

PRODUCT INFORMATION

Cat. No. IA3109/IA3112

2651EC

Please note that the concentration of CA125 is higher in this lot than previous lots.

If you have any queries, please contact Technical Services at

technical.services@randox.com.

CCS INC2172

IMMUNOASSAY PREMIUM PLUS - LEVEL I (IA PREMIUM PLUS I)

CAT. NO. IA3109	GTIN: 05055273207255	SIZE: 12 x 5 ml
CAT. NO. IA3112	GTIN: 05055273207286	SIZE: 4 x 5 ml
LOT NO. 2651EC	EXPIRY: 2028-08-28	

INTENDED USE

This product is intended for in vitro diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and 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 infectious diseases and disposed of accordingly.

The Abbott Architect CA19-9 assay utilises an antibody/antigen system based on the 1116-NA-19-9 antibody. There are reports that the formulation employed with this system may return elevated concentrations, when compared to other methods for samples expressing high levels of 1116-NA-19-9 reactive determinants.

Health and Safety Data Sheets are available on request.

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, or 4 weeks frozen once at -20°C. C-Peptide is stable for 1 day at +2°C to +8°C. Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

ACTH should be tested immediately after the 30-minute reconstitution period. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide. 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

Immunoassay Premium Plus is supplied lyophilized.

- Carefully reconstitute each vial of lyophilised serum with exactly 5 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Premium Plus - Level I: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

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. 09 Dec '25 me

Table of Content

Method

2

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
17-OH-Progesterone	ng/ml	1.23	0.923	1.54	0.155	0.310	DIAsource, ELISA
	nmol/l	3.72	2.79	4.65	0.465	0.930	
25-OH-Vitamin D	ng/ml	16.1	12.1	20.1	2.00	4.00	Abbott Alinity i
	nmol/l	40.1	30.1	50.1	5.00	10.0	
	ng/ml	16.5	12.4	20.6	2.05	4.10	Abbott Architect (3L52)
	nmol/l	41.3	31.0	51.6	5.15	10.3	
	ng/ml	16.1	12.1	20.1	2.00	4.00	Abbott Architect (5P02)
	nmol/l	40.3	30.2	50.4	5.05	10.1	
	ng/ml	36.5	27.4	45.6	4.55	9.10	Beckman Dxl 600/800
	nmol/l	91.2	68.4	114	11.4	22.8	
	ng/ml	20.0	15.0	25.0	2.50	5.00	bioMerieux Vidas/mini Vidas/Vidas 3
	nmol/l	50.0	37.5	62.5	6.25	12.5	
	ng/ml	69.7	52.3	87.1	8.70	17.4	Ortho Vitros 3600/5600/ECi/XT 7600
	nmol/l	174	131	217	21.5	43.0	
ng/ml	11.7	8.78	14.6	1.45	2.90	Roche Vitamin D total III	
nmol/l	29.3	22.0	36.6	3.65	7.30		
ng/ml	12.6	9.45	15.8	1.60	3.20	Roche Vitamin D Total III e402/e801	
nmol/l	31.4	23.6	39.2	3.90	7.80		
ACTH	pg/ml	8.91	6.68	11.1	1.10	2.19	Roche Cobas 4000/e411
	pmol/l	1.96	1.47	2.45	0.245	0.490	
	pg/ml	9.86	7.40	12.3	1.22	2.44	Roche Cobas e402/e801
	pmol/l	2.17	1.63	2.71	0.270	0.540	
	pg/ml	5.45	4.09	6.81	0.680	1.36	Siemens/DPC Immulite 2000/2500
	pmol/l	1.20	0.900	1.50	0.150	0.300	
Alpha-fetoprotein	ng/ml	9.56	7.65	11.5	0.970	1.94	3HB-GGG Start
	KIU/l = IU/ml	7.90	6.32	9.48	0.790	1.58	
	ng/ml	9.63	7.70	11.6	0.985	1.97	Abbott Alinity i
	KIU/l = IU/ml	7.96	6.37	9.55	0.795	1.59	
	ng/ml	11.0	8.80	13.2	1.10	2.20	Ortho Vitros 3600/5600/ECi/XT 7600
	KIU/l = IU/ml	9.07	7.26	10.9	0.915	1.83	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Alpha-fetoprotein	ng/ml	10.6	8.48	12.7	1.05	2.10	Roche Cobas 4000/e411
	KIU/l = IU/ml	8.75	7.00	10.5	0.875	1.75	
	ng/ml	11.2	8.96	13.4	1.10	2.20	Roche Cobas e402/e801
	KIU/l = IU/ml	9.28	7.42	11.1	0.910	1.82	
Alpha-fetoprotein	ng/ml	10.3	8.24	12.4	1.05	2.10	Roche Cobas e601/ 602
	KIU/l = IU/ml	8.48	6.78	10.2	0.860	1.72	
Alpha-fetoprotein	ng/ml	11.4	9.12	13.7	1.15	2.30	Siemens Atellica IM
	KIU/l = IU/ml	9.45	7.56	11.3	0.925	1.85	
Androstenedione	ng/ml	0.904	0.678	1.13	0.113	0.226	Roche Elecsys
	nmol/l	3.15	2.36	3.94	0.395	0.790	
	ng/ml	1.20	0.900	1.50	0.150	0.300	Siemens/DPC Immulite 2000
Androstenedione	nmol/l	4.17	3.13	5.21	0.520	1.04	
	ng/ml	1.20	0.900	1.50	0.150	0.300	Siemens/DPC Immulite 2000
Beta-2-Microglobulin	µg/ml = mg/l	0.697	0.558	0.836	0.070	0.139	Roche Cobas 6000/8000
	µg/ml = mg/l	0.727	0.582	0.872	0.073	0.145	Siemens/DPC Immulite 2000/2500
C-Peptide	ng/ml	1.25	0.938	1.56	0.155	0.310	Roche Cobas e402/e801
	nmol/l	0.414	0.311	0.517	0.052	0.103	
CA 125	U/ml	219	175	263	22.0	44.0	Abbott Alinity
	U/ml	221	177	265	22.0	44.0	Abbott Architect
	U/ml	140	112	168	14.0	28.0	Ortho Vitros 3600/5600/ECi/XT 7600
	U/ml	136	109	163	13.5	27.0	Roche Cobas 4000/e411
	U/ml	130	104	156	13.0	26.0	Roche Cobas e402/e801
	U/ml	135	108	162	13.5	27.0	Roche Cobas e601/ 602
	U/ml	190	152	228	19.0	38.0	Siemens Atellica IM
CA 15-3	U/ml	21.3	17.0	25.6	2.15	4.30	Abbott Alinity i
	U/ml	21.2	17.0	25.4	2.10	4.20	Abbott Architect
	U/ml	19.6	15.7	23.5	1.95	3.90	Roche Cobas 4000/e411
	U/ml	18.9	15.1	22.7	1.90	3.80	Roche Cobas e402/e801
	U/ml	19.1	15.3	22.9	1.90	3.80	Roche Cobas e601/ 602
	U/ml	17.9	14.3	21.5	1.80	3.60	Siemens Atellica IM

