9.14	7.31	11.0			
Unconjugated Estriol	nmol/L	6.65	4.99	8.31	Siemens Immulite 2000/2500	
	ng/mL	1.92	1.44	2.40		
	nmol/L	6.77	5.08	8.46	Siemens Immulite 1000	
	ng/mL	1.95	1.47	2.43		
	nmol/L	5.75	4.31	7.19	Beckman Dxl 600/800	
	ng/mL	1.66	1.24	2.08		
	nmol/L	2.78	2.09	3.48	Brahms Kryptor	
	ng/mL	0.802	0.603	1.00		

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Range					
Analyte	unit	Target	low	high	methods
Unconjugated Estriol	nmol/L	5.79	4.34	7.24	Beckman Access
	ng/mL	1.67	1.25	2.09	
	nmol/L	16.6	12.5	20.8	DELFI/AutoDELFI/A
	ng/mL	4.79	3.61	6.00	
	nmol/L	13.0	9.75	16.3	DELFI/A Xpress
	ng/mL	3.75	2.81	4.70	
nmol/L	8.39	5.87	10.9	SNIBE Maglumi Analysers	
ng/mL	2.42	1.69	3.15		