

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

CAT. NO. MSS5025

LOT NO. 7796MS

SIZE: 3 x 1 ml

EXPIRY: 2023-05-28

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

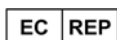
Distilled water

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.



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

29 Sep '20 ne

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

Cat. No. MSS5025 Lot No. 7796MS Size: 3 x 1 ml Expiry: 2023-05-28

Analyte	unit	Target	Range		methods	
			low	high		
Alpha-fetoprotein	KIU/l = IU/ml	59.5	47.6	71.4	Siemens Immulite 1000	
	ng/ml	72.0	57.6	86.4		
	KIU/l = IU/ml	58.2	46.6	69.8	Abbott Architect	
	ng/ml	70.4	56.4	84.4		
	KIU/l = IU/ml	58.9	47.1	70.7	Siemens Immulite 2000/2500	
	ng/ml	71.3	57.0	85.6		
	KIU/l = IU/ml	69.9	55.9	83.9	Siemens Centaur XP/XPT/Classic	
	ng/ml	84.6	67.6	102		
	KIU/l = IU/ml	55.7	44.6	66.8	Beckman Dxl800	
	ng/ml	67.4	54.0	80.8		
	KIU/l = IU/ml	56.5	45.2	67.8	Brahms Kryptor	
	ng/ml	68.4	54.7	82.1		
Free Beta hCG	KIU/l = IU/ml	58.3	46.6	70.0	Beckman Access	
	ng/ml	70.5	56.4	84.6		
	KIU/l = IU/ml	64.8	51.8	77.8	Roche Cobas 6000/8000	
	ng/ml	78.4	62.7	94.1		
	KIU/l = IU/ml	61.3	49.0	73.6	Roche Cobas E411	
	ng/ml	74.2	59.3	89.1		
	Inhibin A	mU/mL=U/L	87.8	65.9	110	Siemens Immulite 2000/2500
		mU/mL=U/L	85.0	63.8	106	Siemens Immulite 1000
		mU/mL=U/L	64.3	48.2	80.4	Brahms Kryptor
		mU/mL=U/L	64.9	48.7	81.1	Roche Cobas 6000/8000
		mU/mL=U/L	65.1	48.8	81.4	Roche Cobas 4000/E411
	PAPP-A	ng/L = pg/ml	202	152	253	Beckman Dxl 600/800
ng/L = pg/ml		301	226	376	Brahms Kryptor	
ng/L = pg/ml		212	159	265	Beckman Access/LXi725	
PAPP-A	U/L=mIU/ml	6.84	5.13	8.55	Siemens Immulite 1000	
	ng/ml	30811	23108	38514		
	U/L=mIU/ml	7.13	5.35	8.91	Siemens Immulite 2000/2500	
	ng/ml	32117	24099	40135		
	U/L=mIU/ml	0.149	0.112	0.186	Beckman Dxl 600/800	
	ng/ml	671	505	837		
	U/L=mIU/ml	1.64	1.23	2.05	Brahms Kryptor	
	ng/ml	7387	5541	9233		
	U/L=mIU/ml	2.49	1.87	3.11	Roche Cobas 6000/8000	
	ng/ml	11216	8423	14009		
	U/L=mIU/ml	2.42	1.82	3.03	Roche Cobas E411	
	ng/ml	10901	8198	13604		
Total Beta hCG	mU/ml=IU/l	16866	13493	20239	Siemens Immulite 1000	
	IU/ml	16.9	13.5	20.3		
	mU/ml=IU/l	9541	7633	11449	Abbott Architect I2000/8200	
	IU/ml	9.54	7.63	11.5		

MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)

Cat. No. MSS5025 Lot No. 7796MS Size: 3 x 1 ml Expiry: 2023-05-28

Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	8745	6996	10494	Siemens Centaur XP/XPT/Classic
	IU/ml	8.75	7.00	10.5	
	mU/ml=IU/l	18969	15175	22763	Siemens Immulite 2000/2500
	IU/ml	19.0	15.2	22.8	
	mU/ml=IU/l	12114	9691	14537	Beckman Dxl 600/800
	IU/ml	12.1	9.69	14.5	
	mU/ml=IU/l	11923	9538	14308	Beckman Access/LXi725
	IU/ml	11.9	9.54	14.3	
	mU/ml=IU/l	11190	8952	13428	Roche Cobas 6000/8000
	IU/ml	11.2	8.95	13.5	
	mU/ml=IU/l	12030	9624	14436	Beckman Access Total BhCG (5th IS)
	IU/ml	12.0	9.62	14.4	
	mU/ml=IU/l	11944	9555	14333	Beckman Dxl Total BhCG (5th IS)
	IU/ml	11.9	9.56	14.2	
Unconjugated Estriol	nmol/L	9.56	7.17	12.0	Siemens Immulite 2000/2500
	ng/mL	2.76	2.07	3.45	
	nmol/L	10.1	7.58	12.6	Siemens Immulite 1000
	ng/mL	2.91	2.19	3.63	
	nmol/L	7.33	5.50	9.16	Beckman Dxl 600/800
	ng/mL	2.11	1.59	2.63	
	nmol/L	4.17	3.13	5.21	Brahms Kryptor
	ng/mL	1.20	0.903	1.50	
	nmol/L	7.83	5.87	9.79	Beckman Access/LXi725
	ng/mL	2.26	1.69	2.83	

**ADDITIONAL VALUES FOR
MATERNAL CONTROL - LEVEL 2
(MATERNAL CONTROL 2)
Cat No. MSS5025
Lot No. 7796MS
GTIN: 05055273207392**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml ng/ml	68.0 82.3	54.4 - 81.6 65.8 - 98.8	Siemens Atellica IM

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

29 Jun '21 me

**ADDITIONAL VALUES FOR
MATERNAL CONTROL - LEVEL 2
(MATERNAL CONTROL 2)
Cat No. MSS5025
Lot No. 7796MS**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Alpha-fetoprotein	KIU/l = IU/ml	60.2	48.2 - 72.2	AutoDELFIA (A/B096-101)
	ng/ml	72.8	58.2 - 87.4	
	KIU/l = IU/ml	60.7	48.6 - 72.8	DELFIA Xpress (6001-0010 / 6001-001C)
	ng/ml	73.4	58.7 - 88.1	
Free Beta hCG	mU/ml = U/l	68.8	51.6 - 86.0	AutoDELFIA (A/B097-101)
	mU/ml = U/l	85.5	64.1 - 107	DELFIA Xpress (6002-0010 / 6002-001C)
Inhibin A	ng/l = pg/ml	358	269 - 447	AutoDELFIA (B064-102)
PAPP-A	U/l = mIU/ml	1.95	1.46 - 2.44	AutoDELFIA (A/B098-201)
	ng/ml	8784	6588 - 10980	
	U/l = mIU/ml	1.82	1.37 - 2.27	DELFIA Xpress (6003-0020 / 6003-002C / 6003-0050 / 6003-005C)
	ng/ml	8198	6149 - 10247	
Unconjugated Estriol	nmol/l	20.7	15.5 - 25.9	AutoDELFIA (B095-101 / B095-101U)
	ng/ml	5.97	4.48 - 7.46	
	nmol/l	16.2	12.2 - 20.2	DELFIA Xpress (6005-0010 / 6005-001C)
	ng/ml	4.67	3.50 - 5.84	

EC REP

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

06 Jan 21 pl