

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. 2229EC	EXPIRY: 2025-12-28	

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
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IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	2.80	2.10	3.50	LC/MS
	ng/ml	0.927	0.695	1.16	
	nmol/l	2.16	1.62	2.70	SNIBE Maglumi Analysers
	ng/ml	0.715	0.536	0.894	
	nmol/l	1.00	0.750	1.25	IDS-Isys 17-OH Progesterone
	ng/ml	0.331	0.248	0.414	
25-OH Vitamin D	nmol/l	53.4	40.1	66.8	Diasorin Liaison
	nmol/l	24.8	18.6	31.0	Siemens Centaur XP/XPT/Classic
	nmol/l	27.7	20.8	34.6	Abbott Architect (3L52)
	nmol/l	58.6	44.0	73.3	SNIBE Maglumi Analysers
	nmol/l	123	92.3	154	Vitros Eci
	nmol/l	28.2	21.2	35.3	Tosoh Series
	nmol/l	34.7	26.0	43.4	BioMerieux Vidas
	nmol/l	48.9	36.7	61.1	Beckman Dxl 600/800
	nmol/l	53.0	39.8	66.3	Beckman Access 25 OH Vitamin D Total
	nmol/l	27.2	20.4	34.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	56.6	42.5	70.8	Diasorin Liaison XL
	nmol/l	27.5	20.6	34.4	Abbott Alinity i
	nmol/l	22.6	17.0	28.3	Siemens Atellica IM
	nmol/l	22.1	16.6	27.6	Roche Vitamin D Total II e801
ACTH	pmol/l	1.08	0.810	1.35	Siemens Immulite 2000/2500
	pg/ml	4.91	3.68	6.14	
Aldosterone	pmol/l	238	179	298	Immunotech RIA
	pg/ml	85.9	64.6	107	
	pmol/l	363	272	454	IDS iSYS
	pg/ml	131	98.1	164	
	pmol/l	121	90.8	151	Diasorin Liaison XL
	pg/ml	43.7	32.8	54.6	
Alphafoetoprotein	KIU/l = IU/ml	9.45	7.56	11.3	Abbott Architect
	ng/ml	11.4	9.15	13.7	
	KIU/l = IU/ml	9.19	7.35	11.0	BioMerieux Vidas
	ng/ml	11.1	8.89	13.3	
	KIU/l = IU/ml	11.5	9.20	13.8	Siemens Centaur XP/XPT/Classic
	ng/ml	13.9	11.1	16.7	
	KIU/l = IU/ml	9.82	7.86	11.8	Siemens Immulite 2000/2500
	ng/ml	11.9	9.51	14.3	
	KIU/l = IU/ml	10.3	8.24	12.4	Siemens Immulite 1000
	ng/ml	12.5	9.97	15.0	
	KIU/l = IU/ml	9.42	7.54	11.3	Beckman Dxl800
	ng/ml	11.4	9.12	13.7	
	KIU/l = IU/ml	10.9	8.72	13.1	Roche Elecsys
	ng/ml	13.2	10.6	15.8	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	9.74	7.79	11.7	Beckman Access
	ng/ml	11.8	9.43	14.2	
	KIU/l = IU/ml	10.4	8.32	12.5	Tosoh Series
	ng/ml	12.6	10.1	15.1	
	KIU/l = IU/ml	10.3	8.24	12.4	Vitros ECi
	ng/ml	10.7	8.56	12.8	
	KIU/l = IU/ml	11.0	8.80	13.2	Roche Cobas e601/602
	ng/ml	13.3	10.6	16.0	
	KIU/l = IU/ml	10.7	8.56	12.8	Roche Cobas 4000/E411
	ng/ml	12.9	10.4	15.4	
	KIU/l = IU/ml	11.8	9.44	14.2	SNIBE Maglumi Analysers
	ng/ml	14.3	11.4	17.2	
	KIU/l = IU/ml	10.3	8.24	12.4	Siemens Centaur CP
	ng/ml	12.5	9.97	15.0	
	KIU/l = IU/ml	11.2	8.96	13.4	Immunotech IRMA
	ng/ml	13.6	10.8	16.4	
	KIU/l = IU/ml	9.76	7.81	11.7	Sysmex HISCL Series
	ng/ml	11.8	9.45	14.2	
	KIU/l = IU/ml	9.60	7.68	11.5	Mindray CL Series
	ng/ml	11.6	9.29	13.9	
KIU/l = IU/ml	10.9	8.72	13.1	Diasorin Liaison XL	
ng/ml	13.2	10.6	15.8		
KIU/l = IU/ml	11.1	8.88	13.3	Siemens Atellica IM	
ng/ml	13.4	10.7	16.1		
KIU/l = IU/ml	9.45	7.56	11.3	Abbott Alinity i	
ng/ml	11.4	9.15	13.7		
KIU/l = IU/ml	12.0	9.60	14.4	Roche Cobas e402/e801	
ng/ml	14.5	11.6	17.4		
KIU/l = IU/ml	9.19	7.35	11.0	Tosoh AIA-CL Series	
ng/ml	11.1	8.89	13.3		
Amikacin	µmol/l	6.28	5.02	7.54	EMIT
	µg/ml	3.68	2.94	4.42	
	µmol/l	6.16	4.93	7.39	Roche Cobas 6000/8000
	µg/ml	3.61	2.89	4.33	
	µmol/l	6.34	5.07	7.61	Abbott Alinity
	µg/ml	3.71	2.97	4.45	
µmol/l	6.40	5.12	7.68	Gravimetric	
µg/ml	3.75	3.00	4.50		
Androstenedione	nmol/l	5.38	4.04	6.73	Siemens Immulite 2000
	ng/ml	1.54	1.16	1.92	
	nmol/l	4.90	3.68	6.13	LC/MS
	ng/ml	1.41	1.06	1.76	
	nmol/l	5.13	3.85	6.41	Diasorin Liaison XL
ng/ml	1.47	1.10	1.84		
Beta-2-microglobulin	µg/ml = mg/l	0.730	0.584	0.876	Abbott Architect
	µg/ml = mg/l	0.840	0.672	1.01	BioMerieux Vidas

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Analyte	unit	Target	Range		methods
			low	high	
Beta-2-microglobulin	µg/ml = mg/l	0.710	0.568	0.852	Behring Nephelometer
	µg/ml = mg/l	0.790	0.632	0.948	Siemens Immulite 2000/2500
	µg/ml = mg/l	0.560	0.448	0.672	Diasorin Liaison
	µg/ml = mg/l	0.830	0.664	0.996	Tosoh Series
	µg/ml = mg/l	0.790	0.632	0.948	Roche Cobas 6000/8000
	µg/ml = mg/l	0.660	0.528	0.792	SNIBE Maglumi Analysers
	µg/ml = mg/l	0.640	0.512	0.768	Siemens Atellica CH
	µg/ml = mg/l	0.770	0.616	0.924	Abbott Alinity
C-Peptide	nmol/l	0.540	0.405	0.675	Siemens Immulite 2000/2500
	ng/ml	1.63	1.22	2.04	
	nmol/l	0.680	0.510	0.850	Roche Elecsys
	ng/ml	2.05	1.54	2.56	
	nmol/l	0.710	0.533	0.888	Roche Cobas e601/602
	ng/ml	2.14	1.61	2.67	
