

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 8245MS
SIZE: 3 x 1 ml **EXPIRY:** 2025-05-28
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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MATERNAL CONTROL LEVEL 2 (MATERNAL CONTROL 2)

Cat. No. MSS5025 Lot. No. 8245MS Size 3x 1ml Expiry 2025-05-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	56.9	45.5	68.3	Siemens Immulite 1000
	ng/ml	68.8	55.1	82.5	
	KIU/l = IU/ml	53.0	42.4	63.6	Abbott Architect
	ng/ml	64.1	51.3	76.9	
	KIU/l = IU/ml	56.1	44.9	67.3	Siemens Immulite 2000/2500
	ng/ml	67.9	54.3	81.5	
	KIU/l = IU/ml	51.8	41.4	62.2	Beckman Dxl800
	ng/ml	62.7	50.1	75.3	
	KIU/l = IU/ml	47.8	38.2	57.4	Brahms Kryptor
	ng/ml	57.8	46.2	69.4	
	KIU/l = IU/ml	53.9	43.1	64.7	Beckman Access
	ng/ml	65.2	52.2	78.2	
	KIU/l = IU/ml	61.3	49.0	73.6	Roche Cobas e601/602
	ng/ml	74.2	59.3	89.1	
	KIU/l = IU/ml	61.3	49.0	73.6	Roche Cobas 4000/E411
	ng/ml	74.2	59.3	89.1	
Free Beta hCG	KIU/l = IU/ml	56.9	45.5	68.3	Roche Cobas e402/e801
	ng/ml	68.8	55.1	82.5	
	KIU/l = IU/ml	55.7	44.6	66.8	DELFI/AutoDELFI/A (A/B096-101)
	ng/ml	67.4	54.0	80.8	
	KIU/l = IU/ml	53.3	42.6	64.0	DELFI/A Xpress (6001-0010 / 6001-001C)
	ng/ml	64.5	51.5	77.4	
	mU/mL=U/L	58.6	44.0	73.3	Siemens Immulite 2000/2500
	mU/mL=U/L	51.9	38.9	64.9	Siemens Immulite 1000
Inhibin A	mU/mL=U/L	50.6	38.0	63.3	Brahms Kryptor
	mU/mL=U/L	45.7	34.3	57.1	Roche Cobas e601/602
	mU/mL=U/L	46.6	35.0	58.3	Roche Cobas 4000/E411
	mU/mL=U/L	45.0	33.8	56.3	Roche Cobas e402/e801
	mU/mL=U/L	47.1	35.3	58.9	DELFI/AutoDELFI/A (A/B097-101)
	mU/mL=U/L	56.4	42.3	70.5	DELFI/A Xpress (6002-0010 / 6002-001C)
	ng/L = pg/ml	194	146	243	Beckman Dxl 600/800
	ng/L = pg/ml	279	209	349	Brahms Kryptor
PAPP-A	ng/L = pg/ml	189	142	236	Beckman Access
	ng/L = pg/ml	331	248	414	AutoDELFI/A (B064-102)
	U/L=mIU/ml	2.63	1.97	3.29	Siemens Centaur XP/XPT/Classic
	ng/ml	11847	8874	14820	
	U/L=mIU/ml	7.66	5.75	9.58	Siemens Immulite 1000
	ng/ml	34504	25901	43107	
	U/L=mIU/ml	7.70	5.78	9.63	Siemens Immulite 2000/2500
	ng/ml	34685	26036	43334	
	U/L=mIU/ml	0.182	0.137	0.228	Beckman Dxl 600/800
	ng/ml	820	617	1023	

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Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mlU/ml	1.74	1.31	2.18	Brahms Kryptor
	ng/ml	7838	5901	9775	
	U/L=mlU/ml	0.176	0.132	0.220	Beckman Access
	ng/ml	793	595	991	
	U/L=mlU/ml	2.74	2.06	3.43	Roche Cobas e601/602
	ng/ml	12342	9279	15405	
	U/L=mlU/ml	2.72	2.04	3.40	Roche Cobas 4000/E411
	ng/ml	12252	9189	15315	
	U/L=mlU/ml	2.63	1.97	3.29	Roche Cobas e402/e801
	ng/ml	11847	8874	14820	
	U/L=mlU/ml	2.10	1.58	2.63	DELFLIA/AutoDELFLIA (A/B098-201)
	ng/ml	9459	7117	11801	
	U/L=mlU/ml	1.87	1.40	2.34	DELFLIA Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	8423	6306	10504	
Total Beta hCG	mU/ml=IU/l	12782	10226	15338	Abbott Architect / Alinity
	IU/ml	12.8	10.2	15.4	
	mU/ml=IU/l	23130	18504	27756	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	23.1	18.5	27.7	
	mU/ml=IU/l	20675	16540	24810	Siemens Immulite 2000/2500
	IU/ml	20.7	16.6	24.8	
	mU/ml=IU/l	23672	18938	28406	Siemens Immulite 1000
	IU/ml	23.7	19.0	28.4	
	mU/ml=IU/l	15880	12704	19056	Beckman Dxl 600/800
	IU/ml	15.9	12.7	19.1	
	mU/ml=IU/l	15986	12789	19183	Beckman Access
	IU/ml	16.0	12.8	19.2	
	mU/ml=IU/l	13508	10806	16210	Roche Cobas 6000/8000
	IU/ml	13.5	10.8	16.2	
	mU/ml=IU/l	15067	12054	18080	Beckman Access Total BhCG (5th IS)
	IU/ml	15.1	12.1	18.1	
	mU/ml=IU/l	15495	12396	18594	Beckman Dxl Total BhCG (5th IS)
	IU/ml	15.5	12.4	18.6	
	mU/ml=IU/l	13213	10570	15856	Roche hCG+Beta e801
	IU/ml	13.2	10.6	15.8	
	mU/ml=IU/l	11164	8931	13397	Siemens Atellica IM
	IU/ml	11.2	8.93	13.5	
Unconjugated Estriol	nmol/L	6.68	5.01	8.35	Siemens Immulite 2000/2500
	ng/mL	1.93	1.44	2.42	
	nmol/L	6.49	4.87	8.11	Siemens Immulite 1000
	ng/mL	1.87	1.40	2.34	
	nmol/L	5.55	4.16	6.94	Beckman Dxl 600/800
	ng/mL	1.60	1.20	2.00	
	nmol/L	2.42	1.82	3.03	Brahms Kryptor
	ng/mL	0.698	0.525	0.871	
	nmol/L	5.78	4.34	7.23	Beckman Access
	ng/mL	1.67	1.25	2.09	

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Range					
Analyte	unit	Target	low	high	methods
Unconjugated Estriol	nmol/L	15.2	11.4	19.0	DELFI/AutoDELFI (B095-101/B095-101U)
	ng/mL	4.38	3.29	5.48	
	nmol/L	12.5	9.38	15.6	DELFI Xpress (6005-0010 / 6005-001C)
	ng/mL	3.61	2.71	4.50	