

IMMUNOASSAY PREMIUM PLUS - LEVEL 1 (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. 1975EC	EXPIRY: 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. Free PSA and Total PSA are stable for 2 days when stored at +2°C to +8°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 1: 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.

EC	REP
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Randox Teoranta, Meenmore,
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IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	2.83	2.12	3.54	Immunotech RIA
	ng/ml	0.937	0.702	1.17	
25-OH Vitamin D	nmol/l	42.2	31.7	52.8	Siemens Centaur XP/XPT/Classic
	nmol/l	23.7	17.8	29.6	Roche Vitamin D Total
	nmol/l	25.3	19.0	31.6	Abbott Architect
	nmol/l	111	83.3	139	Vitros ECi
	nmol/l	31.8	23.9	39.8	BioMerieux Vidas
	nmol/l	41.0	30.8	51.3	Beckman Dxl 600/800
	nmol/l	24.9	18.7	31.1	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	24.8	18.6	31.0	Roche Vitamin D Total II
ACTH	pmol/l	6.65	4.99	8.31	Siemens Immulite 2000/2500
	pg/ml	30.2	22.7	37.7	
	pmol/l	11.2	8.40	14.0	Roche Cobas E411
	pg/ml	50.9	38.2	63.6	
	pmol/l	10.5	7.88	13.1	Roche Cobas 6000/8000
	pg/ml	47.7	35.8	59.6	
	pmol/l	8.57	6.43	10.7	Siemens Immulite 1000
	pg/ml	39.0	29.2	48.8	
pmol/l	12.7	9.53	15.9	Diasorin Liaison XL	
pg/ml	57.7	43.3	72.1		
Alphafoetoprotein	KIU/l = IU/ml	9.01	7.21	10.8	BioMerieux Vidas
	ng/ml	10.9	8.72	13.1	
	KIU/l = IU/ml	9.46	7.57	11.4	Vitros ECi
	ng/ml	9.84	7.87	11.8	
	KIU/l = IU/ml	10.6	8.37	12.8	Siemens Centaur XP/XPT/Classic
	ng/ml	12.8	10.1	15.5	
	KIU/l = IU/ml	8.18	6.54	9.82	Siemens Immulite 2000/2500
	ng/ml	9.90	7.91	11.9	
	KIU/l = IU/ml	8.50	6.80	10.2	Abbott Architect
	ng/ml	10.3	8.23	12.4	
	KIU/l = IU/ml	8.44	6.75	10.1	Beckman Dxl800
	ng/ml	10.2	8.17	12.2	
	KIU/l = IU/ml	9.32	7.46	11.2	Roche Cobas 6000/8000
	ng/ml	11.3	9.03	13.6	
KIU/l = IU/ml	9.12	7.30	10.9	Roche Cobas E411	
ng/ml	11.0	8.83	13.2		
Amikacin	µmol/l	6.40	5.12	7.68	Gravimetric
	µg/ml	3.75	3.00	4.50	
Androstenedione	nmol/l	4.58	3.44	5.73	Siemens Immulite 2000
	ng/ml	1.31	0.987	1.63	
Beta-2-microglobulin	µg/ml = mg/l	0.928	0.742	1.11	BioMerieux Vidas
	µg/ml = mg/l	0.922	0.738	1.11	Siemens Immulite 2000/2500

