

IMPORTANT NOTICE

MSS5024

7460MS

The reconstituted stability for Maternal Control Level 1 lot 7460MS for Free Beta hCG is **2 days**
when stored at +2°C to +8°C.

Free Beta hCG is stable for 7 days when frozen once at -18°C to -24°C.

Authorised by: Gareth Little
Serum QC Manager
Date: 10 September 2019

Ref: CCS5842

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

CAT. NO. MSS5024

LOT NO. 7460MS

SIZE: 3 x 1 ml

EXPIRY: 2022-04-28

GTIN: 05055273207385

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. The reconstituted stability for Free Beta hCG is 2 days when stored at +2°C to +8°C, and 7 days when frozen once at -18°C to -24°C.

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 I 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 9445 1070 or email Technical.Services@randox.com.

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

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 7460MS Size: 3 x 1 ml Expiry: 2022-04-28

Analyte	unit	Target	Range		methods	
			low	high		
Alpha-fetoprotein	KIU/l = IU/ml	14.1	11.3	16.9	Siemens Immulite 1000	
	ng/ml	17.1	13.7	20.5		
	KIU/l = IU/ml	13.5	10.8	16.2	Abbott Architect	
	ng/ml	16.3	13.1	19.5		
	KIU/l = IU/ml	14.1	11.3	16.9	Siemens Immulite 2000/2500	
	ng/ml	17.1	13.7	20.5		
	KIU/l = IU/ml	16.3	13.0	19.6	Siemens Centaur XP/XPT/Classic	
	ng/ml	19.7	15.7	23.7		
	KIU/l = IU/ml	13.6	10.9	16.3	Beckman Dxl800	
	ng/ml	16.5	13.2	19.8		
	KIU/l = IU/ml	14.3	11.4	17.2	Brahms Kryptor	
	ng/ml	17.3	13.8	20.8		
	KIU/l = IU/ml	14.2	11.4	17.0	Beckman Access	
	ng/ml	17.2	13.8	20.6		
Free Beta hCG	KIU/l = IU/ml	15.6	12.5	18.7	Roche Cobas 6000/8000	
	ng/ml	18.9	15.1	22.7		
	KIU/l = IU/ml	15.4	12.3	18.5	Roche Cobas E411	
	ng/ml	18.6	14.9	22.3		
	KIU/l = IU/ml	15.2	12.2	18.2	AutoDELFLIA (A/B096-101)	
	ng/ml	18.4	14.8	22.0		
	KIU/l = IU/ml	14.4	11.5	17.3	DELFLIA Xpress (6001-0010 / 6001-001C)	
	ng/ml	17.4	13.9	20.9		
	Free Beta hCG	mU/mL=U/L	24.0	18.0	30.0	Siemens Immulite 2000/2500
		mU/mL=U/L	24.9	18.7	31.1	Siemens Immulite 1000
mU/mL=U/L		20.5	15.4	25.6	Brahms Kryptor	
mU/mL=U/L		15.2	11.4	19.0	Roche Cobas 6000/8000	
mU/mL=U/L		14.6	11.0	18.3	Roche Cobas 4000/E411	
mU/mL=U/L		19.3	14.5	24.1	AutoDELFLIA (A/B097-101)	
mU/mL=U/L		29.4	22.1	36.8	DELFLIA Xpress (6002-0010 / 6002-001C)	
Inhibin A	ng/L = pg/ml	107	80.3	134	Beckman Dxl 600/800	
	ng/L = pg/ml	138	104	173	Brahms Kryptor	
	ng/L = pg/ml	108	81.0	135	Beckman Access/LXi725	
	ng/L = pg/ml	170	128	213	AutoDELFLIA (B064-102)	
PAPP-A	U/L=mIU/ml	1.52	1.14	1.90	Siemens Immulite 1000	
	ng/ml	6847	5135	8559		
	U/L=mIU/ml	1.64	1.23	2.05	Siemens Immulite 2000/2500	
	ng/ml	7387	5541	9233		
	U/L=mIU/ml	0.038	0.029	0.048	Beckman Dxl 600/800	
	ng/ml	171	131	211		
	U/L=mIU/ml	0.481	0.361	0.601	Brahms Kryptor	
	ng/ml	2167	1626	2708		
	U/L=mIU/ml	0.701	0.526	0.876	Roche Cobas 6000/8000	
	ng/ml	3158	2369	3947		

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot No. 7460MS Size: 3 x 1 ml Expiry: 2022-04-28

Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	0.704	0.528	0.880	Roche Cobas E411
	ng/ml	3171	2378	3964	
	U/L=mIU/ml	0.517	0.390	0.650	AutoDELFLIA (A/B098-201)
	ng/ml	2329	1757	2928	
	U/L=mIU/ml	0.481	0.360	0.600	DELFLIA Xpress (6003-0020 / 6003-002C /
	ng/ml	2167	1622	2703	6003-0050 / 6003-005C)
Total Beta hCG	mU/ml=IU/l	2583	2066	3100	Abbott Architect I2000/8200
	IU/ml	2.58	2.07	3.09	
	mU/ml=IU/l	576	461	691	Siemens Centaur XP/XPT/Classic
	IU/ml	0.576	0.461	0.691	
	mU/ml=IU/l	8529	6823	10235	Siemens Immulite 2000/2500
	IU/ml	8.53	6.82	10.2	
	mU/ml=IU/l	10299	8239	12359	Siemens Immulite 1000
	IU/ml	10.3	8.24	12.4	
	mU/ml=IU/l	3300	2640	3960	Beckman Dxl 600/800
	IU/ml	3.30	2.64	3.96	
	mU/ml=IU/l	3331	2665	3997	Beckman Access/LXi725
	IU/ml	3.33	2.67	3.99	
	mU/ml=IU/l	4395	3516	5274	Roche Cobas 6000/8000
	IU/ml	4.40	3.52	5.28	
	mU/ml=IU/l	3275	2620	3930	Beckman Access Total BhCG (5th IS)
	IU/ml	3.28	2.62	3.94	
	mU/ml=IU/l	3064	2451	3677	Beckman Dxl Total BhCG (5th IS)
	IU/ml	3.06	2.45	3.67	
mU/ml=IU/l	8284	6627	9941	Perkin Elmer DELFLIA / DELFLIA Xpress / AutoDELFLIA	
IU/ml	8.28	6.63	9.94		
Unconjugated Estriol	nmol/L	2.01	1.51	2.51	Siemens Immulite 2000/2500
	ng/mL	0.580	0.435	0.725	
	nmol/L	1.77	1.33	2.21	Siemens Immulite 1000
	ng/mL	0.510	0.384	0.636	
	nmol/L	2.29	1.72	2.86	Beckman Dxl 600/800
	ng/mL	0.660	0.496	0.824	
	nmol/L	1.10	0.825	1.38	Brahms Kryptor
	ng/mL	0.317	0.238	0.396	
	nmol/L	2.33	1.75	2.91	Beckman Access/LXi725
	ng/mL	0.672	0.505	0.839	
	nmol/L	5.97	4.48	7.46	AutoDELFLIA (B095-101/B095-101U)
	ng/mL	1.72	1.29	2.15	
nmol/L	4.83	3.62	6.04	DELFLIA Xpress (6005-0010 / 6005-001C)	
ng/mL	1.39	1.04	1.74		