

## IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

<b>CAT. NO.</b> IA3110	<b>GTIN:</b> 05055273207262	<b>SIZE:</b> 12 x 5 ml
<b>CAT. NO.</b> IA3112	<b>GTIN:</b> 05055273207286	<b>SIZE:</b> 4 x 5 ml
<b>LOT NO.</b> 1977EC	<b>EXPIRY:</b> 2023-04-28	

### 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 lyophilised.

- 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 2: 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. Aldosterone is present in control levels 2 and level 3 only. 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](mailto:Technical.Services@randox.com).



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## IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1977EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	15.1	11.3	18.9	DIAsource ELISA
	ng/ml	5.00	3.74	6.26	
25-OH Vitamin D	nmol/l	100	75.0	125	Siemens Centaur XP/XPT/Classic
	nmol/l	60.1	45.1	75.1	Roche Vitamin D Total
	nmol/l	62.9	47.2	78.6	Abbott Architect
	nmol/l	83.6	62.7	105	Vitros ECI
	nmol/l	65.9	49.4	82.4	BioMerieux Vidas
	nmol/l	60.4	45.3	75.5	Beckman Dxl 600/800
	nmol/l	60.5	45.4	75.6	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	66.8	50.1	83.5	Roche Vitamin D Total II
ACTH	pmol/l	14.8	11.1	18.5	Siemens Immulite 2000/2500
	pg/ml	67.3	50.4	84.2	
	pmol/l	16.2	12.2	20.3	Roche Cobas E411
	pg/ml	73.6	55.4	91.8	
	pmol/l	14.9	11.2	18.6	Roche Cobas 6000/8000
	pg/ml	67.7	50.9	84.5	
Aldosterone	pmol/l	406	305	508	Diasorin Liaison XL
	pg/ml	146	110	182	
Alpha-fetoprotein	KIU/l = IU/ml	39.8	31.8	47.8	BioMerieux Vidas
	ng/ml	48.2	38.5	57.9	
	KIU/l = IU/ml	44.7	35.8	53.6	Vitros ECI
	ng/ml	46.5	37.2	55.8	
	KIU/l = IU/ml	52.0	41.1	62.9	Siemens Centaur XP/XPT/Classic
	ng/ml	62.9	49.7	76.1	
	KIU/l = IU/ml	39.6	31.7	47.5	Siemens Immulite 2000/2500
	ng/ml	47.9	38.4	57.4	
	KIU/l = IU/ml	42.3	33.8	50.8	Abbott Architect
	ng/ml	51.2	40.9	61.5	
	KIU/l = IU/ml	39.6	31.7	47.5	Beckman Dxl800
	ng/ml	47.9	38.4	57.4	
KIU/l = IU/ml	47.8	38.2	57.4	Roche Cobas 6000/8000	
ng/ml	57.8	46.2	69.4		
Amikacin	KIU/l = IU/ml	47.1	37.7	56.5	Roche Cobas E411
	ng/ml	57.0	45.6	68.4	
Amikacin	µmol/l	15.2	12.2	18.2	Gravimetric
	µg/ml	8.90	7.14	10.7	
Androstenedione	nmol/l	11.9	8.93	14.9	Siemens Immulite 2000
	ng/ml	3.42	2.56	4.28	
Beta-2-microglobulin	µg/ml = mg/l	3.21	2.57	3.85	BioMerieux Vidas
	µg/ml = mg/l	3.07	2.46	3.68	Abbott Architect