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
CA 19-9	U/ml	51.3	41.0	61.6	5.15	10.3	Abbott Alinity XR
	U/ml	49.1	39.3	58.9	4.90	9.80	Abbott Architect XR
	U/ml	19.3	15.4	23.2	1.95	3.90	bioMerieux, VIDAS
	U/ml	33.8	27.0	40.6	3.40	6.80	Ortho Vitros 3600/5600/ECi/XT 7600
	U/ml	23.4	18.7	28.1	2.35	4.70	Roche Cobas 4000/e411
	U/ml	25.6	20.5	30.7	2.55	5.10	Roche Cobas e402/e801
	U/ml	23.0	18.4	27.6	2.30	4.60	Roche Cobas e601/ 602
	U/ml	35.0	28.0	42.0	3.50	7.00	Siemens Atellica IM
Carbamazepine	µg/ml	3.71	2.97	4.45	0.370	0.740	Abbott Architect (CMIA)
	µmol/l	15.7	12.6	18.8	1.55	3.10	
	µg/ml	3.40	2.72	4.08	0.340	0.680	Roche Cobas 6000/8000
	µmol/l	14.4	11.5	17.3	1.45	2.90	
CEA	ng/ml = µg/l	4.95	3.96	5.94	0.495	0.990	Abbott Alinity i
	ng/ml = µg/l	4.89	3.91	5.87	0.490	0.980	Abbott Architect
	ng/ml = µg/l	4.25	3.40	5.10	0.425	0.850	Ortho Vitros 3600/5600/ECi/XT 7600
	ng/ml = µg/l	4.61	3.69	5.53	0.460	0.920	Roche Cobas 4000/e411
	ng/ml = µg/l	4.26	3.41	5.11	0.425	0.850	Roche Cobas e402/e801
	ng/ml = µg/l	4.27	3.42	5.12	0.425	0.850	Roche Cobas e601/ 602
	ng/ml = µg/l	5.05	4.04	6.06	0.505	1.01	Siemens Atellica IM
Cortisol	nmol/l	192	144	240	24.0	48.0	Abbott Alinity i
	µg/dl	6.91	5.18	8.64	0.865	1.73	
	nmol/l	197	148	246	24.5	49.0	Abbott Architect
	µg/dl	7.09	5.32	8.86	0.885	1.77	
	nmol/l	201	151	251	25.0	50.0	Beckman Dxl 600/800
	µg/dl	7.24	5.43	9.05	0.905	1.81	
	nmol/l	151	113	189	19.0	38.0	Ortho Vitros 3600/5600/ECi/XT 7600
	µg/dl	5.44	4.08	6.80	0.680	1.36	
	nmol/l	186	140	232	23.0	46.0	Roche Cobas 4000/e411 Gen II
	µg/dl	6.70	5.03	8.37	0.835	1.67	
nmol/l	169	127	211	21.0	42.0	Roche Cobas e402/e801	
µg/dl	6.08	4.56	7.60	0.760	1.52		