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range					
Analyte	unit	Target	low	high	methods
Beta-2-microglobulin	µg/ml = mg/l	0.896	0.717	1.08	Abbott Architect
	µg/ml = mg/l	1.05	0.840	1.26	Roche Cobas 6000/8000
C-Peptide	nmol/l	0.602	0.452	0.753	Siemens Immulite 2000/2500
	ng/ml	1.82	1.36	2.28	
	nmol/l	0.794	0.596	0.993	Roche Cobas 6000/8000
	ng/ml	2.40	1.80	3.00	
	nmol/l	0.659	0.494	0.824	Abbott Architect
	ng/ml	1.99	1.49	2.49	
CA 15-3	U/ml	23.5	15.5	31.5	Siemens Centaur XP/XPT/Classic
	U/ml	24.7	19.8	29.6	Abbott Architect
	U/ml	22.8	18.2	27.4	Siemens Immulite 2000/2500
	U/ml	20.1	16.1	24.1	Vitros Eci
	U/ml	9.75	7.80	11.7	Beckman Dxl800
	U/ml	22.5	18.0	27.0	Roche Cobas 6000/8000
	U/ml	22.4	17.9	26.9	Roche Cobas E411
CA 19-9	U/ml	13.2	10.6	15.8	BioMerieux Vidas
	U/ml	15.8	10.4	21.2	Siemens Centaur XP/XPT/Classic
	U/ml	78.1	62.5	93.7	Siemens Immulite 2000/2500
	U/ml	33.3	26.6	40.0	Vitros Eci
	U/ml	95.9	76.7	115	Beckman Dxl800
	U/ml	24.4	19.5	29.3	Abbott Architect XR/XR2 kit
	U/ml	22.6	18.1	27.1	Roche Cobas 6000/8000
	U/ml	22.6	18.1	27.1	Roche Cobas E411
CA125	U/ml	14.7	11.8	17.6	BioMerieux Vidas
	U/ml	7.62	6.10	9.14	Siemens Immulite 2000/2500
	U/ml	9.74	7.79	11.7	Vitros Eci
	U/ml	18.2	14.6	21.8	Abbott Architect
	U/ml	9.65	6.37	12.9	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	4.13	3.30	4.96	Beckman Access
	U/ml	4.66	3.73	5.59	Beckman Dxl800
	U/ml	19.0	15.2	22.8	Roche Cobas E411
	U/ml	19.1	15.3	22.9	Roche Cobas 6000/8000
Carbamazepine	µmol/l	17.2	12.4	22.0	Siemens Centaur XP/XPT/Classic
	µg/ml	4.07	2.93	5.21	
	µmol/l	12.4	9.92	14.9	Siemens Immulite 2000/2500
	µg/ml	2.93	2.35	3.51	
	µmol/l	15.3	12.2	18.4	Abbott Architect
	µg/ml	3.62	2.88	4.36	
	µmol/l	14.4	11.5	17.3	Roche Cobas 6000/8000
	µg/ml	3.40	2.72	4.08	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	3.78	3.02	4.54	BioMerieux Vidas
	ng/ml = µg/l	3.97	3.18	4.76	Vitros Eci
	ng/ml = µg/l	3.94	3.15	4.73	Beckman Access
	ng/ml = µg/l	4.65	3.07	6.23	Siemens Centaur XP/XPT/Classic