	nmol/l	0.750	0.563	0.938	Diasorin Liaison
	ng/ml	2.26	1.70	2.82	
	nmol/l	0.700	0.525	0.875	Roche Cobas 4000/E411
	ng/ml	2.11	1.58	2.64	
	nmol/l	0.640	0.480	0.800	Abbott Architect
	ng/ml	1.93	1.45	2.41	
	nmol/l	0.570	0.428	0.713	Siemens Centaur XP/XPT/Classic
	ng/ml	1.72	1.29	2.15	
	nmol/l	0.670	0.503	0.838	Tosoh Series
	ng/ml	2.02	1.52	2.52	
	nmol/l	1.010	0.758	1.260	SNIBE Maglumi Analysers
	ng/ml	3.05	2.29	3.81	
	nmol/l	0.700	0.525	0.875	Roche Cobas e402/e801
	ng/ml	2.11	1.58	2.64	
nmol/l	0.530	0.398	0.663	Siemens Atellica IM	
ng/ml	1.60	1.20	2.00		
nmol/l	0.670	0.503	0.838	Vitros ECi	
ng/ml	2.02	1.52	2.52		
nmol/l	0.690	0.518	0.863	Tosoh AIA-CL Series	
ng/ml	2.08	1.56	2.60		
nmol/l	0.480	0.360	0.600	Beckman Access	
ng/ml	1.45	1.09	1.81		
nmol/l	0.630	0.473	0.788	Abbott Alinity i	
ng/ml	1.90	1.43	2.37		
CA 15-3	U/ml	25.8	20.6	31.0	Abbott Architect
	U/ml	24.4	19.5	29.3	BioMerieux Vidas
	U/ml	23.5	18.8	28.2	Siemens Centaur XP/XPT/Classic
	U/ml	22.5	18.0	27.0	Siemens Immulite 2000/2500
	U/ml	26.9	21.5	32.3	Siemens Immulite 1000
	U/ml	11.0	8.80	13.2	Beckman Dxl800
	U/ml	24.0	19.2	28.8	Roche Elecsys
	U/ml	10.8	8.64	13.0	Beckman Access

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
CA 15-3	U/ml	19.9	15.9	23.9	Vitros ECI
	U/ml	24.0	19.2	28.8	Roche Cobas e601/602
	U/ml	22.6	18.1	27.1	Immunotech IRMA
	U/ml	23.9	19.1	28.7	Roche Cobas 4000/E411
	U/ml	29.5	23.6	35.4	SNIBE Maglumi Analysers
	U/ml	12.8	10.2	15.4	Mindray CL 8000i/6000i/2000i/1200i/1000i
	U/ml	24.1	19.3	28.9	Diasorin Liaison XL
	U/ml	26.6	21.3	31.9	Siemens Atellica IM
	U/ml	23.4	18.7	28.1	Roche Cobas e402/e801
	U/ml	25.2	20.2	30.2	Abbott Alinity i
CA 19-9	U/ml	24.2	19.4	29.0	BioMerieux Vidas
	U/ml	29.7	23.8	35.6	Siemens Centaur XP/XPT/Classic
	U/ml	27.7	22.2	33.2	Siemens Immulite 2000/2500
	U/ml	33.3	26.6	40.0	Beckman Dxl800
	U/ml	19.5	15.6	23.4	Roche Elecsys
	U/ml	35.8	28.6	43.0	Beckman Access
	U/ml	27.1	21.7	32.5	Tosoh Series
	U/ml	38.2	30.6	45.8	Vitros ECI
	U/ml	57.4	45.9	68.9	Abbott Architect XR/XR2/XRL
	U/ml	21.4	17.1	25.7	Roche Cobas e601/602
	U/ml	21.2	17.0	25.4	Roche Cobas 4000/E411
	U/ml	19.7	15.8	23.6	SNIBE Maglumi Analysers
	U/ml	27.5	22.0	33.0	Izotop RIA
	U/ml	31.2	25.0	37.4	Siemens Centaur CP
	U/ml	19.6	15.7	23.5	Immunotech IRMA
	U/ml	18.4	14.7	22.1	Mindray CL 8000i/6000i/2000i/1200i/1000i
	U/ml	29.4	23.5	35.3	Diasorin Liaison XL
	U/ml	35.6	28.5	42.7	Siemens Atellica IM
	U/ml	23.3	18.6	28.0	Roche Cobas e402/e801
	U/ml	59.3	47.4	71.2	Abbott Alinity XR/XR2/XRL
CA125	U/ml	27.3	21.8	32.8	Abbott Architect
	U/ml	20.1	16.1	24.1	BioMerieux Vidas
	U/ml	20.9	16.7	25.1	Siemens Centaur XP/XPT/Classic OV Kit
	U/ml	21.3	17.0	25.6	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	16.8	13.4	20.2	Siemens Immulite 2000/2500
	U/ml	15.7	12.6	18.8	Beckman Dxl800
	U/ml	18.2	14.6	21.8	Roche Elecsys
	U/ml	16.2	13.0	19.4	Beckman Access
	U/ml	33.9	27.1	40.7	Tosoh Series
	U/ml	16.3	13.0	19.6	Vitros ECI
	U/ml	18.7	15.0	22.4	Roche Cobas 4000/E411
	U/ml	18.4	14.7	22.1	Roche Cobas e601/602
	U/ml	10.5	8.40	12.6	Immunotech IRMA
	U/ml	21.8	17.4	26.2	SNIBE Maglumi Analysers
	U/ml	21.7	17.4	26.0	Siemens Centaur CP CA125 II kit
U/ml	35.8	28.6	43.0	Mindray CL 8000i/6000i/2000i/1200i/1000i	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
CA125	U/ml	23.7	19.0	28.4	Diasorin Liaison XL
	U/ml	26.3	21.0	31.6	Siemens Atellica IM
	U/ml	17.5	14.0	21.0	Roche Cobas e402/e801
	U/ml	27.4	21.9	32.9	Abbott Alinity i
Carbamazepine	µmol/l	15.6	12.5	18.7	Abbott Architect (CMIA)
	µg/ml	3.69	2.96	4.42	
	µmol/l	15.9	12.7	19.1	Siemens Centaur XP/XPT/Classic
	µg/ml	3.76	3.00	4.52	
	µmol/l	13.7	11.0	16.4	Siemens Immulite 2000/2500
	µg/ml	3.24	2.60	3.88	
	µmol/l	15.2	12.2	18.2	Roche Integra
	µg/ml	3.59	2.88	4.30	
	µmol/l	14.6	11.7	17.5	Roche Cobas 6000/8000
	µg/ml	3.45	2.77	4.13	
	µmol/l	14.5	11.6	17.4	Beckman AU400/600/640/2700/5400
	µg/ml	3.43	2.74	4.12	
	µmol/l	14.2	11.4	17.0	Abbott Architect (PETINA)
	µg/ml	3.36	2.69	4.03	
	µmol/l	12.8	10.2	15.4	Siemens Atellica CH
	µg/ml	3.03	2.41	3.65	
	µmol/l	12.6	10.1	15.1	Abbott Alinity (CMIA)
	µg/ml	2.98	2.39	3.57	
µmol/l	13.6	10.9	16.3	Abbott Alinity (PETINA)	
µg/ml	3.22	2.58	3.86		
µmol/l	15.4	12.3	18.5	Gravimetric	
µg/ml	3.64	2.91	4.37		
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	3.75	3.00	4.50	Abbott Architect
	ng/ml = µg/l	2.94	2.35	3.53	BioMerieux Vidas