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Cortisol	nmol/l	171	128	214	21.5	43.0	Roche Cobas e402/e801 Gen II
	µg/dl	6.16	4.62	7.70	0.770	1.54	
	nmol/l	174	131	217	21.5	43.0	Roche Cobas e601/ 602
	µg/dl	6.26	4.70	7.82	0.780	1.56	
	nmol/l	175	131	219	22.0	44.0	Roche Cobas e601/602 Gen II
	µg/dl	6.30	4.73	7.87	0.785	1.57	
DHEA-S	nmol/l	181	136	226	22.5	45.0	Siemens Atellica IM
	µg/dl	6.52	4.89	8.15	0.815	1.63	
	nmol/l	186	140	232	23.0	46.0	Siemens/DPC Immulite 2000/2500
	µg/dl	6.70	5.03	8.37	0.835	1.67	
	µmol/l	2.84	2.27	3.41	0.285	0.570	Abbott Alinity i
	µmol/l	2.76	2.21	3.31	0.275	0.550	Abbott Architect
Digoxin	µmol/l	3.30	2.64	3.96	0.330	0.660	Roche Cobas e402/e801
	µmol/l	3.53	2.82	4.24	0.355	0.710	Roche Cobas e601/ 602
	µmol/l	2.37	1.90	2.84	0.235	0.470	Siemens/DPC Immulite 2000/2500
	ng/ml	0.640	0.512	0.768	0.064	0.128	Roche Cobas e402/e801
	nmol/l	0.820	0.656	0.984	0.082	0.164	
Ferritin	ng/ml = µg/l	34.4	27.5	41.3	3.45	6.90	Abbott Architect Chemilum
	ng/ml = µg/l	18.2	14.6	21.8	1.80	3.60	Beckman Dxl 600/800
	ng/ml = µg/l	22.4	17.9	26.9	2.25	4.50	bioMerieux, VIDAS
	ng/ml = µg/l	18.9	15.1	22.7	1.90	3.80	Ortho Vitros 3600/5600/ECi/XT/7600
	ng/ml = µg/l	28.2	22.6	33.8	2.80	5.60	Roche Cobas C303/501/502/503/701/702
	ng/ml = µg/l	30.5	24.4	36.6	3.05	6.10	Roche Cobas e402/e801
	ng/ml = µg/l	32.7	26.2	39.2	3.25	6.50	Roche Elecsys / Cobas e411
	ng/ml = µg/l	31.8	25.4	38.2	3.20	6.40	Roche Modular E170 /Cobas e601/602
	ng/ml = µg/l	20.5	16.4	24.6	2.05	4.10	Siemens Atellica IM
Folate	ng/ml	3.59	2.73	4.45	0.430	0.860	Abbott Alinity i
	nmol/l	8.15	6.19	10.1	0.975	1.95	
	ng/ml	3.56	2.71	4.41	0.425	0.850	Abbott Architect
	nmol/l	8.07	6.13	10.0	0.965	1.93	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)						
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28								
Size: 12 x 5 ml / 4 x 5 ml		Range						
Analyte	Unit	Target	Low	High	1SD	2SD	Method	
Folate	ng/ml	3.61	2.74	4.48	0.435	0.870	Beckman Dxl 600/800 - A98032	
	nmol/l	8.18	6.22	10.1	0.960	1.92		
	ng/ml	2.74	2.08	3.40	0.330	0.660	Ortho Vitros 3600/5600/ECi/XT/7600	
	nmol/l	6.22	4.73	7.71	0.745	1.49		
	ng/ml	2.94	2.23	3.65	0.355	0.710	Roche e402/e801	
	nmol/l	6.66	5.06	8.26	0.800	1.60		
	ng/ml	8.95	6.80	11.1	1.08	2.15	Siemens Atellica IM	
	nmol/l	20.3	15.4	25.2	2.45	4.90		
	ng/ml	2.78	2.11	3.45	0.335	0.670	Siemens/DPC Immulite 2000	
	nmol/l	6.30	4.79	7.81	0.755	1.51		
	Free T3	ng/dl	0.538	0.404	0.672	0.067	0.134	Abbott Alinity, 2 point cal
		pg/ml	5.38	4.04	6.72	0.670	1.34	
pmol/l		8.27	6.20	10.3	1.02	2.03		
ng/dl		0.518	0.389	0.647	0.065	0.129	Abbott Alinity, 6 point cal	
pg/ml		5.19	3.89	6.49	0.650	1.30		
pmol/l		7.97	5.98	9.96	0.995	1.99		
ng/dl		0.530	0.398	0.662	0.066	0.132	Abbott Architect, 2 point cal	
pg/ml		5.31	3.98	6.64	0.665	1.33		
pmol/l		8.16	6.12	10.2	1.02	2.04		
ng/dl		0.493	0.370	0.616	0.062	0.123	Abbott Architect, 6 point cal	
pg/ml		4.93	3.70	6.16	0.615	1.23		
pmol/l		7.58	5.69	9.47	0.945	1.89		
ng/dl		0.499	0.374	0.624	0.063	0.125	Beckman Dxl 600/800	
pg/ml		4.99	3.74	6.24	0.625	1.25		
pmol/l		7.67	5.75	9.59	0.960	1.92		
ng/dl		1.31	0.983	1.64	0.165	0.330	Ortho Vitros 3600/5600/ECi/XT 7600	
pg/ml		13.2	9.90	16.5	1.65	3.30		
pmol/l		20.2	15.2	25.2	2.50	5.00		
ng/dl		0.619	0.464	0.774	0.078	0.155	Roche Cobas 4000/e411	
pg/ml		6.20	4.65	7.75	0.775	1.55		
pmol/l		9.53	7.15	11.9	1.19	2.37		
ng/dl		0.609	0.457	0.761	0.076	0.152	Roche Cobas e402/e801	
pg/ml		6.10	4.58	7.62	0.760	1.52		
pmol/l		9.37	7.03	11.7	1.17	2.33		
ng/dl	0.618	0.464	0.772	0.077	0.154	Roche Cobas e601/ 602		
pg/ml	6.19	4.64	7.74	0.775	1.55			
pmol/l	9.51	7.13	11.9	1.20	2.39			

