

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025

LOT NO. 7944MS

SIZE: 3 x 1 ml

EXPIRY: 2023-10-28

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 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 2 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.

EC REP

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

17 May 21 bm

MATERNAL CONTROL LEVEL 2 (MATERNAL CONTROL 2)

Cat. No. MSS5025 Lot. No. 7944MS Size 3 x 1ml Expiry 2023-10-28

Range						
Analyte	unit	Target	low	high	methods	
Alphafoetoprotein	KIU/l = IU/ml	54.2	43.4	65.0	Siemens Immulite 1000	
	ng/ml	65.6	52.5	78.7		
	KIU/l = IU/ml	52.0	41.6	62.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	62.9	50.3	75.5		
	KIU/l = IU/ml	51.9	41.5	62.3	Abbott Architect	
	ng/ml	62.8	50.2	75.4		
	KIU/l = IU/ml	52.7	42.2	63.2	Siemens Immulite 2000/2500	
	ng/ml	63.8	51.1	76.5		
	KIU/l = IU/ml	58.2	46.6	69.8	Siemens Centaur XP/XPT/Classic	
	ng/ml	70.4	56.4	84.4		
	KIU/l = IU/ml	50.7	40.6	60.8	Beckman Dxl800	
	ng/ml	61.3	49.1	73.5		
	KIU/l = IU/ml	48.4	38.7	58.1	Brahms Kryptor	
	ng/ml	58.6	46.8	70.4		
Free Beta hCG	KIU/l = IU/ml	52.2	41.8	62.6	Beckman Access	
	ng/ml	63.2	50.6	75.8		
	KIU/l = IU/ml	57.7	46.2	69.2	Roche Cobas e601/602	
	ng/ml	69.8	55.9	83.7		
	KIU/l = IU/ml	57.8	46.2	69.4	Roche Cobas 4000/E411	
	ng/ml	69.9	55.9	83.9		
	KIU/l = IU/ml	56.5	45.2	67.8	Roche Cobas e801	
	ng/ml	68.4	54.7	82.1		
	Inhibin A	mU/mL=U/L	78.7	59.0	98.4	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	86.3	64.7	108	Siemens Immulite 2000/2500
		mU/mL=U/L	77.4	58.1	96.8	Siemens Immulite 1000
		mU/mL=U/L	64.4	48.3	80.5	Brahms Kryptor
		mU/mL=U/L	63.7	47.8	79.6	Roche Cobas e601/602
		mU/mL=U/L	64.6	48.5	80.8	Roche Cobas 4000/E411
mU/mL=U/L		62.8	47.1	78.5	Roche Cobas e801	
Inhibin A	ng/L = pg/ml	175	131	219	Beckman Dxl 600/800	
	ng/L = pg/ml	265	199	331	Brahms Kryptor	
	ng/L = pg/ml	171	128	214	Beckman Access	
PAPP-A	U/L=mIU/ml	1.81	1.36	2.26	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	8153	6126	10180		
	U/L=mIU/ml	6.65	4.99	8.31	Siemens Immulite 1000	
	ng/ml	29955	22477	37433		
	U/L=mIU/ml	6.96	5.22	8.70	Siemens Immulite 2000/2500	
	ng/ml	31351	23513	39189		
	U/L=mIU/ml	0.150	0.113	0.188	Beckman Dxl 600/800	
	ng/ml	676	509	843		
PAPP-A	U/L=mIU/ml	1.63	1.22	2.04	Brahms Kryptor	
	ng/ml	7342	5495	9189		