	ng/ml = µg/l	3.42	2.74	4.10	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	3.60	2.88	4.32	Siemens Immulite 2000/2500
	ng/ml = µg/l	3.99	3.19	4.79	Siemens Immulite 1000
	ng/ml = µg/l	3.09	2.47	3.71	Beckman Dxl800
	ng/ml = µg/l	3.34	2.67	4.01	Roche Elecsys
	ng/ml = µg/l	3.22	2.58	3.86	Beckman Access
	ng/ml = µg/l	4.73	3.78	5.68	Tosoh Series
	ng/ml = µg/l	3.34	2.67	4.01	Vitros ECi
	ng/ml = µg/l	3.25	2.60	3.90	Roche Cobas e601/602
	ng/ml = µg/l	2.96	2.37	3.55	Immunotech IRMA
	ng/ml = µg/l	3.36	2.69	4.03	Roche Cobas 4000/E411
	ng/ml = µg/l	4.26	3.41	5.11	SNIBE Maglumi Analysers
	ng/ml = µg/l	4.05	3.24	4.86	Boditech Med Inc i-CHROMA
	ng/ml = µg/l	3.57	2.86	4.28	Siemens Centaur CP
	ng/ml = µg/l	2.90	2.32	3.48	Mindray CL 8000i/6000i/2000i/1200i/1000i
	ng/ml = µg/l	3.55	2.84	4.26	Diasorin Liaison XL
ng/ml = µg/l	3.34	2.67	4.01	Siemens Atellica IM	
ng/ml = µg/l	3.12	2.50	3.74	Roche Cobas e402/e801	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Carcinoembryonic	ng/ml = µg/l	3.63	2.90	4.36	Abbott Alinity i
Cortisol	nmol/l	216	162	270	Abbott Architect
	µg/dl	7.78	5.83	9.73	
	nmol/l	143	107	179	BioMerieux Vidas
	µg/dl	5.15	3.85	6.45	
	nmol/l	173	130	216	Siemens Centaur XP/XPT/Classic
	µg/dl	6.23	4.68	7.78	
	nmol/l	178	134	223	Siemens Immulite 2000/2500
	µg/dl	6.41	4.82	8.00	
	nmol/l	184	138	230	Siemens Immulite 1000
	µg/dl	6.62	4.97	8.27	
	nmol/l	205	154	256	Beckman Dxl800
	µg/dl	7.38	5.54	9.22	
	nmol/l	188	141	235	Roche Elecsys
	µg/dl	6.77	5.08	8.46	
	nmol/l	212	159	265	Beckman Access
	µg/dl	7.63	5.72	9.54	
	nmol/l	202	152	253	Tosoh Series
	µg/dl	7.27	5.47	9.07	
	nmol/l	147	110	184	Vitros ECi
	µg/dl	5.29	3.96	6.62	
	nmol/l	188	141	235	Roche Cobas e601/602
	µg/dl	6.77	5.08	8.46	
	nmol/l	199	149	249	Roche Cobas 4000/E411
	µg/dl	7.16	5.36	8.96	
	nmol/l	379	284	474	Immunotech RIA
	µg/dl	13.6	10.2	17.0	
	nmol/l	297	223	371	SNIBE Maglumi Analysers
	µg/dl	10.7	8.03	13.4	
nmol/l	197	148	246	Siemens Centaur CP	
µg/dl	7.09	5.33	8.85		
nmol/l	196	147	245	Roche Cobas 4000/e411 Gen II	
µg/dl	7.06	5.29	8.83		
nmol/l	191	143	239	Roche Cobas e601/602 Gen II	
µg/dl	6.88	5.15	8.61		
nmol/l	195	146	244	Roche Elecsys Gen II	
µg/dl	7.02	5.26	8.78		
nmol/l	194	146	243	Diasorin Liaison XL	
µg/dl	6.98	5.26	8.70		
nmol/l	169	127	211	Siemens Atellica IM	
µg/dl	6.08	4.57	7.59		
nmol/l	188	141	235	Roche Cobas e402/e801	
µg/dl	6.77	5.08	8.46		
nmol/l	196	147	245	Tosoh AIA-CL Series	
µg/dl	7.06	5.29	8.83		
nmol/l	217	163	271	Abbott Alinity i	
µg/dl	7.81	5.87	9.75		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
DHEA-S	µmol/l	2.12	1.70	2.54	Abbott Architect
	µmol/l	1.74	1.39	2.09	Siemens Immulite 2000/2500
	µmol/l	1.58	1.26	1.90	Siemens Immulite 1000
	µmol/l	2.11	1.69	2.53	Beckman Dxl800
	µmol/l	3.02	2.42	3.62	Roche Elecsys
	µmol/l	2.25	1.80	2.70	Beckman Access
	µmol/l	1.99	1.59	2.39	Siemens Centaur XP/XPT/Classic
	µmol/l	2.76	2.21	3.31	Roche Cobas 4000/E411
	µmol/l	2.65	2.12	3.18	Roche Cobas e601/602
	µmol/l	1.54	1.23	1.85	SNIBE Maglumi Analysers
	µmol/l	2.03	1.62	2.44	Siemens Atellica IM
	µmol/l	2.64	2.11	3.17	Roche Cobas e402/e801
µmol/l	2.04	1.63	2.45	Abbott Alinity i	
Digoxin	nmol/l	0.600	0.480	0.720	Abbott Architect (CMIA)
	ng/ml	0.470	0.370	0.560	
	nmol/l	0.590	0.470	0.710	BioMerieux Vidas
	ng/ml	0.460	0.370	0.550	
	nmol/l	0.909	0.730	1.09	Siemens Centaur XP/XPT/Classic
	ng/ml	0.710	0.570	0.850	
	nmol/l	0.680	0.540	0.820	Siemens Dimension EXL
	ng/ml	0.530	0.420	0.640	
	nmol/l	0.803	0.640	0.960	Beckman Dxl800
	ng/ml	0.630	0.500	0.750	
	nmol/l	0.807	0.650	0.970	Roche Cobas e601/602
	ng/ml	0.630	0.510	0.760	
	nmol/l	0.881	0.700	1.06	Beckman AU400/600/640/2700/5400
	ng/ml	0.690	0.550	0.830	
	nmol/l	0.867	0.690	1.04	Roche Cobas 4000/E411
	ng/ml	0.680	0.540	0.810	
	nmol/l	0.861	0.690	1.03	Roche Cobas e402/e801
	ng/ml	0.670	0.540	0.800	
	nmol/l	1.04	0.830	1.25	Siemens Atellica IM
	ng/ml	0.810	0.650	0.980	
nmol/l	0.648	0.520	0.780	Siemens Atellica CH	
ng/ml	0.510	0.410	0.610		
nmol/l	0.814	0.650	0.980	Abbott Alinity (CMIA)	
ng/ml	0.640	0.510	0.770		
nmol/l	0.782	0.630	0.940	Abbott Alinity (PETINA)	
ng/ml	0.610	0.490	0.730		
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	19.9	15.9	23.9	Abbott Architect
	ng/ml = µg/l	16.0	12.8	19.2	BioMerieux Vidas

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Ferritin	ng/ml = µg/l	14.7	11.8	17.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	22.5	18.0	27.0	Siemens Dimension