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Free T3	ng/dl	0.715	0.536	0.894	0.090	0.179	Siemens Atellica IM
	pg/ml	7.16	5.37	8.95	0.895	1.79	
	pmol/l	11.0	8.25	13.8	1.40	2.80	
Free T4	ng/dl	0.967	0.725	1.21	0.122	0.243	Abbott Alinity i
	pg/ml	9.67	7.25	12.1	1.22	2.43	
	pmol/l	12.4	9.30	15.5	1.55	3.10	
	ng/dl	0.967	0.725	1.21	0.122	0.243	Abbott Architect
	pg/ml	9.67	7.25	12.1	1.22	2.43	
	pmol/l	12.4	9.30	15.5	1.55	3.10	
	ng/dl	1.05	0.788	1.31	0.130	0.260	Beckman Access/LXi725
	pg/ml	10.5	7.88	13.1	1.30	2.60	
	pmol/l	13.5	10.1	16.9	1.70	3.40	
	ng/dl	0.991	0.743	1.24	0.125	0.249	Beckman Dxl 600/800
	pg/ml	9.91	7.43	12.4	1.25	2.49	
	pmol/l	12.7	9.53	15.9	1.60	3.20	
	ng/dl	2.35	1.76	2.94	0.295	0.590	Ortho Vitros 3600/5600/ECi/XT/7600
	pg/ml	23.5	17.6	29.4	2.95	5.90	
	pmol/l	30.1	22.6	37.6	3.75	7.50	
	ng/dl	1.29	0.968	1.61	0.160	0.320	Roche Cobas 4000/e411
	pg/ml	12.9	9.68	16.1	1.60	3.20	
	pmol/l	16.5	12.4	20.6	2.05	4.10	
	ng/dl	1.30	0.975	1.63	0.165	0.330	Roche Cobas e402/e801
	pg/ml	13.0	9.75	16.3	1.65	3.30	
	pmol/l	16.7	12.5	20.9	2.10	4.20	
	ng/dl	1.29	0.968	1.61	0.160	0.320	Roche Cobas e601/ 602
	pg/ml	12.9	9.68	16.1	1.60	3.20	
	pmol/l	16.6	12.5	20.7	2.05	4.10	
ng/dl	0.991	0.743	1.24	0.125	0.249	Siemens Atellica IM	
pg/ml	9.91	7.43	12.4	1.25	2.49		
pmol/l	12.7	9.53	15.9	1.60	3.20		
ng/dl	0.936	0.702	1.17	0.117	0.234	Siemens Centaur	
pg/ml	9.36	7.02	11.7	1.17	2.34		
pmol/l	12.0	9.00	15.0	1.50	3.00		
FSH	mU/ml	5.38	4.30	6.46	0.540	1.08	Abbott Alinity i
	mU/ml	5.22	4.18	6.26	0.520	1.04	Abbott Architect
	mU/ml	5.77	4.62	6.92	0.575	1.15	Beckman Dxl 600/800
	mU/ml	7.13	5.70	8.56	0.715	1.43	bioMerieux, VIDAS
	mU/ml	6.27	5.02	7.52	0.625	1.25	Roche Cobas 4000/e411
	mU/ml	5.78	4.62	6.94	0.580	1.16	Roche Cobas e402/e801