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Analyte	unit	Target	Range		methods
			low	high	
Beta-2-microglobulin	µg/ml = mg/l	3.06	2.45	3.67	Roche Cobas 6000/8000
C-Peptide	nmol/l	2.220	1.670	2.780	Siemens Immulite 2000/2500
	ng/ml	6.70	5.04	8.36	
	nmol/l	2.270	1.700	2.840	Roche Cobas 6000/8000
	ng/ml	6.85	5.13	8.57	
CA 15-3	U/ml	37.9	25.8	50.0	Siemens Centaur XP/XPT/Classic
	U/ml	41.3	33.0	49.6	Abbott Architect
	U/ml	17.2	13.8	20.6	Beckman Dxl800
	U/ml	40.0	32.0	48.0	Roche Cobas 6000/8000
	U/ml	38.8	31.0	46.6	Roche Cobas E411
CA 19-9	U/ml	39.9	31.9	47.9	BioMerieux Vidas
	U/ml	47.6	32.4	62.8	Siemens Centaur XP/XPT/Classic
	U/ml	300	240	360	Siemens Immulite 2000/2500
	U/ml	104	83.2	125	Vitros ECi
	U/ml	301	241	361	Beckman Dxl800
	U/ml	66.9	53.5	80.3	Abbott Architect XR/XR2 kit
	U/ml	67.4	53.9	80.9	Roche Cobas 6000/8000
	U/ml	68.6	54.9	82.3	Roche Cobas E411
CA125	U/ml	57.7	46.2	69.2	BioMerieux Vidas
	U/ml	27.7	22.2	33.2	Siemens Immulite 2000/2500
	U/ml	40.8	32.6	49.0	Vitros ECi
	U/ml	62.6	50.1	75.1	Abbott Architect
	U/ml	36.2	24.6	47.8	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	15.5	12.4	18.6	Beckman Dxl800
	U/ml	76.8	61.4	92.2	Roche Cobas E411
	U/ml	75.5	60.4	90.6	Roche Cobas 6000/8000
Carbamazepine	µmol/l	36.8	29.4	44.2	Abbott Architect
	µg/ml	8.70	6.95	10.5	
	µmol/l	37.8	30.2	45.4	Roche Cobas 6000/8000
	µg/ml	8.94	7.14	10.7	
	µmol/l	38.5	30.8	46.2	Gravimetric
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	24.1	19.3	28.9	BioMerieux Vidas
	ng/ml = µg/l	25.6	20.5	30.7	Vitros ECi
	ng/ml = µg/l	22.2	17.8	26.6	Beckman Access
	ng/ml = µg/l	25.7	17.5	33.9	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	30.1	24.1	36.1	Siemens Immulite 2000/2500
	ng/ml = µg/l	26.8	21.4	32.2	Abbott Architect
	ng/ml = µg/l	21.7	17.4	26.0	Beckman Dxl800
	ng/ml = µg/l	21.8	17.4	26.2	Roche Cobas 6000/8000
	ng/ml = µg/l	22.5	18.0	27.0	Roche Cobas E411
Cortisol	nmol/l	799	599	999	Beckman Access
	µg/dl	28.8	21.6	36.0	
	nmol/l	783	540	1026	Siemens Centaur XP/XPT/Classic
	µg/dl	28.2	19.5	36.9	
	nmol/l	684	513	855	Siemens Immulite 2000/2500
µg/dl	24.6	18.5	30.7		