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	4.86	3.89	5.83	Siemens Immulite 2000/2500
	ng/ml = µg/l	4.69	3.75	5.63	Abbott Architect
	ng/ml = µg/l	3.94	3.15	4.73	Beckman Dxl800
	ng/ml = µg/l	4.09	3.27	4.91	Roche Cobas 6000/8000
	ng/ml = µg/l	4.27	3.42	5.12	Roche Cobas E411
Cortisol	nmol/l	176	116	236	Siemens Centaur XP/XPT/Classic
	µg/dl	6.34	4.18	8.50	
	nmol/l	192	144	240	Siemens Immulite 2000/2500
	µg/dl	6.91	5.18	8.64	
	nmol/l	134	101	168	Vitros ECI
	µg/dl	4.82	3.64	6.00	
	nmol/l	207	155	259	Abbott Architect
	µg/dl	7.45	5.58	9.32	
	nmol/l	194	146	243	Beckman Dxl800
	µg/dl	6.98	5.26	8.70	
	nmol/l	191	143	239	Roche Cobas 6000/8000
	µg/dl	6.88	5.15	8.61	
	nmol/l	196	147	245	Roche Cobas E411
µg/dl	7.06	5.29	8.83		
nmol/l	197	148	246	Roche Cobas 4000/e411 Gen II	
µg/dl	7.09	5.33	8.85		
nmol/l	180	135	225	Roche Cobas 6000/8000 Gen II	
µg/dl	6.48	4.86	8.10		
DHEA-S	µmol/l	1.91	1.53	2.29	Siemens Immulite 2000/2500
	µmol/l	2.53	2.02	3.04	Abbott Architect
	µmol/l	2.43	1.58	3.28	Siemens Centaur XP/XPT/Classic
	µmol/l	3.23	2.58	3.88	Roche Cobas E411
	µmol/l	3.03	2.42	3.64	Roche Cobas 6000/8000
Digoxin	nmol/l	0.680	0.544	0.816	Siemens Immulite 2000/2500
	ng/ml	0.531	0.425	0.637	
	nmol/l	0.618	0.494	0.742	Abbott Architect
	ng/ml	0.483	0.386	0.580	
	nmol/l	0.781	0.625	0.937	Beckman Dxl800
	ng/ml	0.610	0.488	0.732	
	nmol/l	0.896	0.720	1.08	Gravimetric
ng/ml	0.700	0.560	0.840		
Ethosuximide	µmol/l	226	181	271	Gravimetric
	µg/ml	32.0	25.7	38.4	
Ferritin	ng/ml = µg/l	19.1	15.3	22.9	BioMerieux Vidas
	ng/ml = µg/l	19.0	15.2	22.8	Roche Elecsys
	ng/ml = µg/l	11.6	9.28	13.9	Beckman Access
	ng/ml = µg/l	12.7	10.2	15.2	Vitros ECI
	ng/ml = µg/l	15.0	11.3	18.7	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	16.1	12.9	19.3	Siemens Immulite 2000/2500
	ng/ml = µg/l	18.0	14.4	21.6	Abbott Architect
ng/ml = µg/l	18.9	15.1	22.7	Roche Modular E170	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range					
Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	12.3	9.84	14.8	Beckman Dxl800
	ng/ml = µg/l	18.9	15.1	22.7	Roche Cobas E411
Folate	nmol/l	4.81	3.66	5.96	Siemens Immulite 2000
	ng/ml	2.12	1.61	2.63	
	nmol/l	4.71	3.58	5.84	Vitros ECI
	ng/ml	2.08	1.58	2.58	
	nmol/l	6.01	4.57	7.45	Abbott Architect
	ng/ml	2.65	2.02	3.28	
	nmol/l	13.8	7.59	20.0	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	6.09	3.35	8.83	
Free T3	pmol/l	3.28	2.46	4.10	Roche Elecsys
	ng/dl	0.213	0.160	0.266	
	pg/ml	2.14	1.60	2.68	
	pmol/l	2.82	2.12	3.53	Beckman Access
	ng/dl	0.183	0.138	0.228	
	pg/ml	1.84	1.38	2.30	
	pmol/l	5.32	3.99	6.65	Vitros ECI
	ng/dl	0.346	0.259	0.433	
	pg/ml	3.46	2.60	4.32	
	pmol/l	2.77	1.66	3.88	Siemens Centaur XP/XPT/Classic
	ng/dl	0.180	0.108	0.252	
	pg/ml	1.80	1.08	2.52	
	pmol/l	2.27	1.70	2.84	Siemens Immulite 2000/2500
	ng/dl	0.148	0.111	0.185	
	pg/ml	1.48	1.11	1.85	
	pmol/l	2.37	1.78	2.96	Abbott Architect
	ng/dl	0.154	0.116	0.192	
	pg/ml	1.54	1.16	1.92	
	pmol/l	2.84	2.13	3.55	Beckman Dxl800
	ng/dl	0.185	0.138	0.232	
pg/ml	1.85	1.39	2.31		
pmol/l	3.30	2.48	4.13	Roche Cobas E411	
ng/dl	0.215	0.161	0.269		
pg/ml	2.15	1.61	2.69		
pmol/l	3.01	2.26	3.76	Roche Cobas 6000/8000	
ng/dl	0.196	0.147	0.245		
pg/ml	1.96	1.47	2.45		
Free T4	pmol/l	13.9	10.4	17.4	Siemens Immulite 1000
	ng/dl	1.08	0.811	1.35	
	pg/ml	10.8	8.11	13.5	
	pmol/l	10.2	7.65	12.8	Beckman Access
	ng/dl	0.796	0.597	0.995	
	pg/ml	7.96	5.97	9.95	
	pmol/l	15.2	11.4	19.0	Vitros ECI
	ng/dl	1.19	0.889	1.49	
	pg/ml	11.9	8.89	14.9	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range					
Analyte	unit	Target	low	high	methods
Free T4	pmol/l	8.27	6.20	10.3	Siemens Centaur XP/XPT/Classic
	ng/dl	0.645	0.484	0.806	
	pg/ml	6.45	4.84	8.06	
	pmol/l	13.5	10.1	16.9	Siemens Immulite 2000/2500
	ng/dl	1.05	0.788	1.31	
	pg/ml	10.5	7.88	13.1	
	pmol/l	9.43	7.07	11.8	Abbott Architect
	ng/dl	0.736	0.551	0.921	
	pg/ml	7.36	5.51	9.21	
	pmol/l	10.2	7.65	12.8	Beckman Dxl800
	ng/dl	0.796	0.597	0.995	
	pg/ml	7.96	5.97	9.95	
	pmol/l	12.5	9.38	15.6	Roche Cobas 6000/8000
	ng/dl	0.975	0.732	1.22	
	pg/ml	9.75	7.32	12.2	
	pmol/l	12.6	9.45	15.8	Roche Cobas E411
ng/dl	0.983	0.737	1.23		
pg/ml	9.83	7.37	12.3		
pmol/l	9.53	7.15	11.9	Biomérieux Vidas FT4N Kit	
ng/dl	0.743	0.558	0.928		
pg/ml	7.43	5.58	9.28		
FSH	mU/ml	6.23	4.98	7.48	BioMérieux Vidas
	mU/ml	5.96	4.77	7.15	Beckman Access
	mU/ml	4.72	3.78	5.66	Vitros Eci
	mU/ml	8.24	5.77	10.7	Siemens Centaur XP/XPT/Classic
	mU/ml	6.43	5.14	7.72	Siemens Immulite 2000/2500
	mU/ml	5.26	4.21	6.31	Abbott Architect
	mU/ml	6.56	5.25	7.87	Beckman Dxl800
	mU/ml	5.85	4.68	7.02	Roche Cobas E411
	mU/ml	5.54	4.43	6.65	Roche Cobas 6000/8000
Gentamicin	µmol/l	4.85	3.88	5.82	Gravimetric
	µg/ml	2.32	1.85	2.78	
Growth Hormone (GH)	µU/ml	4.81	3.85	5.77	Siemens Immulite 2000/2500
	ng/ml	1.60	1.28	1.92	
	µU/ml	3.47	2.78	4.16	Beckman Dxl800
	ng/ml	1.16	0.926	1.39	
	µU/ml	4.25	3.40	5.10	Roche Cobas 6000/8000
	ng/ml	1.42	1.13	1.71	
	µU/ml	3.60	2.88	4.32	Diasorin Liaison XL
	ng/ml	1.20	0.959	1.44	
Immunoglobulin E	KIU/l = IU/ml	285	228	342	Siemens Immulite 1000
	KIU/l = IU/ml	213	170	256	BioMérieux Vidas
	KIU/l = IU/ml	271	163	379	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	269	215	323	Siemens Immulite 2000/2500