	ng/ml = µg/l	17.6	14.1	21.1	Siemens Immulite 2000/2500
	ng/ml = µg/l	18.9	15.1	22.7	Siemens Immulite 1000
	ng/ml = µg/l	12.4	9.92	14.9	Beckman Dxl800
	ng/ml = µg/l	20.9	16.7	25.1	Roche Elecsys/Cobas e411
	ng/ml = µg/l	20.6	16.5	24.7	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	13.1	10.5	15.7	Beckman Access
	ng/ml = µg/l	12.4	9.92	14.9	Tosoh Series
	ng/ml = µg/l	14.0	11.2	16.8	Vitros Eci
	ng/ml = µg/l	21.3	17.0	25.6	Roche Cobas 4000/c311
	ng/ml = µg/l	16.4	13.1	19.7	Beckman AU400/600/640/2700/5400
	ng/ml = µg/l	21.8	17.4	26.2	Roche Cobas c501/502/503/701/702
	ng/ml = µg/l	16.6	13.3	19.9	SNIBE Maglumi Analysers
	ng/ml = µg/l	13.7	11.0	16.4	Siemens Centaur CP
	ng/ml = µg/l	17.4	13.9	20.9	Diasorin Liaison XL
	ng/ml = µg/l	20.6	16.5	24.7	Abbott Alinity i
	ng/ml = µg/l	13.7	11.0	16.4	Siemens Atellica IM
ng/ml = µg/l	20.5	16.4	24.6	Roche Cobas e402/e801	
Folate	nmol/l	5.99	4.55	7.43	Abbott Architect
	ng/ml	2.64	2.01	3.27	
	nmol/l	14.1	10.7	17.5	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	6.22	4.72	7.72	
	nmol/l	4.26	3.24	5.28	Siemens Immulite 2000
	ng/ml	1.88	1.43	2.33	
	nmol/l	5.40	4.10	6.70	Beckman Dxl 600 / 800 - A14208
	ng/ml	2.38	1.81	2.95	
	nmol/l	5.82	4.42	7.22	Beckman Access
	ng/ml	2.57	1.95	3.19	
	nmol/l	7.63	5.80	9.46	Tosoh Series
	ng/ml	3.36	2.56	4.16	
	nmol/l	4.59	3.49	5.69	Vitros Eci
	ng/ml	2.02	1.54	2.50	
	nmol/l	5.73	4.35	7.11	Beckman Dxl 600 / 800 - A98032
	ng/ml	2.53	1.92	3.14	
	nmol/l	5.41	4.11	6.71	Roche Folate III - 07559992
	ng/ml	2.39	1.81	2.97	
nmol/l	16.6	12.6	20.6	Siemens Atellica IM	
ng/ml	7.32	5.56	9.08		
nmol/l	6.23	4.73	7.73	Abbott Alinity i	
ng/ml	2.75	2.09	3.41		
nmol/l	4.99	3.79	6.19	Roche Folate 07027290 e801	
ng/ml	2.20	1.67	2.73		
Free T3	pmol/l	3.33	2.50	4.16	Abbott Architect, 2 point calibration
	ng/dl	0.216	0.163	0.269	
	pg/ml	2.17	1.63	2.71	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Free T3	pmol/l	3.55	2.66	4.44	BioMerieux Vidas
	ng/dl	0.231	0.173	0.289	
	pg/ml	2.31	1.73	2.89	
	pmol/l	4.68	3.51	5.85	Siemens Centaur XP/XPT/Classic
	ng/dl	0.304	0.228	0.380	
	pg/ml	3.05	2.29	3.81	
	pmol/l	3.43	2.57	4.29	Siemens Immulite 2000/2500
	ng/dl	0.223	0.167	0.279	
	pg/ml	2.23	1.67	2.79	
	pmol/l	2.94	2.21	3.68	Siemens Immulite 1000
	ng/dl	0.191	0.144	0.238	
	pg/ml	1.91	1.44	2.38	
	pmol/l	3.92	2.94	4.90	Beckman DxI800
	ng/dl	0.255	0.191	0.319	
	pg/ml	2.55	1.91	3.19	
	pmol/l	4.71	3.53	5.89	Roche Elecsys
	ng/dl	0.306	0.229	0.383	
	pg/ml	3.07	2.30	3.84	
	pmol/l	4.01	3.01	5.01	Beckman Access
	ng/dl	0.261	0.196	0.326	
	pg/ml	2.61	1.96	3.26	
	pmol/l	3.64	2.73	4.55	Tosoh Series
	ng/dl	0.237	0.177	0.297	
	pg/ml	2.37	1.78	2.96	
	pmol/l	7.67	5.75	9.59	Vitros ECI
	ng/dl	0.499	0.374	0.624	
	pg/ml	4.99	3.74	6.24	
	pmol/l	4.82	3.62	6.03	Roche Cobas 4000/E411
	ng/dl	0.313	0.235	0.391	
	pg/ml	3.14	2.36	3.92	
pmol/l	4.61	3.46	5.76	Roche Cobas e601/602	
ng/dl	0.300	0.225	0.375		
pg/ml	3.00	2.25	3.75		
pmol/l	4.67	3.50	5.84	Siemens Centaur CP	
ng/dl	0.304	0.228	0.380		
pg/ml	3.04	2.28	3.80		
pmol/l	4.08	3.06	5.10	Mindray CL 8000i/6000i/2000i/1200i/1000i	
ng/dl	0.265	0.199	0.331		
pg/ml	2.66	1.99	3.33		
pmol/l	3.29	2.47	4.11	Sysmex HISCL Series	
ng/dl	0.214	0.161	0.267		
pg/ml	2.14	1.61	2.67		
pmol/l	3.65	2.74	4.56	Diasorin Liaison XL	
ng/dl	0.237	0.178	0.296		
pg/ml	2.38	1.78	2.98		
pmol/l	5.04	3.78	6.30	Siemens Atellica IM	
ng/dl	0.328	0.246	0.410		
pg/ml	3.28	2.46	4.10		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Free T3	pmol/l	3.34	2.51	4.18	Abbott Alinity, 2 point cal
	ng/dl	0.217	0.163	0.271	
	pg/ml	2.17	1.63	2.71	
	pmol/l	3.38	2.54	4.23	Abbott Architect, 6 point calibration
	ng/dl	0.220	0.165	0.275	
	pg/ml	2.20	1.65	2.75	
	pmol/l	4.58	3.44	5.73	Roche Cobas e402/e801
	ng/dl	0.298	0.224	0.372	
	pg/ml	2.98	2.24	3.72	
	pmol/l	2.91	2.18	3.64	Tosoh AIA-CL Series
	ng/dl	0.189	0.142	0.236	
	pg/ml	1.89	1.42	2.36	
pmol/l	3.32	2.49	4.15	Abbott Alinity, 6 point cal	
ng/dl	0.220	0.160	0.270		
pg/ml	2.16	1.62	2.70		
pmol/l	2.73	2.05	3.41	SNIBE Maglumi Analysers	
ng/dl	0.180	0.130	0.220		
pg/ml	1.78	1.33	2.22		
Free T4	pmol/l	9.55	7.16	11.9	Abbott Architect
	ng/dl	0.745	0.558	0.932	
	pg/ml	7.45	5.58	9.32	
	pmol/l	8.38	6.29	10.5	Siemens Centaur XP/XPT/Classic
	ng/dl	0.654	0.491	0.817	
	pg/ml	6.54	4.91	8.17	
	pmol/l	12.7	9.53	15.9	Siemens Immulite 2000/2500
	ng/dl	0.991	0.743	1.24	
	pg/ml	9.91	7.43	12.4	
	pmol/l	11.8	8.85	14.8	Siemens Immulite 1000
