



PRODUCT INFORMATION

MSS5025

Lot 8627MS

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 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025 **LOT NO.** 8627MS
SIZE 3 x 1 ml **EXPIRY:** 2027-02-28
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 9445 1070 or email Technical.Services@randox.com.

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Cat. No. MSS5025 Lot. No. 8627MS Size 3 x 1 ml Expiry 2027-02-28

Analyte	unit	Target	Range		methods	
			low	high		
Alphafoetoprotein	KIU/l = IU/ml	55.3	44.2	66.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	66.9	53.5	80.3		
	KIU/l = IU/ml	52.8	42.2	63.4	Siemens Immulite 2000/2500	
	ng/ml	63.9	51.1	76.7		
	KIU/l = IU/ml	58.8	47.0	70.6	Siemens Centaur XP/XPT/Classic	
	ng/ml	71.1	56.9	85.3		
	KIU/l = IU/ml	49.6	39.7	59.5	Beckman Dxl800	
	ng/ml	60.0	48.0	72.0		
	KIU/l = IU/ml	46.2	37.0	55.4	Brahms Kryptor	
	ng/ml	55.9	44.8	67.0		
	KIU/l = IU/ml	52.8	42.2	63.4	Beckman Access	
	ng/ml	63.9	51.1	76.7		
Free Beta hCG	KIU/l = IU/ml	54.5	43.6	65.4	Roche Cobas e601/602	
	ng/ml	65.9	52.8	79.0		
	KIU/l = IU/ml	54.9	43.9	65.9	Roche Cobas 4000/E411	
	ng/ml	66.4	53.1	79.7		
	KIU/l = IU/ml	55.7	44.6	66.8	Roche Cobas e402/e801	
	ng/ml	67.4	54.0	80.8		
	Free Beta hCG	mU/mL=U/L	73.7	55.3	92.1	Siemens Centaur XP/XPT/Classic
		mU/mL=U/L	57.4	43.1	71.8	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	69.2	51.9	86.5	Siemens Immulite 2000/2500
		mU/mL=U/L	59.4	44.6	74.3	Brahms Kryptor
		mU/mL=U/L	46.9	35.2	58.6	Roche Cobas e601/602
		mU/mL=U/L	49.3	37.0	61.6	Roche Cobas 4000/E411
mU/mL=U/L		46.7	35.0	58.4	Roche Cobas e402/e801	
mU/mL=U/L		62.6	47.0	78.3	Siemens Atellica IM	
Inhibin A	ng/L = pg/ml	299	224	374	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	177	133	221	Beckman Dxl 600/800	
	ng/L = pg/ml	248	186	310	Brahms Kryptor	
	ng/L = pg/ml	169	127	211	Beckman Access	
PAPP-A	U/L=mIU/ml	4.64	3.48	5.80	Siemens Centaur XP/XPT/Classic	
	ng/ml	20901	15676	26126		
	U/L=mIU/ml	0.960	0.720	1.20	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	4324	3243	5405		
	U/L=mIU/ml	4.42	3.32	5.53	Siemens Immulite 2000/2500	
	ng/ml	19910	14955	24865		
	U/L=mIU/ml	1.26	0.945	1.58	Brahms Kryptor	
	ng/ml	5676	4257	7095		
U/L=mIU/ml	2.46	1.85	3.08	Roche Cobas e601/602		
ng/ml	11081	8333	13829			
U/L=mIU/ml	2.44	1.83	3.05	Roche Cobas 4000/E411		
ng/ml	10991	8243	13739			

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Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	2.35	1.76	2.94	Roche Cobas e402/e801
	ng/ml	10586	7928	13244	
Total Beta hCG	mU/ml=IU/l	13300	10640	15960	Siemens Centaur XP/XPT/Classic
	IU/ml	13.3	10.6	16.0	
	mU/ml=IU/l	22200	17760	26640	Siemens Immulite 2000/2500
	IU/ml	22.2	17.8	26.6	
	mU/ml=IU/l	16700	13360	20040	Beckman Dxl 600/800
	IU/ml	16.7	13.4	20.0	
	mU/ml=IU/l	26700	21360	32040	Brahms Kryptor
	IU/ml	26.7	21.4	32.0	
	mU/ml=IU/l	16300	13040	19560	Beckman Access
	IU/ml	16.3	13.0	19.6	
	mU/ml=IU/l	14100	11280	16920	Roche Cobas 6000/8000
	IU/ml	14.1	11.3	16.9	
	mU/ml=IU/l	15800	12640	18960	Beckman Access Total BhCG (5th IS)
	IU/ml	15.8	12.6	19.0	
	mU/ml=IU/l	16400	13120	19680	Beckman Dxl Total BhCG (5th IS)
	IU/ml	16.4	13.1	19.7	
Unconjugated Estriol	mU/ml=IU/l	14400	11520	17280	Roche hCG+Beta e801
	IU/ml	14.4	11.5	17.3	
	mU/ml=IU/l	12500	10000	15000	Siemens Atellica IM
	IU/ml	12.5	10.0	15.0	
	nmol/L	19.5	14.6	24.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	5.62	4.21	7.03	
	nmol/L	8.19	6.14	10.2	Siemens Immulite 2000/2500
	ng/mL	2.36	1.77	2.95	
	nmol/L	6.83	5.12	8.54	Beckman Dxl 600/800
	ng/mL	1.97	1.48	2.46	
nmol/L	2.83	2.12	3.54	Brahms Kryptor	
ng/mL	0.816	0.611	1.02		
nmol/L	7.32	5.49	9.15	Beckman Access	
ng/mL	2.11	1.58	2.64		