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Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin E	KIU/l = IU/ml	244	195	293	Abbott Architect
	KIU/l = IU/ml	262	210	314	Roche Cobas E411
	KIU/l = IU/ml	260	208	312	Roche Cobas 6000/8000
Insulin	mU/l	1.27	0.953	1.59	Siemens Centaur XP/XPT/Classic
	µU/ml	1.27	0.953	1.59	
	mU/l	0.963	0.722	1.20	Abbott Architect
	µU/ml	0.963	0.722	1.20	
	mU/l	1.81	1.36	2.26	Roche Cobas E411
	µU/ml	1.81	1.36	2.26	
	mU/l	1.79	1.34	2.24	Roche Cobas 6000/8000
	µU/ml	1.79	1.34	2.24	
Luteinising Hormone (LH)	mU/ml	2.22	1.78	2.66	Beckman Access
	mU/ml	2.90	2.32	3.48	BioMerieux Vidas
	mU/ml	5.41	4.33	6.49	Vitros Eci
	mU/ml	3.00	2.25	3.75	Siemens Centaur XP/XPT/Classic
	mU/ml	5.95	4.76	7.14	Siemens Immulite 2000
	mU/ml	2.44	1.95	2.93	Abbott Architect
	mU/ml	2.27	1.82	2.72	Beckman Dxl800
	mU/ml	3.98	3.18	4.78	Roche Cobas E411
Oestradiol	mU/ml	3.80	3.04	4.56	Roche Cobas 6000/8000
	pmol/l	293	234	352	BioMerieux Vidas
	pg/ml	79.7	63.6	95.8	
	pmol/l	101	80.8	121	Vitros Eci
	pg/ml	27.5	22.0	33.0	
	pmol/l	210	168	252	Abbott Architect
	pg/ml	57.1	45.7	68.5	
	pmol/l	235	188	282	Roche Cobas 6000/8000 (Estradiol II)
	pg/ml	63.9	51.1	76.7	
	pmol/l	205	164	246	Roche Cobas 4000/E411 (Estradiol II)
	pg/ml	55.8	44.6	67.0	
	pmol/l	190	114	266	Siemens Centaur XP/XPT/Classic Enhanced (eE2)
	pg/ml	51.7	31.0	72.4	
	pmol/l	218	174	262	Roche Cobas 6000/8000 (Estradiol III)
	pg/ml	59.3	47.3	71.3	
	pmol/l	209	167	251	Roche Cobas 4000/E411 (Estradiol III)
pg/ml	56.8	45.4	68.2		
pmol/l	174	139	209	Beckman Access / Access 2 Sensitive B84493	
pg/ml	47.3	37.8	56.8		
pmol/l	161	129	193	Beckman Dxl600/800 Sensitive B84493	
pg/ml	43.8	35.1	52.5		
Paracetamol	mmol/l	0.158	0.126	0.190	Roche Cobas 6000/8000
	mg/l	23.9	19.1	28.7	
	mmol/l	0.166	0.130	0.200	Gravimetric
	mg/l	25.1	19.7	30.3	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
Phenobarbital	µmol/l	35.5	28.4	42.6	Abbott Architect
	µg/ml	8.24	6.59	9.89	
	µmol/l	36.1	28.9	43.3	Siemens Immulite 2000/2500
	µg/ml	8.38	6.70	10.1	
Phenytoin	µmol/l	34.5	27.6	41.4	Gravimetric
	µg/ml	8.00	6.40	9.60	
	µmol/l	19.3	15.4	23.2	Abbott Architect
	µg/ml	4.87	3.89	5.85	
Phenytoin	µmol/l	18.3	14.6	22.0	Roche Cobas 6000/8000
	µg/ml	4.62	3.69	5.55	
	µmol/l	20.2	16.2	24.2	Gravimetric
	µg/ml	5.10	4.09	6.11	
Primidone	µmol/l	12.3	9.84	14.8	Gravimetric
	µg/ml	2.69	2.15	3.23	
Progesterone	nmol/l	4.19	3.35	5.03	BioMerieux Vidas
	ng/ml	1.31	1.05	1.57	
	nmol/l	2.55	2.04	3.06	Vitros ECI
	ng/ml	0.798	0.639	0.957	
	nmol/l	2.57	1.41	3.73	Siemens Centaur XP/XPT/Classic
	ng/ml	0.804	0.442	1.17	
	nmol/l	2.69	2.15	3.23	Siemens Immulite 2000/2500
	ng/ml	0.842	0.673	1.01	
	nmol/l	3.07	2.46	3.68	Abbott Architect
	ng/ml	0.961	0.770	1.15	
	nmol/l	2.53	2.02	3.04	Beckman Dxl Prog Cal 33555
	ng/ml	0.792	0.632	0.952	
	nmol/l	3.39	2.71	4.07	Roche Cobas 4000/e411 (Prog. II)
