

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 8377MS
SIZE: 3 x 1ml **EXPIRY:** 2025-10-28
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 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 94451070 or email Technical.Services@randox.com.

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Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	102	81.6	122	Siemens Immulite 1000
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	105	84.0	126	Abbott Architect
	ng/ml	127	102	152	
	KIU/l = IU/ml	105	84.0	126	Siemens Immulite 2000/2500
	ng/ml	127	102	152	
	KIU/l = IU/ml	98.7	79.0	118	Beckman Dxl800
	ng/ml	119	95.6	142	
	KIU/l = IU/ml	93.2	74.6	112	Brahms Kryptor
	ng/ml	113	90.3	136	
	KIU/l = IU/ml	102	81.6	122	Beckman Access
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	116	92.8	139	Roche Cobas e601/602
	ng/ml	140	112	168	
KIU/l = IU/ml	118	94.4	142	Roche Cobas 4000/E411	
ng/ml	143	114	172		
KIU/l = IU/ml	113	90.4	136	Roche Cobas e402/e801	
ng/ml	137	109	165		
KIU/l = IU/ml	121	84.7	157	SNIBE Maglumi Analysers	
ng/ml	146	102	190		
KIU/l = IU/ml	104	83.2	125	DELFLIA/AutoDELFLIA	
ng/ml	126	101	151		
KIU/l = IU/ml	104	83.2	125	DELFLIA Xpress	
ng/ml	126	101	151		
Free Beta hCG	mU/mL=U/L	183	137	229	Siemens Immulite 2000/2500
	mU/mL=U/L	209	157	261	Brahms Kryptor
	mU/mL=U/L	166	125	208	Roche Cobas e601/602
	mU/mL=U/L	169	127	211	Roche Cobas 4000/E411
	mU/mL=U/L	168	126	210	Roche Cobas e402/e801
	mU/mL=U/L	301	226	376	SNIBE Maglumi Analysers
	mU/mL=U/L	171	128	214	DELFLIA/AutoDELFLIA
	mU/mL=U/L	196	147	245	DELFLIA Xpress
Inhibin A	ng/L = pg/ml	364	273	455	Beckman Dxl 600/800
	ng/L = pg/ml	564	423	705	Brahms Kryptor
	ng/L = pg/ml	364	273	455	Beckman Access
	ng/L = pg/ml	636	477	795	Auto Delphia
PAPP-A	U/L=mIU/ml	5.12	3.84	6.40	Siemens Centaur XP/XPT/Classic
	ng/ml	23063	17297	28829	
	U/L=mIU/ml	16.4	12.3	20.5	Siemens Immulite 2000/2500
	ng/ml	73874	55405	92342	
	U/L=mIU/ml	0.370	0.278	0.463	Beckman Dxl 600/800
ng/ml	1667	1252	2082		

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			low	high	
PAPP-A	U/L=mIU/ml	3.28	2.46	4.10	Brahms Kryptor
	ng/ml	14775	11081	18468	
	U/L=mIU/ml	0.370	0.278	0.463	Beckman Access
	ng/ml	1667	1252	2082	
	U/L=mIU/ml	5.64	4.23	7.05	Roche Cobas e601/602
	ng/ml	25405	19054	31757	
	U/L=mIU/ml	5.73	4.30	7.16	Roche Cobas 4000/E411
	ng/ml	25811	19369	32252	
	U/L=mIU/ml	5.32	3.99	6.65	Roche Cobas e402/e801
	ng/ml	23964	17973	29955	
U/L=mIU/ml	3.84	2.67	4.96	SNIBE Maglumi Analysers	
ng/ml	17297	12108	22486		
U/L=mIU/ml	4.32	3.24	5.40	DELFI/AutoDELFI/A	
ng/ml	19459	14595	24324		
U/L=mIU/ml	3.94	2.96	4.93	DELFI/A Xpress	
ng/ml	17748	13333	22207		
Total Beta hCG	mU/ml=IU/l	11162	8930	13394	Abbott Architect / Alinity
	IU/ml	11.2	8.93	13.4	
	mU/ml=IU/l	39755	31804	47706	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	39.8	31.8	47.7	
	mU/ml=IU/l	34440	27552	41328	Siemens Immulite 2000/2500
	IU/ml	34.4	27.6	41.3	
	mU/ml=IU/l	14378	11502	17254	Beckman Dxl 600/800
	IU/ml	14.4	11.5	17.3	
	mU/ml=IU/l	13266	10613	15919	Beckman Access
	IU/ml	13.3	10.6	15.9	
	mU/ml=IU/l	15616	12493	18739	Roche Cobas 6000/8000
	IU/ml	15.6	12.5	18.7	
	mU/ml=IU/l	19107	15286	22928	Roche hCG STAT (Intact)
	IU/ml	19.1	15.3	22.9	
	mU/ml=IU/l	13711	10969	16453	Beckman Access Total BhCG (5th IS)
	IU/ml	13.7	11.0	16.5	
	mU/ml=IU/l	14362	11490	17234	Beckman Dxl Total BhCG (5th IS)
	IU/ml	14.4	11.5	17.2	
	mU/ml=IU/l	15006	12005	18007	Roche hCG+Beta e801
	IU/ml	15.0	12.0	18.0	
mU/ml=IU/l	8857	7086	10628	Siemens Atellica IM	
IU/ml	8.86	7.09	10.6		
Unconjugated Estriol	nmol/L	12.4	9.30	15.5	Siemens Immulite 2000/2500
	ng/mL	3.58	2.68	4.48	
	nmol/L	13.3	9.98	16.6	Siemens Immulite 1000
	ng/mL	3.84	2.88	4.80	
	nmol/L	10.7	8.03	13.4	Beckman Dxl 600/800
	ng/mL	3.09	2.32	3.86	
	nmol/L	6.27	4.70	7.84	Brahms Kryptor
	ng/mL	1.81	1.36	2.26	

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Analyte	unit	Target	Range		methods
			low	high	
Unconjugated Estriol	nmol/L	10.8	8.10	13.5	Beckman Access
	ng/mL	3.11	2.34	3.88	
	nmol/L	17.9	12.5	23.2	SNIBE Maglumi Analysers
	ng/mL	5.15	3.61	6.70	
	nmol/L	33.0	24.8	41.3	DELFI/AutoDELFI/A
	ng/mL	9.52	7.15	11.9	
	nmol/L	25.0	18.8	31.3	DELFI/A Xpress
	ng/mL	7.21	5.42	9.03	