	ng/dl	0.920	0.690	1.15	
	pg/ml	9.20	6.90	11.5	
	pmol/l	9.77	7.33	12.2	Beckman Dxl800
	ng/dl	0.762	0.572	0.952	
	pg/ml	7.62	5.72	9.52	
	pmol/l	12.7	9.53	15.9	Roche Elecsys
	ng/dl	0.991	0.743	1.24	
	pg/ml	9.91	7.43	12.4	
pmol/l	10.0	7.50	12.5	Beckman Access	
ng/dl	0.780	0.585	0.975		
pg/ml	7.80	5.85	9.75		
pmol/l	9.77	7.33	12.2	Tosoh Series	
ng/dl	0.762	0.572	0.952		
pg/ml	7.62	5.72	9.52		
pmol/l	15.5	11.6	19.4	Vitros ECi	
ng/dl	1.21	0.905	1.52		
pg/ml	12.1	9.05	15.2		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	12.9	9.68	16.1	Roche Cobas e601/602
	ng/dl	1.01	0.755	1.27	
	pg/ml	10.1	7.55	12.7	
	pmol/l	13.0	9.75	16.3	Roche Cobas 4000/E411
	ng/dl	1.01	0.761	1.26	
	pg/ml	10.1	7.61	12.6	
	pmol/l	12.1	9.08	15.1	SNIBE Maglumi Analysers
	ng/dl	0.944	0.708	1.18	
	pg/ml	9.44	7.08	11.8	
	pmol/l	11.6	8.70	14.5	Biomerieux Vidas FT4N Kit
	ng/dl	0.905	0.679	1.13	
	pg/ml	9.05	6.79	11.3	
	pmol/l	10.7	8.03	13.4	Immunotech RIA
	ng/dl	0.835	0.626	1.04	
	pg/ml	8.35	6.26	10.4	
	pmol/l	9.29	6.97	11.6	Siemens Dimension Exl LOCI
	ng/dl	0.725	0.544	0.906	
	pg/ml	7.25	5.44	9.06	
	pmol/l	8.80	6.60	11.0	Siemens Centaur CP
	ng/dl	0.686	0.515	0.857	
	pg/ml	6.86	5.15	8.57	
	pmol/l	10.6	7.95	13.3	Mindray CL 8000i/6000i/2000i/1200i/1000i
	ng/dl	0.827	0.620	1.03	
	pg/ml	8.27	6.20	10.3	
pmol/l	9.10	6.83	11.4	Sysmex HISCL Series	
ng/dl	0.710	0.533	0.887		
pg/ml	7.10	5.33	8.87		
pmol/l	11.1	8.33	13.9	Diasorin Liaison XL	
ng/dl	0.866	0.650	1.08		
pg/ml	8.66	6.50	10.8		
pmol/l	9.06	6.80	11.3	Siemens Atellica IM	
ng/dl	0.707	0.530	0.884		
pg/ml	7.07	5.30	8.84		
pmol/l	9.69	7.27	12.1	Abbott Alinity i	
ng/dl	0.756	0.567	0.945		
pg/ml	7.56	5.67	9.45		
pmol/l	12.9	9.68	16.1	Roche Cobas e402/e801	
ng/dl	1.01	0.755	1.27		
pg/ml	10.1	7.55	12.7		
pmol/l	10.9	8.18	13.6	Tosoh AIA-CL Series	
ng/dl	0.850	0.640	1.06		
pg/ml	8.50	6.38	10.6		
FSH	mU/ml	7.01	5.61	8.41	Abbott Architect
	mU/ml	7.50	6.00	9.00	BioMerieux Vidas
	mU/ml	9.93	7.94	11.9	Siemens Centaur XP/XPT/Classic

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
FSH	mU/ml	7.95	6.36	9.54	Siemens Immulite 2000/2500
	mU/ml	8.04	6.43	9.65	Siemens Immulite 1000
	mU/ml	7.97	6.38	9.56	Beckman Dxl800
	mU/ml	7.53	6.02	9.04	Roche/BM Elecsys
	mU/ml	7.89	6.31	9.47	Beckman Access
	mU/ml	9.26	7.41	11.1	Tosoh Series
	mU/ml	6.24	4.99	7.49	Vitros ECi
	mU/ml	8.11	6.49	9.73	Roche Cobas 4000/E411
	mU/ml	7.54	6.03	9.05	Roche Cobas e601/602
	mU/ml	7.83	6.26	9.40	SNIBE Maglumi Analysers
	mU/ml	8.11	6.49	9.73	Siemens Centaur CP
	mU/ml	8.92	7.14	10.7	Mindray CL 8000i/6000i/2000i/1200i/1000i
	mU/ml	10.8	8.64	13.0	Diasorin Liaison XL
	mU/ml	8.60	6.88	10.3	Siemens Atellica IM
	Gentamicin	mU/ml	7.24	5.79	8.69
mU/ml		7.74	6.19	9.29	Roche Cobas e402/e801
µmol/l		4.66	3.73	5.59	Roche Integra
µg/ml		2.23	1.78	2.68	
µmol/l		4.41	3.53	5.29	Abbott Architect (CMIA)
µg/ml		2.11	1.69	2.53	
µmol/l		3.41	2.73	4.09	Roche Cobas 6000/8000 Online KIMS
µg/ml		1.63	1.30	1.96	
µmol/l		4.53	3.62	5.44	Siemens Atellica CH
µg/ml		2.17	1.73	2.61	
Growth Hormone (GH)	µmol/l	4.87	3.90	5.84	Abbott Alinity (PETINA)
	µg/ml	2.33	1.86	2.80	
	µmol/l	4.85	3.88	5.82	Gravimetric
	µg/ml	2.32	1.85	2.78	
	µU/ml	4.66	3.73	5.59	Siemens Immulite 2000/2500
	ng/ml	1.55	1.24	1.86	
	µU/ml	4.55	3.64	5.46	Siemens Immulite 1000
	ng/ml	1.52	1.21	1.83	
	µU/ml	3.18	2.54	3.82	Beckman Dxl800
	ng/ml	1.06	0.846	1.27	
	µU/ml	3.37	2.70	4.04	Beckman Access
	ng/ml	1.12	0.899	1.34	
	µU/ml	4.61	3.69	5.53	Tosoh Series
	ng/ml	1.54	1.23	1.85	
	µU/ml	4.85	3.88	5.82	Roche Cobas 4000/E411
ng/ml	1.62	1.29	1.95		
µU/ml	6.91	5.53	8.29	SNIBE Maglumi Analysers	
ng/ml	2.30	1.84	2.76		
µU/ml	4.78	3.82	5.74	Roche Cobas e601/602	
ng/ml	1.59	1.27	1.91		
µU/ml	4.81	3.85	5.77	Roche Cobas e402/e801	
ng/ml	1.60	1.28	1.92		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Growth Hormone (GH)	µU/ml	3.51	2.81	4.21	Tosoh AIA-CL Series
	ng/ml	1.17	0.936	1.40	
Immunoglobulin E	KIU/I = IU/ml	249	199	299	Abbott Architect
	KIU/I = IU/ml	218	174	262	BioMerieux Vidas
	KIU/I = IU/ml	257	206	308	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	269	215	323	Siemens Immulite 2000/2500
	KIU/I = IU/ml	265	212	318	Siemens Immulite 1000
	KIU/I = IU/ml	260	208	312	Roche Elecsys
	KIU/I = IU/ml	255	204	306	Pharmacia Unicap
	KIU/I = IU/ml	232	186	278	Tosoh Series
	KIU/I = IU/ml	263	210	316	Roche Cobas 4000/E411
	KIU/I = IU/ml	261	209	313	Roche Cobas e601/602