	ng/ml	1.06	0.848	1.27	
	nmol/l	3.13	2.50	3.76	Roche Cobas 6000/8000 (Prog. II)
	ng/ml	0.980	0.783	1.18	
nmol/l	1.76	1.41	2.11	Beckman Dxl Prog DE Cal A80773	
ng/ml	0.551	0.441	0.661		
nmol/l	3.49	2.79	4.19	Roche Cobas 6000/8000 (Prog. III)	
ng/ml	1.09	0.873	1.31		
nmol/l	3.47	2.78	4.16	Roche Cobas 4000/e411 (Prog. III)	
ng/ml	1.09	0.870	1.31		
Prolactin	µU/ml	127	102	152	Beckman Access
	µU/ml	135	108	162	BioMerieux Vidas
	µU/ml	215	172	258	Vitros ECI
	µU/ml	134	93.8	174	Siemens Centaur XP/XPT/Classic
	µU/ml	136	109	163	Siemens Immulite 2000/2500
	µU/ml	152	122	182	Abbott Architect
	µU/ml	131	105	157	Beckman Dxl800
	µU/ml	125	100	150	Roche Elecsys/E170/Cobas 6000/8000 PRLII
	µU/ml	132	106	158	Roche Cobas E411
µU/ml	124	99.0	149	Roche Cobas 6000/8000	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Analyte	unit	Target	Range		methods
			low	high	
PSA Free	ng/ml = µg/l	1.23	0.923	1.54	Abbott Architect
	ng/ml = µg/l	1.28	0.960	1.60	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.55	1.16	1.94	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	1.07	0.803	1.34	Roche Cobas E411
	ng/ml = µg/l	1.13	0.848	1.41	Roche Cobas 6000/8000
PSA Total	ng/ml = µg/l	1.54	1.16	1.93	Beckman Access standardised to Hybritech
	ng/ml = µg/l	1.32	0.990	1.65	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.72	1.29	2.15	bioMerieux VIDAS TPSA
	ng/ml = µg/l	1.15	0.863	1.44	Siemens Immulite 2000/2500 1st generation
	ng/ml = µg/l	1.25	0.938	1.56	Abbott Architect
	ng/ml = µg/l	1.57	1.18	1.96	Vitros ECi
	ng/ml = µg/l	1.47	1.10	1.84	Beckman Dxl standardisd to Hybritech
	ng/ml = µg/l	1.25	0.938	1.56	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	1.56	1.17	1.95	Roche Cobas E411
	ng/ml = µg/l	1.65	1.24	2.06	Roche Cobas 6000/8000
Salicylic Acid	mmol/l	0.286	0.230	0.340	Gravimetric
	mg/dl	3.95	3.18	4.70	
SHBG	nmol/l	11.8	9.44	14.2	Siemens Immulite 2000/2500
	nmol/l	10.4	8.32	12.5	Abbott Architect
	nmol/l	10.4	8.32	12.5	Beckman Dxl800
T Uptake	%U	32.8	26.9	38.7	Siemens Immulite 2000
Testosterone	nmol/l	1.59	1.03	2.15	Siemens Centaur XP/XPT/Classic
	ng/ml	0.458	0.298	0.618	
	ng/dl	45.8	29.8	61.8	
	nmol/l	2.02	1.62	2.42	Abbott Architect
	ng/ml	0.582	0.467	0.697	
	ng/dl	58.2	46.7	69.7	
	nmol/l	1.42	1.14	1.70	Beckman Dxl800
	ng/ml	0.409	0.328	0.490	
	ng/dl	40.9	32.8	49.0	
	nmol/l	1.80	1.44	2.16	Roche Cobas 4000/e411 Test II
	ng/ml	0.518	0.415	0.621	
	ng/dl	51.8	41.5	62.1	
	nmol/l	1.67	1.34	2.00	Roche Cobas 6000 Test 2
	ng/ml	0.481	0.386	0.576	
	ng/dl	48.1	38.6	57.6	
nmol/l	2.00	1.60	2.40	Abbott Architect 2nd Generation	
ng/ml	0.576	0.461	0.691		
ng/dl	57.6	46.1	69.1		
nmol/l	1.65	1.07	2.23	Siemens Centaur TST II	
ng/ml	0.475	0.309	0.641		
ng/dl	47.5	30.9	64.1		
Theophylline	µmol/l	28.3	22.6	34.0	Gravimetric
	µg/ml	5.10	4.07	6.13	
Thyroglobulin	ng/ml	0.692	0.519	0.865	Siemens Immulite 2000

