

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 7703MS
SIZE: 3 x 1ml **EXPIRY:** 2023-01-28
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 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 3 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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Range						
Analyte	unit	Target	low	high	methods	
Alphafoetoprotein	KIU/l = IU/ml	107	85.6	128	Siemens Immulite 1000	
	ng/ml	129	104	154		
	KIU/l = IU/ml	102	81.6	122	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	123	98.7	147		
	KIU/l = IU/ml	102	81.6	122	Abbott Architect	
	ng/ml	123	98.7	147		
	KIU/l = IU/ml	106	84.8	127	Siemens Immulite 2000/2500	
	ng/ml	128	103	153		
	KIU/l = IU/ml	115	92.0	138	Siemens Centaur XP/XPT/Classic	
	ng/ml	139	111	167		
	KIU/l = IU/ml	95.2	76.2	114	Beckman Dxl800	
	ng/ml	115	92.2	138		
Free Beta hCG	KIU/l = IU/ml	91.5	73.2	110	Brahms Kryptor	
	ng/ml	111	88.6	133		
	KIU/l = IU/ml	100	80.0	120	Beckman Access	
	ng/ml	121	96.8	145		
	KIU/l = IU/ml	112	89.6	134	Roche Cobas 6000/8000	
	ng/ml	136	108	164		
	KIU/l = IU/ml	118	94.4	142	Roche Cobas E411	
	ng/ml	143	114	172		
	Free Beta hCG	mU/mL=U/L	194	146	243	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	235	176	294	Siemens Immulite 2000/2500
		mU/mL=U/L	218	164	273	Siemens Immulite 1000
		mU/mL=U/L	198	149	248	Brahms Kryptor
mU/mL=U/L		171	128	214	Roche Cobas 6000/8000	
mU/mL=U/L		179	134	224	Roche Cobas 4000/E411	
Inhibin A	ng/L = pg/ml	668	501	835	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	417	313	521	Beckman Dxl 600/800	
	ng/L = pg/ml	419	314	524	Beckman Access/LXi725	
PAPP-A	U/L=mIU/ml	4.12	3.09	5.15	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	18559	13919	23199		
	U/L=mIU/ml	12.7	9.53	15.9	Siemens Immulite 1000	
	ng/ml	57207	42928	71486		
	U/L=mIU/ml	13.8	10.4	17.3	Siemens Immulite 2000/2500	
	ng/ml	62162	46847	77477		
	U/L=mIU/ml	0.304	0.228	0.380	Beckman Dxl 600/800	
	ng/ml	1369	1027	1711		
	U/L=mIU/ml	3.59	2.69	4.49	Brahms Kryptor	
	ng/ml	16171	12117	20225		
	U/L=mIU/ml	5.43	4.07	6.79	Roche Cobas 6000/8000	
	ng/ml	24459	18333	30585		
U/L=mIU/ml	5.40	4.05	6.75	Roche Cobas E411		
ng/ml	24324	18243	30405			

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Range					
Analyte	unit	Target	low	high	methods
Total Beta hCG	mU/ml=IU/l	24225	19380	29070	Abbott Architect I2000/8200
	IU/ml	24.2	19.4	29.0	
	mU/ml=IU/l	21946	17557	26335	Siemens Centaur XP/XPT/Classic
	IU/ml	21.9	17.6	26.2	
	mU/ml=IU/l	48071	38457	57685	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	48.1	38.5	57.7	
	mU/ml=IU/l	44251	35401	53101	Siemens Immulite 2000/2500
	IU/ml	44.3	35.4	53.2	
	mU/ml=IU/l	51478	41182	61774	Siemens Immulite 1000
	IU/ml	51.5	41.2	61.8	
	mU/ml=IU/l	29580	23664	35496	Beckman Dxl 600/800
	IU/ml	29.6	23.7	35.5	
	mU/ml=IU/l	28767	23014	34520	Beckman Access/LXi725
	IU/ml	28.8	23.0	34.6	
	mU/ml=IU/l	29431	23545	35317	Roche Cobas 6000/8000
	IU/ml	29.4	23.5	35.3	
mU/ml=IU/l	30042	24034	36050	Beckman Access Total BhCG (5th IS)	
IU/ml	30.0	24.0	36.0		
mU/ml=IU/l	31887	25510	38264	Beckman Dxl Total BhCG (5th IS)	
IU/ml	31.9	25.5	38.3		
Unconjugated Estriol	nmol/L	40.2	30.2	50.3	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	11.6	8.71	14.5	
	nmol/L	17.4	13.1	21.8	Siemens Immulite 2000/2500
	ng/mL	5.02	3.78	6.26	
	nmol/L	18.7	14.0	23.4	Siemens Immulite 1000
	ng/mL	5.39	4.04	6.74	
	nmol/L	14.0	10.5	17.5	Beckman Dxl 600/800
	ng/mL	4.04	3.03	5.05	
	nmol/L	8.64	6.48	10.8	Brahms Kryptor
	ng/mL	2.49	1.87	3.11	
	nmol/L	14.4	10.8	18.0	Beckman Access/LXi725
	ng/mL	4.15	3.11	5.19	

**ADDITIONAL VALUES FOR
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(MATERNAL CONTROL 3)
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COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	102	81.6 - 122	AutoDELFIA (A/B096-101)
	ng/ml	123	98.4 - 148	
	KIU/l = IU/ml	104	83.2 - 125	DELFIA Xpress (6001-0010 / 6001-001C)
	ng/ml	126	101 - 151	
Free Beta hCG	mU/ml = U/l	173	130 - 216	AutoDELFIA (A/B097-101)
	mU/ml = U/l	> 200	-	DELFIA Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	661	496 - 826	AutoDELFIA (B064-102)
PAPP-A	U/l = mIU/ml	4.29	3.22 - 5.36	AutoDELFIA (A/B098-201)
	ng/ml	19324	14493 - 24155	
	U/l = mIU/ml	4.02	3.02 - 5.02	DELFIA Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
Unconjugated Estriol	ng/ml	18108	13581 - 22635	
	nmol/l	43.1	32.3 - 53.9	AutoDELFIA (B095-101 / B095-101U)
	ng/ml	12.4	9.30 - 15.5	
	nmol/l	34.7	26.0 - 43.4	DELFIA Xpress (6005-0010 / 6005-001C)
	ng/ml	10.0	7.50 - 12.5	

EC REP

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