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Analyte	unit	Target	Range		methods
			low	high	
Cortisol	nmol/l	651	488	814	Vitros ECI
	µg/dl	23.4	17.6	29.2	
	nmol/l	616	462	770	Abbott Architect
	µg/dl	22.2	16.6	27.8	
	nmol/l	638	479	798	Beckman Dxl800
	µg/dl	23.0	17.2	28.8	
	nmol/l	779	584	974	Roche Cobas 6000/8000
	µg/dl	28.0	21.0	35.0	
	nmol/l	766	575	958	Roche Cobas E411
	µg/dl	27.6	20.7	34.5	
DHEA-S	nmol/l	742	557	928	Roche Cobas 4000/e411 Gen II
	µg/dl	26.7	20.1	33.3	
	nmol/l	693	520	866	Roche Cobas 6000/8000 Gen II
	µg/dl	24.9	18.7	31.1	
	µmol/l	11.1	8.88	13.3	Siemens Immulite 2000/2500
Digoxin	µmol/l	13.1	10.5	15.7	Abbott Architect
	µmol/l	11.2	7.28	15.1	Siemens Centaur XP/XPT/Classic
	µmol/l	15.9	12.7	19.1	Roche Cobas E411
	µmol/l	15.8	12.6	19.0	Roche Cobas 6000/8000
	nmol/l	3.12	2.50	3.74	Siemens Immulite 2000/2500
Ethosuximide	ng/ml	2.44	1.95	2.93	
	nmol/l	2.33	1.86	2.80	Abbott Architect
	ng/ml	1.82	1.45	2.19	
	nmol/l	2.77	2.22	3.32	Beckman Dxl800
	ng/ml	2.16	1.73	2.59	
	nmol/l	3.07	2.46	3.68	Gravimetric
Ferritin	ng/ml	2.40	1.92	2.87	
	µmol/l	360	288	432	Gravimetric
Folate	µg/ml	51.0	40.8	61.3	
	ng/ml = µg/l	86.5	69.2	104	BioMerieux Vidas
	ng/ml = µg/l	104	83.2	125	Roche Elecsys
	ng/ml = µg/l	69.6	55.7	83.5	Beckman Access
	ng/ml = µg/l	63.3	50.6	76.0	Vitros ECI
	ng/ml = µg/l	82.9	62.2	104	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	89.5	71.6	107	Siemens Immulite 2000/2500
	ng/ml = µg/l	102	81.6	122	Abbott Architect
	ng/ml = µg/l	105	84.0	126	Roche Modular E170
	ng/ml = µg/l	67.5	54.0	81.0	Beckman Dxl800
Folate	ng/ml = µg/l	104	83.2	125	Roche Cobas E411
	nmol/l	12.1	9.20	15.0	Beckman Access
	ng/ml	5.34	4.06	6.62	
	nmol/l	8.49	6.45	10.5	Siemens Immulite 2000
	ng/ml	3.74	2.84	4.64	
Folate	nmol/l	7.99	6.07	9.91	Vitros ECI
	ng/ml	3.52	2.68	4.36	

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Analyte	unit	Target	Range		methods
			low	high	
Folate	nmol/l	9.74	7.40	12.1	Abbott Architect
	ng/ml	4.30	3.26	5.34	
	nmol/l	22.7	14.8	30.6	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	10.0	6.50	13.5	
	nmol/l	11.8	8.97	14.6	Beckman DxI800
ng/ml	5.20	3.96	6.44		
Free T3	pmol/l	16.5	12.4	20.6	Roche Elecsys
	ng/dl	1.07	0.806	1.33	
	pg/ml	10.7	8.07	13.3	
	pmol/l	11.4	8.55	14.3	Beckman Access
	ng/dl	0.741	0.556	0.926	
	pg/ml	7.42	5.57	9.27	
	pmol/l	30.9	23.2	38.6	Vitros ECI
	ng/dl	2.01	1.51	2.51	
	pg/ml	20.1	15.1	25.1	
	pmol/l	13.2	7.92	18.5	Siemens Centaur XP/XPT/Classic
	ng/dl	0.858	0.515	1.20	
	pg/ml	8.59	5.15	12.0	
	pmol/l	10.4	7.80	13.0	Siemens Immulite 2000/2500
	ng/dl	0.676	0.507	0.845	
	pg/ml	6.77	5.08	8.46	
	pmol/l	12.6	9.45	15.8	Abbott Architect
	ng/dl	0.819	0.614	1.02	
	pg/ml	8.20	6.15	10.3	
	pmol/l	9.51	7.13	11.9	Beckman DxI800
	ng/dl	0.618	0.463	0.773	
pg/ml	6.19	4.64	7.74		
pmol/l	15.6	11.7	19.5	Roche Cobas E411	
ng/dl	1.01	0.761	1.26		
pg/ml	10.2	7.62	12.8		
pmol/l	16.3	12.2	20.4	Roche Cobas 6000/8000	
ng/dl	1.06	0.793	1.33		
pg/ml	10.6	7.94	13.3		
Free T4	pmol/l	29.2	21.9	36.5	Roche Elecsys
	ng/dl	2.28	1.71	2.85	
	pg/ml	22.8	17.1	28.5	
	pmol/l	23.0	17.3	28.8	Beckman Access
	ng/dl	1.79	1.35	2.23	
	pg/ml	17.9	13.5	22.3	
	pmol/l	57.5	43.1	71.9	Vitros ECI
	ng/dl	4.49	3.36	5.62	
	pg/ml	44.9	33.6	56.2	
	pmol/l	21.9	16.4	27.4	Siemens Centaur XP/XPT/Classic
	ng/dl	1.71	1.28	2.14	
	pg/ml	17.1	12.8	21.4	
	pmol/l	29.1	21.8	36.4	Siemens Immulite 2000/2500
	ng/dl	2.27	1.70	2.84	
	pg/ml	22.7	17.0	28.4	