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range					
Analyte	unit	Target	low	high	methods
Thyroglobulin	ng/ml	3.11	2.33	3.89	Roche Cobas 6000/8000
	ng/ml	3.09	2.32	3.86	Roche Cobas 6000 TGII
	ng/ml	2.97	2.23	3.71	Roche Cobas 4000/E411 TGII
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.100	0.080	0.120	Siemens Immulite 1000
	µU/ml = mIU/l	0.067	0.054	0.080	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	0.076	0.052	0.100	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	0.067	0.054	0.080	Siemens Immulite 2000/2500
	µU/ml = mIU/l	0.066	0.053	0.079	Abbott Architect
	µU/ml = mIU/l	0.103	0.082	0.124	Roche Cobas E411
	µU/ml = mIU/l	0.100	0.080	0.120	Roche Cobas 6000/8000
	µU/ml = mIU/l	0.063	0.050	0.076	Beckman Dxl800 Hyper TSH
	µU/ml = mIU/l	0.079	0.054	0.104	Siemens Centaur XP/XPT/Classic TSH3-Ultra
Tobramycin	µmol/l	4.17	3.34	5.00	Gravimetric
	µg/ml	1.95	1.56	2.34	
Total Beta hCG	mU/ml=IU/l	17.3	13.8	20.8	BioMerieux Vidas
	IU/ml	0.017	0.014	0.020	
	mU/ml=IU/l	9.96	7.97	12.0	Roche Cobas Core EIA
	IU/ml	0.010	0.008	0.012	
	mU/ml=IU/l	18.6	14.9	22.3	Vitros ECI
	IU/ml	0.019	0.015	0.023	
	mU/ml=IU/l	15.0	9.00	21.0	Siemens Centaur XP/XPT/Classic
	IU/ml	0.015	0.009	0.021	
	mU/ml=IU/l	24.8	19.8	29.8	Siemens Immulite 2000
	IU/ml	0.025	0.020	0.030	
	mU/ml=IU/l	10.1	8.08	12.1	Abbott Architect
	IU/ml	0.010	0.008	0.012	
	mU/ml=IU/l	17.8	14.2	21.4	Siemens Dimension
	IU/ml	0.018	0.014	0.022	
	mU/ml=IU/l	11.4	9.12	13.7	Beckman Dxl800
	IU/ml	0.011	0.009	0.013	
	mU/ml=IU/l	13.7	11.0	16.4	Roche STAT (Intact)
	IU/ml	0.014	0.011	0.017	
mU/ml=IU/l	10.6	8.48	12.7	Roche hCG+Beta	
IU/ml	0.011	0.008	0.014		
mU/ml=IU/l	11.6	9.28	13.9	Beckman Access Total BhCG (5th IS)	
IU/ml	0.012	0.009	0.015		
mU/ml=IU/l	11.5	9.20	13.8	Beckman Dxl Total BhCG (5th IS)	
IU/ml	0.012	0.009	0.015		
Total T3	nmol/l	0.403	0.302	0.504	Siemens Centaur XP/XPT/Classic
	ng/ml	0.262	0.197	0.327	
	ng/dl	26.2	19.7	32.7	
	nmol/l	0.616	0.462	0.770	Siemens Immulite 2000/2500
	ng/ml	0.401	0.301	0.501	
	ng/dl	40.1	30.1	50.1	
	nmol/l	0.658	0.494	0.823	Abbott Architect
	ng/ml	0.428	0.322	0.534	
	ng/dl	42.8	32.2	53.4	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range						
Analyte	unit	Target	low	high	methods	
Total T3	nmol/l	0.519	0.389	0.649	Vitros ECI	
	ng/ml	0.338	0.253	0.423		
	ng/dl	33.8	25.3	42.3		
	nmol/l	1.16	0.870	1.45	Roche Cobas E411	
		ng/ml	0.755	0.566		0.944
		ng/dl	75.5	56.6		94.4
	nmol/l	0.872	0.654	1.09	Roche Cobas 6000/8000	
		ng/ml	0.568	0.426		0.710
		ng/dl	56.8	42.6		71.0
Total T4	nmol/l	28.5	21.4	35.6	Vitros ECI	
	µg/dl	2.22	1.67	2.77		
	ng/ml	22.2	16.7	27.7		
	nmol/l	31.5	23.6	39.4	BioMerieux Vidas	
		µg/dl	2.46	1.84		3.08
		ng/ml	24.6	18.4		30.8
	nmol/l	22.7	15.9	29.5	Siemens Centaur XP/XPT/Classic	
		µg/dl	1.77	1.24		2.30
		ng/ml	17.7	12.4		23.0
	nmol/l	22.5	16.9	28.1	Siemens Immulite 2000/2500	
		µg/dl	1.76	1.32		2.20
		ng/ml	17.6	13.2		22.0
	nmol/l	31.8	23.9	39.8	Abbott Architect	
		µg/dl	2.48	1.86		3.10
		ng/ml	24.8	18.6		31.0
	nmol/l	38.3	28.7	47.9	Roche Cobas E411	
		µg/dl	2.99	2.24		3.74
		ng/ml	29.9	22.4		37.4
	nmol/l	37.1	27.8	46.4	Roche Cobas 6000/8000	
		µg/dl	2.89	2.17		3.61
		ng/ml	28.9	21.7		36.1
Valproic Acid	µmol/l	166	133	199	Siemens Immulite 2000/2500	
	µg/ml	24.0	19.2	28.8		
	µmol/l	212	148	276	Siemens Centaur XP/XPT/Classic	
		µg/ml	30.6	21.4		39.8
	µmol/l	202	162	242	Siemens Dimension	
		µg/ml	29.1	23.4		34.8
	µmol/l	162	130	194	Abbott Architect	
		µg/ml	23.4	18.8		28.0
	µmol/l	206	165	247	Roche Cobas 6000/8000	
		µg/ml	29.7	23.8		35.6
	µmol/l	243	194	292	Gravimetric	
		µg/ml	35.1	28.0		42.1
Vancomycin	µmol/l	3.16	2.53	3.79	Abbott Architect	
	µg/ml	4.69	3.76	5.62		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 1975EC Size 12 x 5ml / 4 x 5ml Expiry 2023-04-28

