

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026 **LOT NO.** 8248MS
SIZE: 3 x 1ml **EXPIRY:** 2025-05-28
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 9445 1070 or email Technical.Services@randox.com.

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Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	108	86.4	130	Siemens Immulite 1000
	ng/ml	131	105	157	
	KIU/l = IU/ml	105	84.0	126	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	127	102	152	
	KIU/l = IU/ml	108	86.4	130	Siemens Immulite 2000/2500
	ng/ml	131	105	157	
	KIU/l = IU/ml	120	96.0	144	Siemens Centaur XP/XPT/Classic
	ng/ml	145	116	174	
	KIU/l = IU/ml	102	81.6	122	Beckman Dxl800
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	91.8	73.4	110	Brahms Kryptor
	ng/ml	111	88.8	133	
Free Beta hCG	KIU/l = IU/ml	104	83.2	125	Beckman Access
	ng/ml	126	101	151	
	KIU/l = IU/ml	118	94.4	142	Roche Cobas e601/602
	ng/ml	143	114	172	
	KIU/l = IU/ml	126	101	151	Roche Cobas 4000/E411
	ng/ml	152	122	182	
	KIU/l = IU/ml	110	88.0	132	Roche Cobas e402/e801
	ng/ml	133	106	160	
	mU/mL=U/L	101	75.8	126	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	113	84.8	141	Siemens Immulite 2000/2500
Inhibin A	mU/mL=U/L	110	82.5	138	Siemens Immulite 1000
	mU/mL=U/L	100	75.0	125	Brahms Kryptor
	mU/mL=U/L	89.5	67.1	112	Roche Cobas e601/602
	mU/mL=U/L	89.7	67.3	112	Roche Cobas 4000/E411
	mU/mL=U/L	89.3	67.0	112	Roche Cobas e402/e801
	ng/L = pg/ml	613	460	766	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/L = pg/ml	353	265	441	Beckman Dxl 600/800
PAPP-A	ng/L = pg/ml	539	404	674	Brahms Kryptor
	ng/L = pg/ml	364	273	455	Beckman Access
	U/L=mIU/ml	5.54	4.16	6.93	Siemens Centaur XP/XPT/Classic
	ng/ml	24955	18716	31194	
	U/L=mIU/ml	4.07	3.05	5.09	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	18333	13750	22916	
	U/L=mIU/ml	0.357	0.268	0.446	Beckman Dxl 600/800
	ng/ml	1608	1206	2010	
	U/L=mIU/ml	3.21	2.41	4.01	Brahms Kryptor
	ng/ml	14459	10844	18074	
PAPP-A	U/L=mIU/ml	0.358	0.269	0.448	Beckman Access
	ng/ml	1613	1210	2016	
	U/L=mIU/ml	5.51	4.13	6.89	Roche Cobas e601/602
	ng/ml	24820	18615	31025	

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Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	5.58	4.19	6.98	Roche Cobas 4000/E411
	ng/ml	25135	18851	31419	
	U/L=mIU/ml	5.51	4.13	6.89	Roche Cobas e402/e801
	ng/ml	24820	18615	31025	
Total Beta hCG	mU/ml=IU/l	25890	20712	31068	Abbott Architect / Alinity
	IU/ml	25.9	20.7	31.1	
	mU/ml=IU/l	20390	16312	24468	Siemens Centaur XP/XPT/Classic
	IU/ml	20.4	16.3	24.5	
	mU/ml=IU/l	44622	35698	53546	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	44.6	35.7	53.5	
	mU/ml=IU/l	38048	30438	45658	Siemens Immulite 2000/2500
	IU/ml	38.0	30.4	45.6	
	mU/ml=IU/l	42612	34090	51134	Siemens Immulite 1000
	IU/ml	42.6	34.1	51.1	
	mU/ml=IU/l	32179	25743	38615	Beckman Dxl 600/800
	IU/ml	32.2	25.7	38.7	
	mU/ml=IU/l	29932	23946	35918	Beckman Access
	IU/ml	29.9	23.9	35.9	
	mU/ml=IU/l	27533	22026	33040	Roche Cobas 6000/8000
	IU/ml	27.5	22.0	33.0	
mU/ml=IU/l	29532	23626	35438	Beckman Access Total BhCG (5th IS)	
IU/ml	29.5	23.6	35.4		
mU/ml=IU/l	31072	24858	37286	Beckman Dxl Total BhCG (5th IS)	
IU/ml	31.1	24.9	37.3		
mU/ml=IU/l	26751	21401	32101	Roche hCG+Beta e801	
IU/ml	26.8	21.4	32.2		
Unconjugated Estriol	nmol/L	28.8	21.6	36.0	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	8.31	6.23	10.4	
	nmol/L	12.8	9.60	16.0	Siemens Immulite 2000/2500
	ng/mL	3.69	2.77	4.61	
	nmol/L	12.5	9.38	15.6	Siemens Immulite 1000
	ng/mL	3.61	2.71	4.51	
	nmol/L	10.6	7.95	13.3	Beckman Dxl 600/800
	ng/mL	3.06	2.29	3.83	
	nmol/L	5.63	4.22	7.04	Brahms Kryptor
	ng/mL	1.62	1.22	2.02	
nmol/L	11.0	8.25	13.8	Beckman Access	
ng/mL	3.17	2.38	3.96		