	KIU/I = IU/ml	211	169	253	SNIBE Maglumi Analysers
	KIU/I = IU/ml	259	207	311	Siemens Atellica IM
	KIU/I = IU/ml	270	216	324	Roche Cobas e402/e801
	KIU/I = IU/ml	245	196	294	Abbott Alinity
Insulin	mU/l	2.01	1.51	2.51	Siemens Centaur XP/XPT/Classic
	µU/ml	2.01	1.51	2.51	
	mU/l	7.99	5.99	9.99	Siemens Immulite 2000
	µU/ml	7.99	5.99	9.99	
	mU/l	1.16	0.870	1.45	Beckman Access
	µU/ml	1.16	0.870	1.45	
	mU/l	1.39	1.04	1.74	Abbott Architect
	µU/ml	1.39	1.04	1.74	
	mU/l	1.58	1.19	1.98	Tosoh Series
	µU/ml	1.58	1.19	1.97	
	mU/l	1.43	1.07	1.79	Roche Cobas 4000/E411
	µU/ml	1.43	1.07	1.79	
	mU/l	1.10	0.825	1.38	Beckman Dxl 600/800
	µU/ml	1.10	0.825	1.38	
	mU/l	1.47	1.10	1.84	Roche Cobas 6000/8000
	µU/ml	1.47	1.10	1.84	
	mU/l	1.94	1.46	2.43	Mindray CL Series
	µU/ml	1.94	1.46	2.42	
	mU/l	1.39	1.04	1.74	Diasorin Liaison XL
	µU/ml	1.39	1.04	1.74	
mU/l	1.62	1.22	2.03	Siemens Atellica IM	
µU/ml	1.62	1.22	2.02		
mU/l	1.33	0.998	1.66	Abbott Alinity i	
µU/ml	1.33	0.998	1.66		
mU/l	1.71	1.28	2.14	Tosoh AIA-CL Series	
µU/ml	1.71	1.28	2.14		
Luteinising Hormone (LH)	mU/ml	1.66	1.33	1.99	Abbott Architect
	mU/ml	2.16	1.73	2.59	BioMerieux Vidas
	mU/ml	2.16	1.73	2.59	Siemens Centaur XP/XPT/Classic
	mU/ml	3.90	3.12	4.68	Siemens Immulite 2000

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Luteinising Hormone (LH)	mU/ml	4.48	3.58	5.38	Siemens Immulite 1000
	mU/ml	1.71	1.37	2.05	Beckman Dxl800
	mU/ml	3.17	2.54	3.80	Roche Elecsys
	mU/ml	1.74	1.39	2.09	Beckman Access
	mU/ml	1.96	1.57	2.35	Tosoh Series
	mU/ml	4.63	3.70	5.56	Vitros ECi
	mU/ml	3.17	2.54	3.80	Roche Cobas 4000/E411
	mU/ml	3.09	2.47	3.71	Roche Cobas e601/602
	mU/ml	4.18	3.34	5.02	SNIBE Maglumi Analysers
	mU/ml	2.02	1.62	2.42	Siemens Centaur CP
	mU/ml	3.05	2.44	3.66	Mindray CL 8000i/6000i/2000i/1200i/1000i
	mU/ml	3.10	2.48	3.72	Diasorin Liaison XL
	mU/ml	2.10	1.68	2.52	Siemens Atellica IM
	mU/ml	1.66	1.33	1.99	Abbott Alinity i
mU/ml	3.39	2.71	4.07	Roche Cobas e402/e801	
Oestradiol	pmol/l	152	122	182	Abbott Architect
	pg/ml	41.3	33.2	49.4	
	pmol/l	273	218	328	BioMerieux Vidas
	pg/ml	74.3	59.3	89.3	
	pmol/l	105	84.0	126	Beckman Dxl800
	pg/ml	28.6	22.8	34.4	
	pmol/l	167	134	200	Roche Elecsys (Estradiol II)
	pg/ml	45.4	36.4	54.4	
	pmol/l	104	83.2	125	Beckman Access
	pg/ml	28.3	22.6	34.0	
	pmol/l	71.4	57.1	85.7	Vitros ECi
	pg/ml	19.4	15.5	23.3	
	pmol/l	170	136	204	Roche Cobas e601/602 (Estradiol II)
	pg/ml	46.2	37.0	55.4	
	pmol/l	159	127	191	Roche Cobas 4000/E411 (Estradiol II)
	pg/ml	43.2	34.5	51.9	
	pmol/l	110	88.0	132	Tosoh (iE2-hsE2)
	pg/ml	29.9	23.9	35.9	
	pmol/l	169	135	203	Roche Cobas e601/602 (Estradiol III)
	pg/ml	46.0	36.7	55.3	
	pmol/l	159	127	191	Roche Elecsys (Estradiol III)
	pg/ml	43.2	34.5	51.9	
	pmol/l	157	126	188	Roche Cobas 4000/E411 (Estradiol III)
pg/ml	42.7	34.3	51.1		
pmol/l	113	90.4	136	Beckman Access / Access 2 Sensitive B84493	
pg/ml	30.7	24.6	36.8		
pmol/l	105	84.0	126	Beckman Dxl600/800 Sensitive B84493	
pg/ml	28.6	22.8	34.4		
pmol/l	129	103	155	Siemens Atellica IM	
pg/ml	35.1	28.0	42.2		
pmol/l	143	114	172	Abbott Alinity i	
pg/ml	38.9	31.0	46.8		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Oestradiol	pmol/l	164	131	197	Roche Cobas e801 (Estradiol III)
	pg/ml	44.6	35.6	53.6	
	pmol/l	74.2	59.4	89.0	Tosoh AIA-CL Series
	pg/ml	20.2	16.2	24.2	
Paracetamol	mmol/l	0.150	0.120	0.180	Roche Cobas c501/502/503/701/702
	mg/l	22.7	18.2	27.2	
	mmol/l	0.160	0.128	0.192	Beckman AU Instruments
	mg/l	24.2	19.4	29.0	
	mmol/l	0.160	0.128	0.192	Abbott Alinity
	mg/l	24.2	19.4	29.0	
	mmol/l	0.166	0.130	0.200	Gravimetric
	mg/l	25.1	19.7	30.3	
Phenobarbital	µmol/l	34.9	27.9	41.9	Abbott Architect (CMIA)
	µg/ml	8.10	6.47	9.73	
	µmol/l	29.3	23.4	35.2	Roche Cobas e601/602/801
	µg/ml	6.80	5.43	8.17	
	µmol/l	37.2	29.8	44.6	Beckman AU400/600/640/2700/5400
	µg/ml	8.63	6.91	10.4	
	µmol/l	47.6	38.1	57.1	Siemens Centaur XP/XPT/Classic
	µg/ml	11.0	8.84	13.2	
	µmol/l	33.6	26.9	40.3	Roche Integra
	µg/ml	7.80	6.24	9.36	
	µmol/l	33.4	26.7	40.1	Roche Cobas C303/501/502/503/701
	µg/ml	7.75	6.19	9.31	
	µmol/l	27.8	22.2	33.4	Microgenics CEDIA assay
	µg/ml	6.45	5.15	7.75	
	µmol/l	35.7	28.6	42.8	Siemens Atellica CH
	µg/ml	8.28	6.64	9.92	
Phenytoin	µmol/l	30.5	24.4	36.6	Abbott Alinity (PETINA)
	µg/ml	7.08	5.66	8.50	
	µmol/l	34.5	27.6	41.4	Gravimetric
	µg/ml	8.00	6.40	9.60	
	µmol/l	19.5	15.6	23.4	Abbott Architect
	µg/ml	4.92	3.94	5.90	