Range					
Analyte	unit	Target	low	high	methods
Vancomycin	µmol/l	2.78	2.22	3.34	Roche Cobas 6000/8000
	µg/ml	4.13	3.30	4.96	
	µmol/l	3.43	2.74	4.12	Gravimetric
	µg/ml	5.10	4.07	6.12	
Vitamin B12	pmol/l	108	86.4	130	Beckman Access
	pg/ml	146	117	175	
	pmol/l	148	104	192	Siemens Centaur XP/XPT/Classic
	pg/ml	201	141	261	
	pmol/l	116	92.8	139	Siemens Immulite 2000
	pg/ml	157	126	188	
	pmol/l	168	134	202	Abbott Architect
	pg/ml	228	182	274	
	pmol/l	150	120	180	Vitros ECI
	pg/ml	203	163	243	
	pmol/l	104	83.2	125	Beckman Dxl800
	pg/ml	141	113	169	

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS – LEVEL I
(IA PREMIUM PLUS I)
Cat No. IA3109 / IA3112
Lot No. I975EC
GTIN: 05055273207255 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Cortisol	nmol/l	125	93.8 – 156	BioMerieux VIDAS
	µg/dl	4.50	3.38 – 5.63	
Testosterone	nmol/l	1.03	0.824 – 1.24	BioMerieux VIDAS
	ng/ml	0.297	0.238 – 0.356	
	ng/dl	29.7	23.8 – 35.6	BioMerieux VIDAS Testosterone II
	nmol/l	0.990	0.792 – 1.19	
	ng/ml	0.285	0.228 – 0.342	
	ng/dl	28.5	22.8 – 34.2	
Thyroid Stimulating Hormone	µU/ml=mIU/l	0.048	0.038 – 0.058	BioMerieux VIDAS TSH BioMerieux VIDAS TSH3 (Ultrasensitive)
	µU/ml=mIU/l	0.043	0.034 – 0.052	

