

MATERNAL CONTROL - LEVEL I (MATERNAL CONTROL I)

CAT. NO. MSS5024 **LOT NO.** 8152MS
SIZE 3 x 1 ml **EXPIRY:** 2024-11-28
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. 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

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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
----	-----

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

Rev. 07 Feb '22 me

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot. No. 8152MS Size 3 x 1ml Expiry 2024-11-28

Analyte	unit	Target	Range		methods	
			low	high		
Alphafoetoprotein	KIU/l = IU/ml	12.1	9.68	14.5	Siemens Immulite 1000	
	ng/ml	14.6	11.7	17.5		
	KIU/l = IU/ml	12.7	10.2	15.2	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	15.4	12.3	18.5		
	KIU/l = IU/ml	11.7	9.36	14.0	Abbott Architect	
	ng/ml	14.2	11.3	17.1		
	KIU/l = IU/ml	11.7	9.36	14.0	Siemens Immulite 2000/2500	
	ng/ml	14.2	11.3	17.1		
	KIU/l = IU/ml	14.1	11.3	16.9	Siemens Centaur XP/XPT/Classic	
	ng/ml	17.1	13.7	20.5		
	KIU/l = IU/ml	11.8	9.44	14.2	Beckman Dxl800	
	ng/ml	14.3	11.4	17.2		
	KIU/l = IU/ml	11.9	9.52	14.3	Brahms Kryptor	
	ng/ml	14.4	11.5	17.3		
Free Beta hCG	KIU/l = IU/ml	12.1	9.68	14.5	Beckman Access	
	ng/ml	14.6	11.7	17.5		
	KIU/l = IU/ml	13.1	10.5	15.7	Roche Cobas e601/602	
	ng/ml	15.9	12.7	19.1		
	KIU/l = IU/ml	12.8	10.2	15.4	Roche Cobas 4000/E411	
	ng/ml	15.5	12.3	18.7		
	KIU/l = IU/ml	12.5	10.0	15.0	Roche Cobas e402/e801	
	ng/ml	15.1	12.1	18.1		
	KIU/l = IU/ml	14.4	11.5	17.3	Siemens Atellica IM	
	ng/ml	17.4	13.9	20.9		
	Free Beta hCG	mU/mL=U/L	18.0	13.5	22.5	Siemens Centaur XP/XPT/Classic
		mU/mL=U/L	15.1	11.3	18.9	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
		mU/mL=U/L	17.5	13.1	21.9	Siemens Immulite 2000/2500
		mU/mL=U/L	17.9	13.4	22.4	Siemens Immulite 1000
mU/mL=U/L		15.0	11.3	18.8	Brahms Kryptor	
mU/mL=U/L		14.0	10.5	17.5	Roche Cobas e601/602	
mU/mL=U/L		14.1	10.6	17.6	Roche Cobas 4000/E411	
mU/mL=U/L		13.7	10.3	17.1	Roche Cobas e402/e801	
Inhibin A	ng/L = pg/ml	166	125	208	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/L = pg/ml	92.9	69.7	116	Beckman Dxl 600/800	
	ng/L = pg/ml	129	96.8	161	Brahms Kryptor	
	ng/L = pg/ml	92.0	69.0	115	Beckman Access	
PAPP-A	U/L=mIU/ml	0.606	0.455	0.758	Siemens Centaur XP/XPT/Classic	
	ng/ml	2730	2050	3410		
	U/L=mIU/ml	0.436	0.327	0.545	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia	
	ng/ml	1964	1473	2455		
PAPP-A	U/L=mIU/ml	1.58	1.19	1.98	Siemens Immulite 1000	
	ng/ml	7117	5360	8874		

MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)

Cat. No. MSS5024 Lot. No. 8152MS Size 3 x 1ml Expiry 2024-11-28

Analyte	unit	Target	Range		methods
			low	high	
PAPP-A	U/L=mlU/ml	1.62	1.22	2.03	Siemens Immulite 2000/2500
	ng/ml	7297	5495	9099	
	U/L=mlU/ml	0.040	0.030	0.050	Beckman Dxl 600/800
	ng/ml	180	135	225	
	U/L=mlU/ml	0.408	0.306	0.510	Brahms Kryptor
	ng/ml	1838	1378	2298	
	U/L=mlU/ml	0.041	0.031	0.051	Beckman Access
	ng/ml	185	140	230	
U/L=mlU/ml	0.690	0.518	0.863	Roche Cobas e601/602	
ng/ml	3108	2333	3883		
	U/L=mlU/ml	0.682	0.512	0.853	Roche Cobas 4000/E411
	ng/ml	3072	2306	3838	
	U/L=mlU/ml	0.653	0.490	0.816	Roche Cobas e402/e801
	ng/ml	2941	2207	3675	
Total Beta hCG	mU/ml=IU/l	3594	2875	4313	Abbott Architect / Alinity
	IU/ml	3.59	2.88	4.30	
	mU/ml=IU/l	3934	3147	4721	Siemens Centaur XP/XPT/Classic
	IU/ml	3.93	3.15	4.71	
	mU/ml=IU/l	7631	6105	9157	Siemens Immulite 2000/2500
	IU/ml	7.63	6.11	9.15	
	mU/ml=IU/l	8225	6580	9870	Siemens Immulite 1000
	IU/ml	8.23	6.58	9.88	
	mU/ml=IU/l	5117	4094	6140	Beckman Dxl 600/800
	IU/ml	5.12	4.09	6.15	
	mU/ml=IU/l	5035	4028	6042	Beckman Access
	IU/ml	5.04	4.03	6.05	
	mU/ml=IU/l	4407	3526	5288	Roche Cobas 6000/8000
	IU/ml	4.41	3.53	5.29	
mU/ml=IU/l	4997	3998	5996	Beckman Access Total BhCG (5th IS)	
IU/ml	5.00	4.00	6.00		
mU/ml=IU/l	4775	3820	5730	Beckman Dxl Total BhCG (5th IS)	
IU/ml	4.78	3.82	5.74		
mU/ml=IU/l	4449	3559	5339	Roche hCG+Beta e801	
IU/ml	4.45	3.56	5.34		
Unconjugated Estriol	nmol/L	5.33	4.00	6.66	Perkin Elmer Delfia/Delfia Xpress/AutoDelfia
	ng/mL	1.54	1.15	1.93	
	nmol/L	2.16	1.62	2.70	Siemens Immulite 2000/2500
	ng/mL	0.623	0.467	0.779	
	nmol/L	2.00	1.50	2.50	Siemens Immulite 1000
	ng/mL	0.577	0.433	0.721	
	nmol/L	2.21	1.66	2.76	Beckman Dxl 600/800
	ng/mL	0.637	0.479	0.795	
	nmol/L	0.529	0.397	0.661	Brahms Kryptor
	ng/mL	0.153	0.114	0.192	
nmol/L	2.26	1.70	2.83	Beckman Access	
ng/mL	0.652	0.490	0.814		