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Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	20.3	15.2	25.4	Abbott Architect
	ng/dl	1.58	1.19	1.97	
	pg/ml	15.8	11.9	19.7	
	pmol/l	22.6	17.0	28.3	Beckman Dxl800
	ng/dl	1.76	1.33	2.19	
	pg/ml	17.6	13.3	21.9	
	pmol/l	27.0	20.3	33.8	Roche Cobas 6000/8000
	ng/dl	2.11	1.58	2.64	
	pg/ml	21.1	15.8	26.4	
	pmol/l	26.8	20.1	33.5	Roche Cobas E411
	ng/dl	2.09	1.57	2.61	
	pg/ml	20.9	15.7	26.1	
	pmol/l	28.6	21.5	35.8	Biomerieux Vidas FT4N Kit
	ng/dl	2.23	1.68	2.78	
	pg/ml	22.3	16.8	27.8	
pmol/l	23.4	17.6	29.3	Mindray CL-2000i	
ng/dl	1.83	1.37	2.29		
pg/ml	18.3	13.7	22.9		
FSH	mU/ml	27.7	22.2	33.2	BioMerieux Vidas
	mU/ml	20.4	16.3	24.5	Vitros ECi
	mU/ml	30.8	23.1	38.5	Siemens Centaur XP/XPT/Classic
	mU/ml	23.5	18.8	28.2	Siemens Immulite 2000/2500
	mU/ml	22.8	18.2	27.4	Abbott Architect
	mU/ml	27.6	22.1	33.1	Beckman Dxl800
	mU/ml	23.9	19.1	28.7	Roche Cobas E411
	mU/ml	22.9	18.3	27.5	Roche Cobas 6000/8000
Gentamicin	µmol/l	8.16	6.53	9.79	Gravimetric
	µg/ml	3.90	3.12	4.68	
Growth Hormone (GH)	µU/ml	18.5	14.8	22.2	Siemens Immulite 2000/2500
	ng/ml	6.16	4.93	7.39	
	µU/ml	14.0	11.2	16.8	Beckman Dxl800
	ng/ml	4.66	3.73	5.59	
	µU/ml	16.6	13.3	19.9	Roche Cobas E411
	ng/ml	5.53	4.43	6.63	
	µU/ml	16.3	13.0	19.6	Roche Cobas 6000/8000
	ng/ml	5.43	4.33	6.53	
µU/ml	15.4	12.3	18.5	Diasorin Liaison XL	
ng/ml	5.13	4.10	6.16		
Immunoglobulin E	KIU/I = IU/ml	91.0	72.8	109	BioMerieux Vidas
	KIU/I = IU/ml	128	76.8	179	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	135	108	162	Siemens Immulite 2000/2500
	KIU/I = IU/ml	115	92.0	138	Abbott Architect
	KIU/I = IU/ml	139	111	167	Roche Cobas E411
	KIU/I = IU/ml	140	112	168	Roche Cobas 6000/8000