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
FSH	mU/ml	5.82	4.66	6.98	0.580	1.16	Roche Cobas e601/602
	mU/ml	6.25	5.00	7.50	0.625	1.25	Siemens Atellica IM
	mU/ml	6.01	4.81	7.21	0.600	1.20	Siemens/DPC Immulite 2000/2500
Growth Hormone (GH)	ng/ml	1.46	1.17	1.75	0.145	0.290	DiaSorin Liaison XL
	µU/ml	4.38	3.50	5.26	0.440	0.880	
	ng/ml	1.70	1.36	2.04	0.170	0.340	Roche Cobas e402/e801
	µU/ml	5.11	4.09	6.13	0.510	1.02	
	ng/ml	1.97	1.58	2.36	0.195	0.390	Siemens/DPC Immulite 2000/2500
	µU/ml	5.91	4.73	7.09	0.590	1.18	
Immunoglobulin E	KIU/l = IU/ml	242	194	290	24.0	48.0	Abbott Architect
	KIU/l = IU/ml	201	161	241	20.0	40.0	bioMerieux, VIDAS
	KIU/l = IU/ml	256	205	307	25.5	51.0	Roche Cobas 4000/e411
	KIU/l = IU/ml	237	190	284	23.5	47.0	Roche Cobas e402/e801
	KIU/l = IU/ml	234	187	281	23.5	47.0	Roche Cobas e601/ 602
	KIU/l = IU/ml	241	193	289	24.0	48.0	Siemens Atellica IM
Insulin	mU/l	1.67	1.25	2.09	0.210	0.420	Abbott Alinity i
	µU/ml	1.67	1.25	2.09	0.210	0.420	
	mU/l	1.60	1.20	2.00	0.200	0.400	Abbott Architect
	µU/ml	1.60	1.20	2.00	0.200	0.400	
	mU/l	1.86	1.40	2.32	0.230	0.460	Roche Cobas 4000/e411
	µU/ml	1.86	1.40	2.32	0.230	0.460	
	mU/l	1.75	1.31	2.19	0.220	0.440	Roche Cobas 6000/8000
	µU/ml	1.75	1.31	2.19	0.220	0.440	
	mU/l	1.99	1.49	2.49	0.250	0.500	Siemens Atellica IM
	µU/ml	1.99	1.49	2.49	0.250	0.500	
	mU/l	13.8	10.4	17.2	1.70	3.40	Siemens/DPC Immulite 2000
	µU/ml	13.8	10.4	17.2	1.70	3.40	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Luteinising Hormone (LH)	mU/ml	2.09	1.67	2.51	0.210	0.420	Abbott Alinity i
	mU/ml	2.10	1.68	2.52	0.210	0.420	Abbott Architect
	mU/ml	2.47	1.98	2.96	0.245	0.490	Beckman Dxl 600/800
	mU/ml	2.85	2.28	3.42	0.285	0.570	bioMerieux, VIDAS
	mU/ml	3.51	2.81	4.21	0.350	0.700	Roche Cobas 4000/e411
	mU/ml	3.72	2.98	4.46	0.370	0.740	Roche Cobas e402/e801
	mU/ml	3.77	3.02	4.52	0.375	0.750	Roche Cobas e601/ 602
	mU/ml	2.63	2.10	3.16	0.265	0.530	Siemens Atellica IM
Oestradiol	pg/ml	33.5	26.8	40.2	3.35	6.70	Abbott Alinity i
	pmol/l	123	98.4	148	12.5	25.0	
	pg/ml	31.8	25.4	38.2	3.20	6.40	Abbott Architect
	pmol/l	117	93.6	140	11.5	23.0	
	pg/ml	35.1	28.1	42.1	3.50	7.00	Roche Cobas 4000/e411 (Estradiol III)
	pmol/l	129	103	155	13.0	26.0	
	pg/ml	39.4	31.5	47.3	3.95	7.90	Roche Cobas e402/e801 (Estradiol III)
	pmol/l	145	116	174	14.5	29.0	
Phenobarbital	pg/ml	42.2	33.8	50.6	4.20	8.40	Roche Cobas e601/ 602 (Estradiol III)
	pmol/l	155	124	186	15.5	31.0	
	pg/ml	39.7	31.8	47.6	3.95	7.90	Siemens Atellica IM
	pmol/l	146	117	175	14.5	29.0	
Phenytoin	µg/ml	7.98	6.38	9.58	0.800	1.60	Beckman AU Instruments
	µmol/l	34.4	27.5	41.3	3.45	6.90	
	µg/ml	7.77	6.22	9.32	0.775	1.55	Roche Cobas C303/501/502/503/701
	µmol/l	33.5	26.8	40.2	3.35	6.70	
Progesterone	µg/ml	8.21	6.57	9.85	0.820	1.64	Siemens/DPC Immulite 2000/2500
	µmol/l	35.4	28.3	42.5	3.55	7.10	
	µg/ml	4.57	3.66	5.48	0.455	0.910	Roche Cobas 6000/8000
	µmol/l	18.1	14.5	21.7	1.80	3.60	
Progesterone	ng/ml	0.745	0.596	0.894	0.075	0.149	Abbott Alinity i
	nmol/l	2.38	1.90	2.86	0.240	0.480	
	ng/ml	0.898	0.718	1.08	0.091	0.182	Abbott Architect
	nmol/l	2.87	2.30	3.44	0.285	0.570	
	ng/ml	0.920	0.736	1.10	0.090	0.180	Roche Cobas 4000/e411 (Prog. III)
	nmol/l	2.94	2.35	3.53	0.295	0.590	
	ng/ml	0.964	0.771	1.16	0.098	0.196	Roche Cobas e402/e801 (Prog III)
	nmol/l	3.08	2.46	3.70	0.310	0.620	
Progesterone	ng/ml	0.958	0.766	1.15	0.096	0.192	Roche Cobas e601/ 602 (Prog. III)
	nmol/l	3.06	2.45	3.67	0.305	0.610	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Progesterone	ng/ml	0.754	0.603	0.905	0.076	0.151	Siemens Atellica IM
	nmol/l	2.41	1.93	2.89	0.240	0.480	
	ng/ml	0.923	0.738	1.11	0.094	0.187	Siemens/DPC Immulite 2000/2500
	nmol/l	2.95	2.36	3.54	0.295	0.590	
Prolactin	µIU/mL	148	118	178	15.0	30.0	Abbott Alinity i
	µIU/mL	148	118	178	15.0	30.0	Abbott Architect
	µIU/mL	127	102	152	12.5	25.0	Beckman Dxl 600/800
	µIU/mL	149	119	179	15.0	30.0	bioMerieux, VIDAS
	µIU/mL	147	118	176	14.5	29.0	Roche Cobas 4000/e411
	µIU/mL	141	113	169	14.0	28.0	Roche Cobas e402/e801 PRL II
	µIU/mL	147	118	176	14.5	29.0	Roche Cobas e601/ 602
	µIU/mL	113	90.4	136	11.5	23.0	Siemens Atellica IM
PSA Free	ng/ml = µg/l	1.73	1.30	2.16	0.215	0.430	Abbott Alinity i
	ng/ml = µg/l	1.63	1.22	2.04	0.205	0.410	Abbott Architect
	ng/ml = µg/l	1.39	1.04	1.74	0.175	0.350	Roche Cobas 4000/e411
	ng/ml = µg/l	1.30	0.975	1.63	0.165	0.330	Roche Cobas e402/e801
	ng/ml = µg/l	1.34	1.01	1.67	0.165	0.330	Roche Cobas e601/602
	ng/ml = µg/l	1.65	1.24	2.06	0.205	0.410	Siemens Atellica IM
	ng/ml = µg/l	1.43	1.07	1.79	0.180	0.360	Abbott Alinity i
PSA Total	ng/ml = µg/l	1.43	1.07	1.79	0.180	0.360	Abbott Alinity i
	ng/ml = µg/l	1.37	1.03	1.71	0.170	0.340	Abbott Architect
	ng/ml = µg/l	2.21	1.66	2.76	0.275	0.550	Beckman Access standardised to Hybritech
	ng/ml = µg/l	1.72	1.29	2.15	0.215	0.430	Beckman DXI standard to WHO IRP96/670
	ng/ml = µg/l	1.77	1.33	2.21	0.220	0.440	Ortho Vitros 3600/5600/ECi PSA II/XT7600
	ng/ml = µg/l	1.80	1.35	2.25	0.225	0.450	Roche Cobas 4000/e411
	ng/ml = µg/l	1.76	1.32	2.20	0.220	0.440	Roche Cobas e402/e801
	ng/ml = µg/l	1.76	1.32	2.20	0.220	0.440	Roche Cobas e402/e801