	µmol/l	19.0	15.2	22.8	Siemens Centaur XP/XPT/Classic
	µg/ml	4.80	3.84	5.76	
	µmol/l	19.2	15.4	23.0	Roche Integra
	µg/ml	4.85	3.89	5.81	
	µmol/l	17.7	14.2	21.2	Roche Cobas 6000/8000
	µg/ml	4.47	3.59	5.35	
	µmol/l	19.7	15.8	23.6	Beckman AU Instruments
	µg/ml	4.97	3.99	5.95	
µmol/l	18.9	15.1	22.7	EMIT	
µg/ml	4.77	3.81	5.73		
µmol/l	18.3	14.6	22.0	Siemens Atellica CH	
µg/ml	4.62	3.69	5.55		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Phenytoin	µmol/l	19.5	15.6	23.4	Abbott Alinity
	µg/ml	4.92	3.94	5.90	
	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	2.96	2.37	3.55	Abbott Architect
	ng/ml	0.926	0.742	1.11	
	nmol/l	3.63	2.90	4.36	BioMerieux Vidas
	ng/ml	1.14	0.908	1.37	
	nmol/l	2.70	2.16	3.24	Siemens Centaur XP/XPT/Classic
	ng/ml	0.845	0.676	1.01	
	nmol/l	2.83	2.26	3.40	Siemens Immulite 2000/2500
	ng/ml	0.886	0.707	1.07	
	nmol/l	2.74	2.19	3.29	Siemens Immulite 1000
	ng/ml	0.858	0.685	1.03	
	nmol/l	2.40	1.92	2.88	Beckman Dxl Prog Cal 33555
	ng/ml	0.751	0.601	0.901	
	nmol/l	3.73	2.98	4.48	Roche Elecsys (Prog. II)
	ng/ml	1.17	0.933	1.41	
	nmol/l	2.40	1.92	2.88	Vitros ECi
	ng/ml	0.751	0.601	0.901	
	nmol/l	3.54	2.83	4.25	Roche Cobas 4000/e411 (Prog. II)
	ng/ml	1.11	0.886	1.33	
	nmol/l	3.58	2.86	4.30	Roche Cobas e601/602 (Prog. II)
	ng/ml	1.12	0.895	1.35	
	nmol/l	2.57	2.06	3.08	Beckman Access Prog DE Cal A80773
	ng/ml	0.804	0.645	0.963	
	nmol/l	2.74	2.19	3.29	Mindray CL 8000i/6000i/2000i/1200i/1000i
	ng/ml	0.858	0.685	1.03	
	nmol/l	3.61	2.89	4.33	Roche Cobas e601/602 (Prog. III)
	ng/ml	1.13	0.905	1.36	
	nmol/l	3.56	2.85	4.27	Roche Elecsys (Prog. III)
	ng/ml	1.11	0.892	1.33	
	nmol/l	3.47	2.78	4.16	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	1.09	0.870	1.31	
	nmol/l	2.04	1.63	2.45	Diasorin Liaison XL
	ng/ml	0.639	0.510	0.768	
nmol/l	2.67	2.14	3.20	Abbott Alinity i	
ng/ml	0.836	0.670	1.00		
nmol/l	2.80	2.24	3.36	Siemens Atellica IM	
ng/ml	0.876	0.701	1.05		
nmol/l	3.33	2.66	4.00	Roche Cobas e801 (Prog. III)	
ng/ml	1.04	0.833	1.25		
nmol/l	3.98	3.18	4.78	Tosoh AIA-CL Series	
ng/ml	1.25	0.995	1.51		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Prolactin	µU/ml	137	110	164	Abbott Architect
	µU/ml	127	102	152	BioMerieux Vidas
	µU/ml	125	100	150	Siemens Centaur XP/XPT/Classic
	µU/ml	124	99.0	149	Siemens Immulite 2000/2500
	µU/ml	141	113	169	Siemens Immulite 1000
	µU/ml	116	92.8	139	Beckman Dxl800
	µU/ml	145	116	174	Roche Elecsys
	µU/ml	125	100	150	Beckman Access
	µU/ml	131	105	157	Tosoh Series
	µU/ml	184	147	221	Vitros ECi
	µU/ml	142	114	170	Roche Elecsys/E170/Cobas 6000/8000 PRLII
	µU/ml	129	103	155	Immunotech IRMA
	µU/ml	149	119	179	Roche Cobas 4000/E411
	µU/ml	142	114	170	Roche Cobas e601/602
	µU/ml	153	122	184	SNIBE Maglumi Analysers
	µU/ml	120	96.0	144	Siemens Centaur CP
	µU/ml	178	142	214	Mindray CL 8000i/6000i/2000i/1200i/1000i
	PSA Free	ng/ml = µg/l	1.47	1.10	1.84
ng/ml = µg/l		2.05	1.54	2.56	BioMerieux Vidas
ng/ml = µg/l		1.40	1.05	1.75	Siemens Centaur XP/XPT/Classic
ng/ml = µg/l		1.23	0.923	1.54	Siemens Immulite 2000/2500
ng/ml = µg/l		1.75	1.31	2.19	Beckman DXI standardised to Hybritech
ng/ml = µg/l		1.20	0.900	1.50	Roche Elecsys
ng/ml = µg/l		1.80	1.35	2.25	Beckman Access standardised to Hybritech
ng/ml = µg/l		1.14	0.855	1.43	Tosoh Series
ng/ml = µg/l		1.19	0.893	1.49	Roche Cobas 4000/E411
ng/ml = µg/l		1.20	0.900	1.50	Roche Cobas e601/602
ng/ml = µg/l		1.48	1.11	1.85	Beckman Dxl800 standardised to WHO IRP96/670
ng/ml = µg/l		1.81	1.36	2.26	Beckman Access standardised to WHO IRP96/670
ng/ml = µg/l		0.970	0.728	1.21	SNIBE Maglumi Analysers
ng/ml = µg/l		1.04	0.780	1.30	Ortho Vitros 3600/5600/ECi PSA II
ng/ml = µg/l		1.53	1.15	1.91	Diasorin Liaison XL
ng/ml = µg/l		1.45	1.09	1.81	Siemens Atellica IM
ng/ml = µg/l		1.50	1.13	1.88	Abbott Alinity i
ng/ml = µg/l		1.18	0.885	1.48	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	1.23	0.923	1.54	Abbott Architect
	ng/ml = µg/l	1.62	1.22	2.03	BioMerieux Vidas
	ng/ml = µg/l	1.61	1.21	2.01	bioMerieux VIDAS TPSA
	ng/ml = µg/l	1.55	1.16	1.94	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.17	0.878	1.46	Siemens Immulite 2000/2500 1st generation
	ng/ml = µg/l	1.47	1.10	1.84	Siemens Immulite 1000 1st generation

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
PSA Total	ng/ml = µg/l	1.73	1.30	2.16	Beckman Dxl standardisd to Hybritech
	ng/ml = µg/l	1.50	1.13	1.88	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	1.58	1.19	1.98	Roche Elecsys