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Range					
Analyte	unit	Target	low	high	methods
PAPP-A	U/L=mIU/ml	0.150	0.113	0.188	Beckman Access
	ng/ml	676	509	843	
	U/L=mIU/ml	2.45	1.84	3.06	Roche Cobas e601/602
	ng/ml	11036	8288	13784	
	U/L=mIU/ml	2.41	1.81	3.01	Roche Cobas 4000/E411
	ng/ml	10856	8153	13559	
	U/L=mIU/ml	2.42	1.82	3.03	Roche Cobas e801
	ng/ml	10901	8198	13604	
Total Beta hCG	mU/ml=IU/l	9456	7565	11347	Abbott Architect / Alinity
	IU/ml	9.46	7.57	11.4	
	mU/ml=IU/l	19621	15697	23545	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	19.6	15.7	23.5	
	mU/ml=IU/l	17785	14228	21342	Siemens Immulite 2000/2500
	IU/ml	17.8	14.2	21.4	
	mU/ml=IU/l	19231	15385	23077	Siemens Immulite 1000
	IU/ml	19.2	15.4	23.0	
	mU/ml=IU/l	11804	9443	14165	Beckman Dxl 600/800
	IU/ml	11.8	9.44	14.2	
	mU/ml=IU/l	11182	8946	13418	Beckman Access
	IU/ml	11.2	8.95	13.5	
	mU/ml=IU/l	10690	8552	12828	Roche Cobas 6000/8000
	IU/ml	10.7	8.55	12.9	
mU/ml=IU/l	11451	9161	13741	Beckman Access Total BhCG (5th IS)	
IU/ml	11.5	9.16	13.8		
mU/ml=IU/l	11499	9199	13799	Beckman Dxl Total BhCG (5th IS)	
IU/ml	11.5	9.20	13.8		
Unconjugated Estriol	nmol/L	18.8	14.1	23.5	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	5.42	4.07	6.77	
	nmol/L	8.51	6.38	10.6	Siemens Immulite 2000/2500
	ng/mL	2.45	1.84	3.06	
	nmol/L	9.07	6.80	11.3	Siemens Immulite 1000
	ng/mL	2.62	1.96	3.28	
	nmol/L	7.15	5.36	8.94	Beckman Dxl 600/800
	ng/mL	2.06	1.55	2.57	
	nmol/L	3.47	2.60	4.34	Brahms Kryptor
	ng/mL	1.00	0.750	1.25	
	nmol/L	7.60	5.70	9.50	Beckman Access
	ng/mL	2.19	1.64	2.74	

**ADDITIONAL VALUES FOR
MATERNAL CONTROL - LEVEL 2
(MATERNAL CONTROL 2)
Cat No. MSS5025
Lot No. 7944MS
GTIN: 05055273207392**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	52.6	42.1 - 63.1	AutoDELFI A (A/B096-101)
	ng/ml	63.6	50.9 - 76.3	
	KIU/l = IU/ml	50.0	40.0 - 60.0	DELFI A Xpress (6001-0010 / 6001-001C)
	ng/ml	60.5	48.4 - 72.6	
Free Beta hCG	mU/ml = U/l	66.1	49.6 – 82.6	AutoDELFI A (A/B097-101)
	mU/ml = U/l	81.8	61.4 - 102	DELFI A Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	300	225 - 375	AutoDELFI A (B064-102)
PAPP-A	U/l = mIU/ml	1.91	1.43 – 2.39	AutoDELFI A (A/B098-201)
	ng/ml	8604	6453 - 10755	
	U/l = mIU/ml	1.62	1.22 - 2.02	DELFI A Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	7297	5473 - 9121	
Unconjugated Estriol	nmol/l	19.8	14.9 – 24.7	AutoDELFI A (B095-101 / B095-101U)
	ng/ml	5.71	4.28 – 7.14	
	nmol/l	16.3	12.2 – 20.4	DELFI A Xpress (6005-0010 / 6005-001C)
	ng/ml	4.70	3.53 – 5.87	

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Dungloe, Donegal,
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Cat No. MSS5025
Lot No. 7944MS
GTIN: 05055273207392**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	54.7	38.3 - 71.1	Snibe Maglumi
	ng/ml	66.2	46.3 - 86.0	
Free Beta hCG	mU/ml = U/l	101	70.7 - 131	Snibe Maglumi



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04 Aug '21 me