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
PSA Total	ng/ml = µg/l	1.81	1.36	2.26	0.225	0.450	Roche Cobas e601/602
	ng/ml = µg/l	1.79	1.34	2.24	0.225	0.450	Siemens Atellica IM
	ng/ml = µg/l	1.76	1.32	2.20	0.220	0.440	Siemens Centaur
SHBG	nmol/l	5.61	4.49	6.73	0.560	1.12	Abbott Alinity i
	nmol/l	5.28	4.22	6.34	0.530	1.06	Abbott Architect
	nmol/l	6.06	4.85	7.27	0.605	1.21	Roche analysers
	nmol/l	5.94	4.75	7.13	0.595	1.19	Roche e402/e801
	nmol/l	5.23	4.18	6.28	0.525	1.05	Siemens Atellica IM
	nmol/l	4.99	3.99	5.99	0.500	1.00	Siemens/DPC Immulite 2000/2500
Testosterone	ng/dl	43.5	34.8	52.2	4.35	8.70	Abbott Alinity i
	ng/ml	0.435	0.348	0.522	0.044	0.087	
	nmol/l	1.51	1.21	1.81	0.150	0.300	
	ng/dl	45.8	36.6	55.0	4.60	9.20	Abbott Architect
	ng/ml	0.458	0.366	0.550	0.046	0.092	
	nmol/l	1.59	1.27	1.91	0.160	0.320	
	ng/dl	45.5	36.4	54.6	4.55	9.10	Abbott Architect 2nd gen
	ng/ml	0.455	0.364	0.546	0.046	0.091	
	nmol/l	1.58	1.26	1.90	0.160	0.320	
	ng/dl	44.1	35.3	52.9	4.40	8.80	Beckman Dxl 600/800
	ng/ml	0.441	0.353	0.529	0.044	0.088	
	nmol/l	1.53	1.22	1.84	0.155	0.310	
	ng/dl	48.7	39.0	58.4	4.85	9.70	Roche Cobas 4000/e411 Test II
	ng/ml	0.487	0.390	0.584	0.049	0.097	
	nmol/l	1.69	1.35	2.03	0.170	0.340	
	ng/dl	50.7	40.6	60.8	5.05	10.1	Roche Cobas e402/e801 Test II
	ng/ml	0.507	0.406	0.608	0.051	0.101	
	nmol/l	1.76	1.41	2.11	0.175	0.350	
	ng/dl	47.6	38.1	57.1	4.75	9.50	Roche Cobas e601/ 602 Test II
	ng/ml	0.475	0.380	0.570	0.048	0.095	
	nmol/l	1.65	1.32	1.98	0.165	0.330	
ng/dl	34.6	27.7	41.5	3.45	6.90	Siemens Atellica IM	
ng/ml	0.346	0.277	0.415	0.035	0.069		
nmol/l	1.20	0.960	1.44	0.120	0.240		
Thyroglobulin	ng/ml	2.80	2.10	3.50	0.350	0.700	Abbott Alinity i
	ng/ml	2.27	1.70	2.84	0.285	0.570	Roche Cobas e402/e801 Tg II
	ng/ml	1.03	0.773	1.29	0.130	0.260	Siemens/DPC Immulite 2000/2500

