

## IMPORTANT NOTICE

MSS5026

7462MS

The reconstituted stability for Maternal Control Level 3 lot 7462MS 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 3 (MATERNAL CONTROL 3)

**CAT. NO.** MSS5026                      **LOT NO.** 7462MS  
**SIZE:** 3 x 1ml                      **EXPIRY:** 2022-04-28  
**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 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](http://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 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](mailto:Technical.Services@randox.com).

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Cat. No. MSS5026 Lot No. 7462MS Size: 3 x 1 ml Expiry: 2022-04-28

Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	KIU/l = IU/ml	106	84.8	127	Siemens Immulite 1000
	ng/ml	128	103	153	
	KIU/l = IU/ml	104	83.2	125	Abbott Architect
	ng/ml	126	101	151	
	KIU/l = IU/ml	107	85.6	128	Siemens Immulite 2000/2500
	ng/ml	129	104	154	
	KIU/l = IU/ml	115	92.0	138	Siemens Centaur XP/XPT/Classic
	ng/ml	139	111	167	
	KIU/l = IU/ml	97.4	77.9	117	Beckman Dxl800
	ng/ml	118	94.3	142	
	KIU/l = IU/ml	88.4	70.7	106	Brahms Kryptor
	ng/ml	107	85.5	129	
	KIU/l = IU/ml	102	81.6	122	Beckman Access
	ng/ml	123	98.7	147	
Free Beta hCG	KIU/l = IU/ml	117	93.6	140	Roche Cobas 6000/8000
	ng/ml	142	113	171	
	KIU/l = IU/ml	110	88.0	132	Roche Cobas E411
	ng/ml	133	106	160	
	KIU/l = IU/ml	102	81.6	122	AutoDELFI A (A/B096-101)
	ng/ml	123	98.7	148	
	KIU/l = IU/ml	94.3	75.4	113	DELFI A Xpress (6001-0010 / 6001-001C)
	ng/ml	114	91.2	137	
	mU/mL=U/L	216	162	270	Siemens Immulite 2000/2500
	mU/mL=U/L	210	158	263	Siemens Immulite 1000
	mU/mL=U/L	172	129	215	Brahms Kryptor
	mU/mL=U/L	133	100	166	Roche Cobas 6000/8000
	mU/mL=U/L	141	106	176	Roche Cobas 4000/E411
	mU/mL=U/L	156	117	195	AutoDELFI A (A/B097-101)
mU/mL=U/L	>200	----	----	DELFI A Xpress (6002-0010 / 6002-001C)	
Inhibin A	ng/L = pg/ml	386	290	483	Beckman Dxl 600/800
	ng/L = pg/ml	402	302	503	Beckman Access/LXi725
	ng/L = pg/ml	625	469	781	AutoDELFI A (B064-102)
PAPP-A	U/L=mIU/ml	13.9	10.4	17.4	Siemens Immulite 1000
	ng/ml	62613	46847	78379	
	U/L=mIU/ml	14.6	11.0	18.3	Siemens Immulite 2000/2500
	ng/ml	65766	49550	81982	
	U/L=mIU/ml	0.328	0.246	0.410	Beckman Dxl 600/800
	ng/ml	1477	1108	1846	
	U/L=mIU/ml	3.94	2.96	4.93	Brahms Kryptor
	ng/ml	17748	13333	22163	
PAPP-A	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	Range		methods
			low	high	
PAPP-A	U/L=mIU/ml	5.80	4.35	7.25	Roche Cobas E411
	ng/ml	26126	19595	32657	
	U/L=mIU/ml	4.84	3.63	6.05	AutoDELFI A (A/B098-201)
	ng/ml	21802	16351	27253	
Total Beta hCG	U/L=mIU/ml	4.45	3.34	5.56	DELFI A Xpress (6003-0020 / 6003-002C /
	ng/ml	20045	15045	25045	6003-0050 / 6003-005C)
	mU/ml=IU/l	13674	10939	16409	Abbott Architect I2000/8200
	IU/ml	13.7	10.9	16.5	
	mU/ml=IU/l	18031	14425	21637	Siemens Centaur XP/XPT/Classic
	IU/ml	18.0	14.4	21.6	
	mU/ml=IU/l	68808	55046	82570	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	IU/ml	68.8	55.0	82.6	
	mU/ml=IU/l	54021	43217	64825	Siemens Immulite 2000/2500
	IU/ml	54.0	43.2	64.8	
	mU/ml=IU/l	74036	59229	88843	Siemens Immulite 1000
	IU/ml	74.0	59.2	88.8	
	mU/ml=IU/l	25326	20261	30391	Beckman Dxl 600/800
	IU/ml	25.3	20.3	30.3	
	mU/ml=IU/l	24437	19550	29324	Beckman Access/LXi725
	IU/ml	24.4	19.6	29.2	
mU/ml=IU/l	32642	26114	39170	Roche Cobas 6000/8000	
IU/ml	32.6	26.1	39.1		
mU/ml=IU/l	24471	19577	29365	Beckman Access Total BhCG (5th IS)	
IU/ml	24.5	19.6	29.4		
mU/ml=IU/l	25328	20262	30394	Beckman Dxl Total BhCG (5th IS)	
IU/ml	25.3	20.3	30.3		
Unconjugated Estriol	nmol/L	16.9	12.7	21.1	Siemens Immulite 2000/2500
	ng/mL	4.87	3.66	6.08	
	nmol/L	17.9	13.4	22.4	Siemens Immulite 1000
	ng/mL	5.16	3.86	6.46	
	nmol/L	16.7	12.5	20.9	Beckman Dxl 600/800
	ng/mL	4.82	3.61	6.03	
	nmol/L	11.3	8.48	14.1	Brahms Kryptor
	ng/mL	3.26	2.45	4.07	
	nmol/L	16.7	12.5	20.9	Beckman Access/LXi725
	ng/mL	4.82	3.61	6.03	
nmol/L	>50.0	-----	-----	AutoDELFI A (B095-101/B095-101U)	
ng/mL	>14.4	-----	-----		
nmol/L	41.2	30.9	51.5	DELFI A Xpress (6005-0010 / 6005-001C)	
ng/mL	11.9	8.91	14.9		