

MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)

CAT. NO. MSS5026

LOT NO. 6069MS

SIZE: 3 x 1 ml

EXPIRY: 2018-09-28

GTIN: 05055273207408

INTENDED USE

This product is intended for *in vitro* use, in the quality control of Alphafoetoprotein, 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.

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 94451070 or email Technical.Services@randox.com.

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Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	115	92.0	138	Siemens Immulite 1000
	ng/ml	139	111	167	
	KIU/l = IU/ml	117	93.6	140	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	142	113	171	
	KIU/l = IU/ml	119	95.2	143	Abbott Architect
	ng/ml	144	115	173	
	KIU/l = IU/ml	115	92.0	138	Siemens Immulite 2000/2500
	ng/ml	139	111	167	
	KIU/l = IU/ml	130	104	156	Siemens Centaur XP/XPT/Classic
	ng/ml	157	126	188	
	KIU/l = IU/ml	115	92.0	138	Beckman Dxl800
	ng/ml	139	111	167	
	KIU/l = IU/ml	102	81.6	122	Brahms Kryptor
	ng/ml	123	98.7	147	
	KIU/l = IU/ml	129	103	155	Beckman Access
	ng/ml	156	125	187	
Free Beta hCG	KIU/l = IU/ml	131	105	157	Roche Cobas 6000/8000
	ng/ml	159	127	191	
	KIU/l = IU/ml	115	92.0	138	Zentech ELISA
	ng/ml	139	111	167	
	KIU/l = IU/ml	141	113	169	Roche Cobas E411
	ng/ml	171	137	205	
Inhibin A	mU/mL=U/L	66.4	49.8	83.0	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	mU/mL=U/L	67.4	50.6	84.3	Siemens Immulite 2000/2500
	mU/mL=U/L	64.8	48.6	81.0	Siemens Immulite 1000
	mU/mL=U/L	64.9	48.7	81.1	Brahms Kryptor
	mU/mL=U/L	56.8	42.6	71.0	Roche Cobas 6000/8000
	mU/mL=U/L	47.8	35.9	59.8	Zentech ELISA
PAPP-A	ng/L = pg/ml	461	346	576	Beckman Dxl 600/800
	ng/L = pg/ml	454	341	568	Beckman Access/LXi725
	U/L=mIU/ml	4.07	3.05	5.09	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/ml	18333	13739	22927	
	U/L=mIU/ml	14.7	11.0	18.4	Siemens Immulite 1000
	ng/ml	66216	49550	82882	
	U/L=mIU/ml	14.3	10.7	17.9	Siemens Immulite 2000/2500
	ng/ml	64414	48198	80630	
	U/L=mIU/ml	0.432	0.324	0.540	Beckman Dxl 600/800
	ng/ml	1946	1459	2433	
	U/L=mIU/ml	3.50	2.63	4.38	Brahms Kryptor
	ng/ml	15766	11847	19685	
	U/L=mIU/ml	5.72	4.29	7.15	Roche Cobas 6000/8000
	ng/ml	25766	19324	32208	

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Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	5.94	4.46	7.43	Roche Cobas E411
	ng/ml	26757	20090	33424	
Total Beta hCG	mU/ml=IU/l	28204	22563	33845	Abbott Architect I2000/8200
	IU/ml	28.2	22.6	33.8	
	mU/ml=IU/l	25160	20128	30192	Siemens Centaur XP/XPT/Classic
	IU/ml	25.2	20.1	30.3	
	mU/ml=IU/l	44014	35211	52817	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	44.0	35.2	52.8	
	mU/ml=IU/l	42731	34185	51277	Siemens Immulite 2000/2500
	IU/ml	42.7	34.2	51.2	
	mU/ml=IU/l	47035	37628	56442	Siemens Immulite 1000
	IU/ml	47.0	37.6	56.4	
	mU/ml=IU/l	31251	25001	37501	Beckman Dxl 600/800
	IU/ml	31.3	25.0	37.6	
	mU/ml=IU/l	30418	24334	36502	Roche Cobas 6000/8000
	IU/ml	30.4	24.3	36.5	
	mU/ml=IU/l	38472	30778	46166	Beckman Access Total BhCG (5th IS)
	IU/ml	38.5	30.8	46.2	
	mU/ml=IU/l	32898	26318	39478	Beckman Dxl Total BhCG (5th IS)
	IU/ml	32.9	26.3	39.5	
Unconjugated Estriol	nmol/L	8.55	6.41	10.7	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	2.47	1.85	3.09	
	nmol/L	3.66	2.75	4.58	Siemens Immulite 2000/2500
	ng/mL	1.06	0.793	1.33	
	nmol/L	3.19	2.39	3.99	Siemens Immulite 1000
	ng/mL	0.920	0.689	1.15	
	nmol/L	4.03	3.02	5.04	Beckman Dxl 600/800
	ng/mL	1.16	0.871	1.45	
	nmol/L	3.55	2.66	4.44	Siemens Centaur CP
	ng/mL	1.02	0.767	1.27	