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.069	0.055	0.083	0.007	0.014	Abbott Alinity i
	µU/ml = mIU/l	0.068	0.054	0.082	0.007	0.014	Abbott Architect
	µU/ml = mIU/l	0.066	0.053	0.079	0.007	0.013	Beckman DXI600/800/ Access 2 (3rd IS)
	µU/ml = mIU/l	0.077	0.062	0.092	0.008	0.015	Ortho Vitros TSH3
	µU/ml = mIU/l	0.098	0.078	0.118	0.010	0.020	Roche Cobas 4000/e411
	µU/ml = mIU/l	0.093	0.074	0.112	0.010	0.019	Roche Cobas e402/e801
	µU/ml = mIU/l	0.099	0.079	0.119	0.010	0.020	Roche Cobas e601/ 602
	µU/ml = mIU/l	0.071	0.057	0.085	0.007	0.014	Siemens Atellica IM
	µU/ml = mIU/l	0.079	0.063	0.095	0.008	0.016	Siemens Centaur TSH3-Ultra
Total Beta hCG	IU/ml	0.013	0.010	0.016	0.002	0.003	Abbott Alinity i
	mU/ml = IU/l	12.9	10.3	15.5	1.30	2.60	
	IU/ml	0.013	0.010	0.016	0.002	0.003	Abbott Architect
	mU/ml = IU/l	12.5	10.0	15.0	1.25	2.50	
	IU/ml	0.002	0.002	0.002	0.000	0.000	bioMerieux, VIDAS
	mU/ml = IU/l	2.00	1.60	2.40	0.200	0.400	
	IU/ml	0.004	0.003	0.005	0.001	0.001	Ortho Vitros 3600/5600/ECi/XT 7600
	mU/ml = IU/l	3.56	2.85	4.27	0.355	0.710	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)						
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28								
Size: 12 x 5 ml / 4 x 5 ml		Range						
Analyte	Unit	Target	Low	High	1SD	2SD	Method	
Total Beta hCG	IU/ml	0.013	0.010	0.016	0.002	0.003	Roche hCG + Beta e402/e801	
	mU/ml = IU/l	12.6	10.1	15.1	1.25	2.50		
	IU/ml	0.013	0.010	0.016	0.002	0.003	Roche hCG+Beta	
	mU/ml = IU/l	13.2	10.6	15.8	1.30	2.60		
	IU/ml	0.008	0.006	0.010	0.001	0.002	Siemens Atellica IM	
	mU/ml = IU/l	7.67	6.14	9.20	0.765	1.53		
	IU/ml	0.009	0.007	0.011	0.001	0.002	Siemens Centaur	
	mU/ml = IU/l	8.88	7.10	10.7	0.910	1.82		
	Total T3	ng/dl	125	93.8	156	15.5	31.0	Abbott Alinity i
		ng/ml	1.25	0.938	1.56	0.155	0.310	
		nmol/l	1.92	1.44	2.40	0.240	0.480	
		ng/dl	125	93.8	156	15.5	31.0	Abbott Architect
ng/ml		1.25	0.938	1.56	0.155	0.310		
nmol/l		1.92	1.44	2.40	0.240	0.480		
ng/dl		142	107	177	17.5	35.0	Ortho Vitros 3600/5600/ECi/XT/7600	
ng/ml		1.43	1.07	1.79	0.180	0.360		
nmol/l		2.19	1.64	2.74	0.275	0.550		
ng/dl		173	130	216	21.5	43.0	Roche Cobas 4000/e411	
ng/ml		1.73	1.30	2.16	0.215	0.430		
nmol/l		2.66	2.00	3.32	0.330	0.660		
ng/dl		175	131	219	22.0	44.0	Roche Cobas e402/e801	
ng/ml		1.75	1.31	2.19	0.220	0.440		
nmol/l		2.69	2.02	3.36	0.335	0.670		
ng/dl		121	90.8	151	15.0	30.0	Siemens Atellica IM	
ng/ml		1.21	0.908	1.51	0.150	0.300		
nmol/l		1.86	1.40	2.32	0.230	0.460		
Total T4		ng/ml	22.2	16.7	27.7	2.75	5.50	Abbott Alinity i
		nmol/l	28.4	21.3	35.5	3.55	7.10	
		µg/dl	2.22	1.67	2.77	0.275	0.550	
		ng/ml	24.6	18.5	30.7	3.05	6.10	Abbott Architect
		nmol/l	31.5	23.6	39.4	3.95	7.90	
		µg/dl	2.46	1.85	3.07	0.305	0.610	
	ng/ml	16.8	12.6	21.0	2.10	4.20	Ortho Vitros 3600/5600/ECi/XT 7600	
	nmol/l	21.5	16.1	26.9	2.70	5.40		
	µg/dl	1.68	1.26	2.10	0.210	0.420		