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Analyte	unit	Target	Range		methods
			low	high	
Insulin	mU/l	3.89	2.92	4.86	Siemens Immulite 2000
	µU/ml	3.89	2.92	4.86	
	mU/l	12.0	9.00	15.0	Beckman Access
	µU/ml	12.0	9.00	15.0	
	mU/l	13.0	9.75	16.3	Abbott Architect
	µU/ml	13.0	9.75	16.3	
	mU/l	15.4	11.6	19.3	Roche Cobas E411
	µU/ml	15.4	11.6	19.2	
	mU/l	14.9	11.2	18.6	Roche Cobas 6000/8000
	µU/ml	14.9	11.2	18.6	
Luteinising Hormone (LH)	mU/ml	31.6	25.3	37.9	Beckman Access
	mU/ml	36.6	29.3	43.9	BioMerieux Vidas
	mU/ml	52.6	42.1	63.1	Vitros ECi
	mU/ml	36.4	28.0	44.8	Siemens Centaur XP/XPT/Classic
	mU/ml	60.9	48.7	73.1	Siemens Immulite 2000
	mU/ml	31.1	24.9	37.3	Abbott Architect
	mU/ml	29.1	23.3	34.9	Beckman Dxl800
	mU/ml	39.6	31.7	47.5	Roche Cobas E411
	mU/ml	38.7	31.0	46.4	Roche Cobas 6000/8000
Oestradiol	pmol/l	1336	1069	1603	BioMerieux Vidas
	pg/ml	363	291	435	
	pmol/l	1076	861	1291	Vitros ECi
	pg/ml	293	234	352	
	pmol/l	756	605	907	Abbott Architect
	pg/ml	206	165	247	
	pmol/l	1006	805	1207	Beckman Dxl800
	pg/ml	274	219	329	
	pmol/l	821	657	985	Roche Cobas 6000/8000 (Estradiol II)
	pg/ml	223	179	267	
	pmol/l	822	658	986	Roche Cobas 4000/E411 (Estradiol II)
	pg/ml	224	179	269	
	pmol/l	1072	643	1501	Siemens Centaur XP/XPT/Classic Enhanced (eE2)
	pg/ml	292	175	409	
	pmol/l	816	653	979	Roche Cobas 6000/8000 (Estradiol III)
	pg/ml	222	178	266	
pmol/l	781	625	937	Roche Cobas 4000/E411 (Estradiol III)	
pg/ml	212	170	254		
pmol/l	856	685	1027	Beckman Dxl600/800 Sensitive B84493	
pg/ml	233	186	280		
Paracetamol	mmol/l	0.316	0.253	0.379	Roche Cobas 6000/8000
	mg/l	47.8	38.3	57.3	
	mmol/l	0.348	0.280	0.420	Gravimetric
	mg/l	52.7	42.4	63.5	
Phenobarbital	µmol/l	78.4	62.7	94.1	Abbott Architect
	µg/ml	18.2	14.5	21.9	