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

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**ADDITIONAL VALUES FOR
 IMMUNOASSAY PREMIUM PLUS – LEVEL I
 (IA PREMIUM PLUS I)
 Cat No. IA3109 / IA3112
 Lot No. I975EC
 GTIN: 05055273207255 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
PSA Free	ng/ml= μ g/l	1.70	1.28 – 2.12	BioMerieux VIDAS

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

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ADDITIONAL VALUES FOR 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. 1975EC **EXPIRY:** 2023-04-28

Analyte	Unit	Target	Low	High	Method
17-OH-Progesterone	nmol/l	2.32	1.62	3.01	Snibe Maglumi
	ng/ml	0.767	0.537	0.997	
Alpha-fetoprotein	KIU/l=IU/ml	12.6	8.81	16.3	Snibe Maglumi
	ng/ml	10.4	7.28	13.5	
Androstenedione	nmol/l	5.99	4.18	7.80	Snibe Maglumi
	ng/ml	1.72	1.20	2.24	
Beta-2-microglobulin	µg/ml=mg/l	0.619	0.433	0.805	Snibe Maglumi
C-Peptide	nmol/l	0.841	0.590	1.09	Snibe Maglumi
	ng/ml	2.54	1.78	3.30	
CA 19-9	U/ml	9.53	6.67	12.4	Snibe Maglumi
CA125	U/ml	13.2	7.92	18.5	Snibe Maglumi
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	4.28	3.00	5.56	Snibe Maglumi
Cortisol	nmol/l	274	192	356	Snibe Maglumi
	µg/dl	9.86	6.90	12.8	
DHEA-S	nmol/l	2.22	1.56	2.88	Snibe Maglumi
	µg/dl	81.8	57.3	106	
Digoxin	nmol/l	0.456	0.319	0.593	Snibe Maglumi
	ng/ml	0.356	0.249	0.463	
Ferritin	ng/ml=µg/l	14.1	9.87	18.3	Snibe Maglumi
Free T3	pmol/l	1.08	0.307	1.84	Snibe Maglumi
	ng/dl	0.070	0.020	0.120	
	pg/ml	0.700	0.200	1.20	
Free T4	pmol/l	11.5	8.03	14.9	Snibe Maglumi
	ng/dl	0.894	0.626	1.16	
	pg/ml	8.94	6.26	11.6	
FSH	mU/ml	6.39	4.47	8.31	Snibe Maglumi
GH	µU/ml	5.65	3.96	7.33	Snibe Maglumi
	ng/ml	1.88	1.32	2.44	
Immunoglobulin E	KIU/l=IU/ml	220	154	286	Snibe Maglumi
Insulin	mU/l	2.69	1.61	3.77	Snibe Maglumi
	µU/ml	2.69	1.61	3.77	
Luteinising Hormone (LH)	mU/ml	4.97	3.48	6.46	Snibe Maglumi
Prolactin	µU/ml	135	94.5	176	Snibe Maglumi
PSA Free	ng/ml=µg/l	0.881	0.617	1.15	Snibe Maglumi
PSA Total	ng/ml=µg/l	1.42	0.994	1.85	Snibe Maglumi
Testosterone	nmol/l	< 0.694	-	-	Snibe Maglumi
	ng/ml	< 0.200	-	-	
	ng/dl	< 20.0	-	-	
Thyroid Stimulating Hormone	µU/ml=mIU/l	< 0.100	-	-	Snibe Maglumi
Total Beta hCG	mU/ml=IU/l	16.8	11.8	21.8	Snibe Maglumi
	IU/ml	0.017	0.012	0.022	
Total T3	nmol/l	< 0.338	-	-	Snibe Maglumi
	ng/ml	< 0.220	-	-	
	ng/dl	< 22.0	-	-	
Total T4	nmol/l	36.0	25.3	46.8	Snibe Maglumi
	µg/dl	2.81	1.97	3.65	
	ng/ml	28.1	19.7	36.5	

EC REP

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

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