



PRODUCT INFORMATION

MSS5026

Lot 8630MS

Please note that the levels of PAPP-A in this control are unsuitable for use on Beckman Instruments

For any questions or queries please contact technical.services@randox.com

QCCS833

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 8630MS
SIZE 3 x 1ml **EXPIRY:** 2027-02-28
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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MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

Cat. No. MSS5026 Lot. No. 8630MS Size 3 x 1 ml Expiry 2027-02-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	96.1	76.9	115	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	116	93.0	139	
	KIU/l = IU/ml	95.9	76.7	115	Abbott Architect
	ng/ml	116	92.8	139	
	KIU/l = IU/ml	95.8	76.6	115	Siemens Immulite 2000/2500
	ng/ml	116	92.7	139	
	KIU/l = IU/ml	93.2	74.6	112	Beckman Dxl800
	ng/ml	113	90.3	136	
	KIU/l = IU/ml	82.0	65.6	98.4	Brahms Kryptor
	ng/ml	99.2	79.4	119	
KIU/l = IU/ml	94.6	75.7	114	Beckman Access	
ng/ml	114	91.6	136		
KIU/l = IU/ml	99.0	79.2	119	Roche Cobas e601/602	
ng/ml	120	95.8	144		
KIU/l = IU/ml	102	81.6	122	Roche Cobas 4000/E411	
ng/ml	123	98.7	147		
KIU/l = IU/ml	105	84.0	126	Roche Cobas e402/e801	
ng/ml	127	102	152		
Free Beta hCG	mU/mL=U/L	139	104	174	Siemens Centaur XP/XPT/Classic
	mU/mL=U/L	104	78.0	130	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	124	93.0	155	Siemens Immulite 2000/2500
	mU/mL=U/L	111	83.3	139	Brahms Kryptor
	mU/mL=U/L	85.7	64.3	107	Roche Cobas e601/602
	mU/mL=U/L	90.2	67.7	113	Roche Cobas 4000/E411
	mU/mL=U/L	87.1	65.3	109	Roche Cobas e402/e801
Inhibin A	ng/L = pg/ml	594	446	743	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/L = pg/ml	333	250	416	Beckman Dxl 600/800
	ng/L = pg/ml	470	353	588	Brahms Kryptor
	ng/L = pg/ml	325	244	406	Beckman Access
PAPP-A	U/L=mIU/ml	7.69	5.77	9.61	Siemens Centaur XP/XPT/Classic
	ng/ml	34640	25991	43289	
	U/L=mIU/ml	1.59	1.19	1.99	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	7162	5360	8964	
	U/L=mIU/ml	7.64	5.73	9.55	Siemens Immulite 2000/2500
	ng/ml	34414	25811	43017	
	U/L=mIU/ml	2.17	1.63	2.71	Brahms Kryptor
	ng/ml	9775	7342	12208	
	U/L=mIU/ml	3.90	2.93	4.88	Roche Cobas e601/602
	ng/ml	17568	13198	21938	
U/L=mIU/ml	3.87	2.90	4.84	Roche Cobas 4000/E411	
ng/ml	17432	13063	21801		
U/L=mIU/ml	3.82	2.87	4.78	Roche Cobas e402/e801	
ng/ml	17207	12928	21486		

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Cat. No. MSS5026 Lot. No. 8630MS Size 3 x 1 ml Expiry 2027-02-28

Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	26700	21360	32040	Abbott Architect / Alinity
	IU/ml	26.7	21.4	32.0	
	mU/ml=IU/l	44300	35440	53160	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	44.3	35.4	53.2	
	mU/ml=IU/l	37100	29680	44520	Siemens Immulite 2000/2500
	IU/ml	37.1	29.7	44.5	
	mU/ml=IU/l	29900	23920	35880	Beckman Dxl 600/800
	IU/ml	29.9	23.9	35.9	
	mU/ml=IU/l	46600	37280	55920	Brahms Kryptor
	IU/ml	46.6	37.3	55.9	
	mU/ml=IU/l	30200	24160	36240	Beckman Access
	IU/ml	30.2	24.2	36.2	
	mU/ml=IU/l	26300	21040	31560	Roche Cobas 6000/8000
	IU/ml	26.3	21.0	31.6	
	mU/ml=IU/l	30800	24640	36960	Beckman Access Total BhCG (5th IS)
	IU/ml	30.8	24.6	37.0	
	mU/ml=IU/l	30700	24560	36840	Beckman Dxl Total BhCG (5th IS)
	IU/ml	30.7	24.6	36.8	
mU/ml=IU/l	26800	21440	32160	Roche hCG+Beta e801	
IU/ml	26.8	21.4	32.2		
mU/ml=IU/l	23000	18400	27600	Siemens Atellica IM	
IU/ml	23.0	18.4	27.6		
Unconjugated Estriol	nmol/L	30.3	22.7	37.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	8.74	6.55	10.9	
	nmol/L	12.3	9.23	15.4	Siemens Immulite 2000/2500
	ng/mL	3.55	2.66	4.44	
	nmol/L	12.3	9.23	15.4	Siemens Immulite 1000
	ng/mL	3.55	2.66	4.44	
	nmol/L	10.1	7.58	12.6	Beckman Dxl 600/800
	ng/mL	2.91	2.19	3.63	
	nmol/L	4.88	3.66	6.10	Brahms Kryptor
	ng/mL	1.41	1.06	1.76	
nmol/L	10.5	7.88	13.1	Beckman Access	
ng/mL	3.03	2.27	3.79		