

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 7701MS
SIZE: 3 x 1 ml **EXPIRY:** 2023-01-28
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 Gonadotrophin, 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

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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Range						
Analyte	unit	Target	low	high	methods	
Alphafoetoprotein	KIU/l = IU/ml	57.7	46.2	69.2	Siemens Immulite 1000	
	ng/ml	69.8	55.9	83.7		
	KIU/l = IU/ml	57.0	45.6	68.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	69.0	55.2	82.8		
	KIU/l = IU/ml	61.8	49.4	74.2	Abbott Architect	
	ng/ml	74.8	59.8	89.8		
	KIU/l = IU/ml	58.0	46.4	69.6	Siemens Immulite 2000/2500	
	ng/ml	70.2	56.1	84.3		
	KIU/l = IU/ml	63.1	50.5	75.7	Siemens Centaur XP/XPT/Classic	
	ng/ml	76.4	61.1	91.7		
	KIU/l = IU/ml	55.6	44.5	66.7	Beckman Dxl800	
	ng/ml	67.3	53.8	80.8		
Free Beta hCG	KIU/l = IU/ml	51.6	41.3	61.9	Brahms Kryptor	
	ng/ml	62.4	50.0	74.8		
	KIU/l = IU/ml	56.0	44.8	67.2	Beckman Access	
	ng/ml	67.8	54.2	81.4		
	KIU/l = IU/ml	63.6	50.9	76.3	Roche Cobas 6000/8000	
	ng/ml	77.0	61.6	92.4		
	KIU/l = IU/ml	64.4	51.5	77.3	Roche Cobas E411	
	ng/ml	77.9	62.3	93.5		
	Free Beta hCG	mU/mL=U/L	76.1	57.1	95.1	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	92.3	69.2	115	Siemens Immulite 2000/2500
		mU/mL=U/L	81.7	61.3	102	Siemens Immulite 1000
		mU/mL=U/L	68.6	51.5	85.8	Brahms Kryptor
mU/mL=U/L		67.7	50.8	84.6	Roche Cobas 6000/8000	
mU/mL=U/L		69.3	52.0	86.6	Roche Cobas 4000/E411	
Inhibin A	ng/L = pg/ml	383	287	479	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	240	180	300	Beckman Dxl 600/800	
	ng/L = pg/ml	306	230	383	Brahms Kryptor	
	ng/L = pg/ml	229	172	286	Beckman Access/LXi725	
PAPP-A	U/L=mIU/ml	2.00	1.50	2.50	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	9009	6757	11261		
	U/L=mIU/ml	6.80	5.10	8.50	Siemens Immulite 1000	
	ng/ml	30631	22973	38289		
	U/L=mIU/ml	6.87	5.15	8.59	Siemens Immulite 2000/2500	
	ng/ml	30946	23198	38694		
	U/L=mIU/ml	0.151	0.113	0.189	Beckman Dxl 600/800	
	ng/ml	680	509	851		
PAPP-A	U/L=mIU/ml	2.78	2.09	3.48	Roche Elecsys 2010/1010	
	ng/ml	12523	9414	15632		
	U/L=mIU/ml	1.92	1.44	2.40	Brahms Kryptor	
	ng/ml	8649	6486	10812		

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Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	2.83	2.12	3.54	Roche Cobas 6000/8000
	ng/ml	12748	9550	15946	
	U/L=mIU/ml	2.66	2.00	3.33	Roche Cobas E411
	ng/ml	11982	9009	14955	
Total Beta hCG	mU/ml=IU/l	9794	7835	11753	Abbott Architect I2000/8200
	IU/ml	9.79	7.84	11.7	
	mU/ml=IU/l	9138	7310	10966	Siemens Centaur XP/XPT/Classic
	IU/ml	9.14	7.31	11.0	
	mU/ml=IU/l	19417	15534	23300	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	19.4	15.5	23.3	
	mU/ml=IU/l	19175	15340	23010	Siemens Immulite 2000/2500
	IU/ml	19.2	15.3	23.1	
	mU/ml=IU/l	20393	16314	24472	Siemens Immulite 1000
	IU/ml	20.4	16.3	24.5	
	mU/ml=IU/l	12901	10321	15481	Beckman Dxl 600/800
	IU/ml	12.9	10.3	15.5	
	mU/ml=IU/l	12573	10058	15088	Beckman Access/LXi725
	IU/ml	12.6	10.1	15.1	
	mU/ml=IU/l	11491	9193	13789	Roche Cobas 6000/8000
	IU/ml	11.5	9.19	13.8	
mU/ml=IU/l	12198	9758	14638	Beckman Access Total BhCG (5th IS)	
IU/ml	12.2	9.76	14.6		
mU/ml=IU/l	12020	9616	14424	Beckman Dxl Total BhCG (5th IS)	
IU/ml	12.0	9.62	14.4		
Unconjugated Estriol	nmol/L	22.6	17.0	28.3	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	6.52	4.90	8.14	
	nmol/L	10.3	7.73	12.9	Siemens Immulite 2000/2500
	ng/mL	2.97	2.23	3.71	
	nmol/L	11.3	8.48	14.1	Siemens Immulite 1000
	ng/mL	3.26	2.45	4.07	
	nmol/L	8.57	6.43	10.7	Beckman Dxl 600/800
	ng/mL	2.47	1.85	3.09	
	nmol/L	5.31	3.98	6.64	Brahms Kryptor
	ng/mL	1.53	1.15	1.91	
	nmol/L	8.61	6.46	10.8	Beckman Access/LXi725
	ng/mL	2.48	1.86	3.10	

ADDITIONAL VALUES FOR MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2) Cat No. MSS5025 Lot No. 770IMS

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	56.5	45.2 - 67.8	AutoDELFIA (A/B096-101)
	ng/ml	68.4	54.7 - 82.1	
	KIU/l = IU/ml	57.2	45.8 - 68.6	DELFIA Xpress (6001-0010 / 6001-001C)
	ng/ml	69.2	55.4 - 83.0	
Free Beta hCG	mU/ml = U/l	71.0	53.3 - 88.7	AutoDELFIA (A/B097-101)
	mU/ml = U/l	85.0	63.8 - 106	DELFIA Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	368	276 - 460	AutoDELFIA (B064-102)
PAPP-A	U/l = mIU/ml	2.07	1.55 - 2.59	AutoDELFIA (A/B098-201)
	ng/ml	9324	6993 - 11655	
	U/l = mIU/ml	1.92	1.44 - 2.40	DELFIA Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	8649	6487 - 10811	
Unconjugated Estriol	nmol/l	23.9	17.9 - 29.9	AutoDELFIA (B095-101 / B095-101U)
	ng/ml	6.89	5.17 - 8.61	
	nmol/l	18.9	14.2 - 23.6	DELFIA Xpress (6005-0010 / 6005-001C)
	ng/ml	5.45	4.09 - 6.81	

EC REP

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