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Analyte	unit	Target	Range		methods
			low	high	
Phenobarbital	µmol/l	75.2	60.2	90.2	Siemens Immulite 2000/2500
	µg/ml	17.4	14.0	20.8	
	µmol/l	77.6	62.1	93.1	Gravimetric
	µg/ml	18.0	14.4	21.6	
Phenytoin	µmol/l	65.3	52.2	78.4	Abbott Architect
	µg/ml	16.5	13.2	19.8	
	µmol/l	65.5	52.4	78.6	Roche Cobas 6000/8000
	µg/ml	16.5	13.2	19.8	
	µmol/l	71.3	57.0	85.6	Gravimetric
Primidone	µmol/l	22.5	18.0	27.0	Gravimetric
	µg/ml	4.91	3.93	5.89	
Progesterone	nmol/l	42.6	34.1	51.1	BioMerieux Vidas
	ng/ml	13.3	10.7	15.9	
	nmol/l	23.6	16.5	30.7	Siemens Centaur XP/XPT/Classic
	ng/ml	7.39	5.17	9.61	
	nmol/l	25.2	20.2	30.2	Siemens Immulite 2000/2500
	ng/ml	7.89	6.32	9.46	
	nmol/l	26.5	21.2	31.8	Abbott Architect
	ng/ml	8.29	6.64	9.94	
	nmol/l	35.0	28.0	42.0	Beckman Dxl Prog Cal 33555
	ng/ml	11.0	8.76	13.2	
	nmol/l	34.9	27.9	41.9	Roche Cobas 4000/e411 (Prog. II)
	ng/ml	10.9	8.73	13.1	
	nmol/l	33.6	26.9	40.3	Roche Cobas 6000/8000 (Prog. II)
	ng/ml	10.5	8.42	12.6	
Prolactin	µU/ml	753	602	904	BioMerieux Vidas
	µU/ml	540	432	648	Vitros ECi
	µU/ml	532	415	649	Siemens Centaur XP/XPT/Classic
	µU/ml	541	433	649	Siemens Immulite 2000/2500
	µU/ml	632	506	758	Abbott Architect
	µU/ml	514	411	617	Beckman Dxl800
	µU/ml	611	489	733	Roche Elecsys/E170/Cobas 6000/8000 PRLII
	µU/ml	643	514	772	Roche Cobas E411
	µU/ml	609	487	731	Roche Cobas 6000/8000
	PSA Free	ng/ml = µg/l	10.4	7.80	13.0
ng/ml = µg/l		13.2	9.90	16.5	Beckman Access standardised to Hybritech
ng/ml = µg/l		10.3	7.73	12.9	Siemens Centaur XP/XPT/Classic
ng/ml = µg/l		11.7	8.78	14.6	Beckman DXI standardised to Hybritech



## IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1977EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
PSA Free	ng/ml = µg/l	9.20	6.90	11.5	Roche Cobas E411
	ng/ml = µg/l	9.30	6.98	11.6	Roche Cobas 6000/8000
PSA Total	ng/ml = µg/l	12.7	9.53	15.9	Beckman Access standardised to Hybritech
	ng/ml = µg/l	10.6	7.95	13.3	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	11.7	8.78	14.6	bioMerieux VIDAS TPSA
	ng/ml = µg/l	8.93	6.70	11.2	Siemens Immulite 2000/2500 1st generation
	ng/ml = µg/l	10.2	7.65	12.8	Abbott Architect
	ng/ml = µg/l	12.8	9.60	16.0	Vitros ECi
	ng/ml = µg/l	12.8	9.60	16.0	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	11.8	8.85	14.8	Beckman Dxl standardisd to Hybritech
	ng/ml = µg/l	9.56	7.17	12.0	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	12.9	9.68	16.1	Roche Cobas E411
	ng/ml = µg/l	12.9	9.68	16.1	Roche Cobas 6000/8000
	ng/ml = µg/l	12.8	9.60	16.0	Ortho Vitros 3600/5600/ECi PSA II
Salicylic Acid	mmol/l	1.22	0.980	1.46	Gravimetric
	mg/dl	16.9	13.5	20.2	
SHBG	nmol/l	39.4	31.5	47.3	Siemens Immulite 2000/2500
	nmol/l	38.1	30.5	45.7	Abbott Architect
	nmol/l	38.8	31.0	46.6	Beckman Dxl800
T Uptake	%U	34.5	28.3	40.7	Siemens Immulite 2000
Testosterone	nmol/l	19.2	15.4	23.0	Vitros ECi
	ng/ml	5.53	4.44	6.62	
	ng/dl	553	444	662	
	nmol/l	17.7	14.2	21.2	Siemens Immulite 2000/2500
	ng/ml	5.10	4.09	6.11	
	ng/dl	510	409	611	
	nmol/l	15.2	12.2	18.2	Abbott Architect
	ng/ml	4.38	3.51	5.25	
	ng/dl	438	351	525	
	nmol/l	13.5	10.8	16.2	Beckman Dxl800
	ng/ml	3.89	3.11	4.67	
	ng/dl	389	311	467	
	nmol/l	16.8	13.4	20.2	Roche Cobas 4000/e411 Test II
	ng/ml	4.84	3.86	5.82	
	ng/dl	484	386	582	
	nmol/l	17.2	13.8	20.6	Roche Cobas 6000 Test 2
	ng/ml	4.95	3.97	5.93	
	ng/dl	495	397	593	
nmol/l	15.5	12.4	18.6	Abbott Architect 2nd Generation	
ng/ml	4.46	3.57	5.35		
ng/dl	446	357	535		
nmol/l	15.3	10.7	19.9	Siemens Centaur TST II	
ng/ml	4.41	3.09	5.73		
ng/dl	441	309	573		
Theophylline	µmol/l	77.3	61.8	92.8	Roche Cobas 6000/8000
	µg/ml	13.9	11.1	16.7	

## IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1977EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
Theophylline	µmol/l	83.8	67.0	101	Gravimetric
	µg/ml	15.1	12.1	18.2	
Thyroglobulin	ng/ml	15.0	11.3	18.8	Siemens Immulite 2000
	ng/ml	36.5	27.4	45.6	Roche Cobas 6000/8000
	ng/ml	36.7	27.5	45.9	Roche Cobas 6000 TGII
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.93	1.54	2.32	bioMerieux VIDAS TSH
	µU/ml = mIU/l	2.33	1.86	2.80	Siemens Immulite 1000
	µU/ml = mIU/l	2.19	1.75	2.63	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	2.62	2.10	3.14	Vitros ECI
	µU/ml = mIU/l	2.24	1.52	2.96	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	2.32	1.86	2.78	Siemens Immulite 2000/2500
	µU/ml = mIU/l	1.94	1.55	2.33	Abbott Architect
	µU/ml = mIU/l	1.74	1.39	2.09	bioMerieux VIDAS TSH3 Ultrasensitive
	µU/ml = mIU/l	2.02	1.62	2.42	Beckman Access Fast TSH
	µU/ml = mIU/l	2.40	1.92	2.88	Roche Cobas E411
	µU/ml = mIU/l	2.40	1.92	2.88	Roche Cobas 6000/8000
	µU/ml = mIU/l	2.12	1.70	2.54	Beckman DxI800 Hyper TSH
	µU/ml = mIU/l	2.23	1.52	2.94	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	3.17	2.54	3.80	Mindray CL-2000i
Tobramycin	µmol/l	7.16	5.73	8.59	Gravimetric
	µg/ml	3.35	2.68	4.02	
Total Beta hCG	mU/ml=IU/l	35.8	28.6	43.0	BioMerieux Vidas
	IU/ml	0.036	0.029	0.043	
	mU/ml=IU/l	36.7	29.4	44.0	Beckman Access
	IU/ml	0.037	0.029	0.045	
	mU/ml=IU/l	35.9	28.7	43.1	Vitros ECI
	IU/ml	0.036	0.029	0.043	
	mU/ml=IU/l	40.6	24.4	56.8	Siemens Centaur XP/XPT/Classic
	IU/ml	0.041	0.024	0.057	
	mU/ml=IU/l	43.2	34.6	51.8	Siemens Immulite 2000
	IU/ml	0.043	0.035	0.051	
	mU/ml=IU/l	36.1	28.9	43.3	Abbott Architect
	IU/ml	0.036	0.029	0.043	
	mU/ml=IU/l	38.2	30.6	45.8	Siemens Dimension
	IU/ml	0.038	0.031	0.045	
	mU/ml=IU/l	38.8	31.0	46.6	Beckman DxI800
	IU/ml	0.039	0.031	0.047	
	mU/ml=IU/l	34.9	27.9	41.9	Roche STAT (Intact)
	IU/ml	0.035	0.028	0.042	
	mU/ml=IU/l	33.8	27.0	40.6	Roche hCG+Beta
	IU/ml	0.034	0.027	0.041	
mU/ml=IU/l	38.3	30.6	46.0	Beckman Access Total BhCG (5th IS)	
IU/ml	0.038	0.031	0.045		
mU/ml=IU/l	38.8	31.0	46.6	Beckman DxI Total BhCG (5th IS)	
IU/ml	0.039	0.031	0.047		

## IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1977EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
Total T3	nmol/l	4.30	3.23	5.38	BioMerieux Vidas
	ng/ml	2.80	2.10	3.50	
	ng/dl	280	210	350	
	nmol/l	4.51	3.38	5.64	Siemens Centaur XP/XPT/Classic
	ng/ml	2.94	2.20	3.68	
	ng/dl	294	220	368	
	nmol/l	4.28	3.21	5.35	Siemens Immulite 2000/2500
	ng/ml	2.79	2.09	3.49	
	ng/dl	279	209	349	
	nmol/l	3.61	2.71	4.51	Abbott Architect
	ng/ml	2.35	1.76	2.94	
	ng/dl	235	176	294	
	nmol/l	4.25	3.19	5.31	Vitros ECI
	ng/ml	2.77	2.08	3.46	
	ng/dl	277	208	346	
nmol/l	4.56	3.42	5.70	Roche Cobas E411	
ng/ml	2.97	2.23	3.71		
ng/dl	297	223	371		
nmol/l	4.34	3.26	5.43	Roche Cobas 6000/8000	
ng/ml	2.83	2.12	3.54		
ng/dl	283	212	354		
Total T4	nmol/l	104	78.0	130	Vitros ECI
	µg/dl	8.11	6.08	10.1	
	ng/ml	81.1	60.8	101	
	nmol/l	117	87.8	146	BioMerieux Vidas
	µg/dl	9.13	6.85	11.4	
	ng/ml	91.3	68.5	114	
	nmol/l	107	80.3	134	Siemens Immulite 1000
	µg/dl	8.35	6.26	10.4	
	ng/ml	83.5	62.6	104	
	nmol/l	112	84.0	140	Beckman Access
	µg/dl	8.74	6.55	10.9	
	ng/ml	87.4	65.5	109	
	nmol/l	102	66.3	138	Siemens Centaur XP/XPT/Classic
	µg/dl	7.96	5.17	10.7	
	ng/ml	79.6	51.7	107	
	nmol/l	103	77.3	129	Siemens Immulite 2000/2500
	µg/dl	8.03	6.03	10.0	
	ng/ml	80.3	60.3	100	
nmol/l	101	75.8	126	Abbott Architect	
µg/dl	7.88	5.91	9.85		
ng/ml	78.8	59.1	98.5		
nmol/l	109	81.8	136	Roche Cobas E411	
µg/dl	8.50	6.38	10.6		
ng/ml	85.0	63.8	106		
nmol/l	106	79.5	133	Roche Cobas 6000/8000	
µg/dl	8.27	6.20	10.3		
ng/ml	82.7	62.0	103		

## IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1977EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
Valproic Acid	µmol/l	523	418	628	Siemens Immulite 2000/2500
	µg/ml	75.5	60.3	90.7	
	µmol/l	513	410	616	Abbott Architect
	µg/ml	74.0	59.2	88.8	
	µmol/l	553	442	664	Roche Cobas 6000/8000
	µg/ml	79.8	63.8	95.8	
Vancomycin	µmol/l	638	510	766	Gravimetric
	µg/ml	92.1	73.6	111	
	µmol/l	7.14	5.71	8.57	Abbott Architect
	µg/ml	10.6	8.48	12.7	
	µmol/l	5.85	4.68	7.02	Roche Cobas 6000/8000
	µg/ml	8.69	6.95	10.4	
Vitamin B12	µmol/l	7.10	5.68	8.52	Gravimetric
	µg/ml	10.5	8.44	12.7	
	pmol/l	359	287	431	Beckman Access
	pg/ml	486	389	583	
	pmol/l	446	335	557	Siemens Centaur XP/XPT/Classic
	pg/ml	604	453	755	
	pmol/l	390	312	468	Siemens Immulite 2000
	pg/ml	528	423	633	
	pmol/l	408	326	490	Abbott Architect
	pg/ml	553	442	664	
pmol/l	383	306	460	Vitros ECi	
pg/ml	519	415	623		
pmol/l	315	252	378	Beckman DxI800	
pg/ml	427	341	513		