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)						
Lot. No: 2651EC Cat. No: IA3109 Expiry: 2028/08/28								
Size: 12 x 5 ml / 4 x 5 ml		Range						
Analyte	Unit	Target	Low	High	1SD	2SD	Method	
Total T4	ng/ml	27.4	20.6	34.2	3.40	6.80	Roche Cobas 4000/e411	
	nmol/l	35.1	26.3	43.9	4.40	8.80		
	µg/dl	2.74	2.06	3.42	0.340	0.680		
	ng/ml	24.2	18.2	30.2	3.00	6.00	Roche Cobas e402/e801	
		nmol/l	31.0	23.3	38.7	3.85		7.70
		µg/dl	2.42	1.82	3.02	0.300		0.600
	ng/ml	28.0	21.0	35.0	3.50	7.00	Roche Cobas e601/ 602	
		nmol/l	35.9	26.9	44.9	4.50		9.00
		µg/dl	2.80	2.10	3.50	0.350		0.700
	ng/ml	17.1	12.8	21.4	2.15	4.30	Siemens Atellica IM	
		nmol/l	21.9	16.4	27.4	2.75		5.50
		µg/dl	1.71	1.28	2.14	0.215		0.430
ng/ml	15.7	11.8	19.6	1.95	3.90	Siemens/DPC Immulite 2000/2500		
	nmol/l	20.1	15.1	25.1	2.50		5.00	
	µg/dl	1.57	1.18	1.96	0.195		0.390	
Valproic Acid	µg/ml	32.2	25.8	38.6	3.20	6.40	Abbott Architect (CMIA)	
	µmol/l	223	178	268	22.5	45.0		
	µg/ml	31.3	25.0	37.6	3.15	6.30	Roche Cobas 6000/8000	
µmol/l	217	174	260	21.5	43.0	Abbott Architect (CMIA)		
	µg/ml	5.20	4.16	6.24	0.520		1.04	
	µmol/l	3.50	2.80	4.20	0.350		0.700	
µg/ml	5.18	4.14	6.22	0.520	1.04	Roche Cobas 6000/8000		
	µmol/l	3.49	2.79	4.19	0.350		0.700	
	pg/ml	362	290	434	36.0		72.0	Abbott Alinity i
pmol/l		267	214	320	26.5	53.0		
pg/ml	213	170	256	21.5	43.0	Abbott Architect		
	pmol/l	157	126	188	15.5		31.0	
pg/ml	144	115	173	14.5	29.0	Beckman Dxl 600/800		
	pmol/l	106	84.8	127	10.5		21.0	
pg/ml	202	162	242	20.0	40.0	Ortho Vitros 3600/5600/ECi/XT 7600		
	pmol/l	149	119	179	15.0		30.0	
pg/ml	262	210	314	26.0	52.0	Roche Cobas 4000/e411 Gen II		
	pmol/l	193	154	232	19.5		39.0	
pg/ml	206	165	247	20.5	41.0	Roche Cobas e402/e801 Gen II		
	pmol/l	152	122	182	15.0		30.0	
pg/ml	225	180	270	22.5	45.0	Roche Cobas e601/ 602 Gen II		
	pmol/l	166	133	199	16.5		33.0	
pg/ml	201	161	241	20.0	40.0	Siemens Atellica IM lot 13290		
	pmol/l	148	118	178	15.0		30.0	