	ng/ml = µg/l	1.80	1.35	2.25	Beckman Access standardised to Hybritech
	ng/ml = µg/l	1.79	1.34	2.24	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	1.12	0.840	1.40	Tosoh Series
	ng/ml = µg/l	1.66	1.25	2.08	Vitros ECi
	ng/ml = µg/l	1.28	0.960	1.60	Immunotech IRMA
	ng/ml = µg/l	1.63	1.22	2.04	Roche Cobas 4000/E411
	ng/ml = µg/l	1.69	1.27	2.11	Roche Cobas e601/602
	ng/ml = µg/l	1.42	1.07	1.78	SNIBE Maglumi Analysers
	ng/ml = µg/l	1.63	1.22	2.04	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	1.53	1.15	1.91	Siemens Centaur CP
	ng/ml = µg/l	1.46	1.10	1.83	Diasorin Liaison XL
	ng/ml = µg/l	1.54	1.16	1.93	Siemens Atellica IM
ng/ml = µg/l	1.29	0.968	1.61	Abbott Alinity i	
ng/ml = µg/l	1.65	1.24	2.06	Roche Cobas e402/e801	
Salicylic Acid	mmol/l	0.270	0.216	0.324	Roche Cobas c501/502/503
	mg/dl	3.73	2.98	4.48	
	mmol/l	0.300	0.240	0.360	EMIT
	mg/dl	4.14	3.31	4.97	
	mmol/l	0.286	0.230	0.340	Gravimetric
mg/dl	3.95	3.18	4.70		
SHBG	nmol/l	10.9	8.72	13.1	Siemens Immulite 2000/2500
	nmol/l	11.1	8.88	13.3	Abbott Architect
	nmol/l	10.7	8.56	12.8	Beckman Dxl800
	nmol/l	13.5	10.8	16.2	SNIBE Maglumi Analysers
	nmol/l	9.38	7.50	11.3	Siemens Atellica IM
	nmol/l	10.6	8.48	12.7	Roche analysers - 413417/15
	nmol/l	10.4	8.32	12.5	Roche Cobas e801 - 413429
	nmol/l	10.8	8.64	13.0	Abbott Alinity i
T Uptake	%U	30.4	24.9	35.9	Siemens Immulite 2000
Testosterone	nmol/l	2.03	1.62	2.44	Abbott Architect
	ng/ml	0.585	0.467	0.703	
	ng/dl	58.5	46.7	70.3	
	nmol/l	1.03	0.824	1.24	BioMerieux Vidas
	ng/ml	0.297	0.237	0.357	
	ng/dl	29.7	23.7	35.7	
	nmol/l	1.35	1.08	1.62	Siemens Centaur XP/XPT/Classic
	ng/ml	0.389	0.311	0.467	
	ng/dl	38.9	31.1	46.7	
	nmol/l	0.910	0.728	1.09	Siemens Immulite 2000/2500
	ng/ml	0.262	0.210	0.314	
	ng/dl	26.2	21.0	31.4	
	nmol/l	1.51	1.21	1.81	Beckman Dxl800
ng/ml	0.435	0.348	0.522		
ng/dl	43.5	34.8	52.2		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	nmol/l	1.60	1.28	1.92	Beckman Access
	ng/ml	0.461	0.369	0.553	
	ng/dl	46.1	36.9	55.3	
	nmol/l	1.02	0.816	1.22	Tosoh Series
	ng/ml	0.294	0.235	0.353	
	ng/dl	29.4	23.5	35.3	
	nmol/l	0.820	0.656	0.984	Vitros ECI
	ng/ml	0.236	0.189	0.283	
	ng/dl	23.6	18.9	28.3	
	nmol/l	1.61	1.29	1.93	Roche Cobas e601/602 Test II
	ng/ml	0.464	0.372	0.556	
	ng/dl	46.4	37.2	55.6	
	nmol/l	1.71	1.37	2.05	Roche Elecsys Test II
	ng/ml	0.492	0.395	0.589	
	ng/dl	49.2	39.5	58.9	
	nmol/l	1.72	1.38	2.06	Roche Cobas 4000/e411 Test II
	ng/ml	0.495	0.397	0.593	
	ng/dl	49.5	39.7	59.3	
	nmol/l	2.60	2.08	3.12	Immunotech RIA
	ng/ml	0.749	0.599	0.899	
	ng/dl	74.9	59.9	89.9	
	nmol/l	1.97	1.58	2.36	Abbott Architect 2nd Generation
	ng/ml	0.567	0.455	0.679	
	ng/dl	56.7	45.5	67.9	
nmol/l	1.08	0.864	1.30	BioMerieux Vidas Testosterone II	
ng/ml	0.311	0.249	0.373		
ng/dl	31.1	24.9	37.3		
nmol/l	1.30	1.04	1.56	Mindray CL 8000i/6000i/2000i/1200i/1000i	
ng/ml	0.374	0.300	0.448		
ng/dl	37.4	30.0	44.8		
nmol/l	1.28	1.02	1.54	Siemens Centaur TST II	
ng/ml	0.369	0.294	0.444		
ng/dl	36.9	29.4	44.4		
nmol/l	1.21	0.968	1.45	Siemens Atellica IM	
ng/ml	0.348	0.279	0.417		
ng/dl	34.8	27.9	41.7		
nmol/l	1.72	1.38	2.06	Roche Cobas e801 Test II	
ng/ml	0.495	0.397	0.593		
ng/dl	49.5	39.7	59.3		
nmol/l	2.06	1.65	2.47	Tosoh AIA-CL Series	
ng/ml	0.593	0.475	0.711		
ng/dl	59.3	47.5	71.1		
nmol/l	1.97	1.58	2.36	Abbott Alinity i	
ng/ml	0.567	0.455	0.679		
ng/dl	56.7	45.5	67.9		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Theophylline	µmol/l	30.3	24.2	36.4	Roche Integra
	µg/ml	5.46	4.36	6.56	
	µmol/l	26.6	21.3	31.9	Roche Cobas 6000/8000
	µg/ml	4.79	3.84	5.74	
	µmol/l	25.2	20.2	30.2	Abbott Alinity Enzyme-Immu
	µg/ml	4.54	3.64	5.44	
Thyroglobulin	µmol/l	28.3	22.6	34.0	Gravimetric
	µg/ml	5.10	4.07	6.13	
	ng/ml	0.220	0.165	0.275	Siemens Immulite 1000
	ng/ml	2.27	1.70	2.84	Roche Elecsys
	ng/ml	1.74	1.31	2.18	Beckman Dxl800
	ng/ml	2.45	1.84	3.06	Roche Cobas 4000/E411
	ng/ml	2.39	1.79	2.99	Roche Cobas e601/602
	ng/ml	1.77	1.33	2.21	Beckman Access
	ng/ml	2.15	1.61	2.69	Abbott Architect 2000i
	ng/ml	0.100	0.075	0.125	SNIBE Maglumi Analysers
	ng/ml	2.42	1.82	3.03	Tosoh Series
	ng/ml	2.37	1.78	2.96	Roche Cobas e601/602 Tg II
	ng/ml	2.50	1.88	3.13	Roche Elecsys TGII
	ng/ml	2.43	1.82	3.04	Roche Cobas 4000/E411 TGII
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.100	0.080	0.120	Abbott Architect
	µU/ml = mIU/l	0.080	0.064	0.096	bioMerieux VIDAS TSH
	µU/ml = mIU/l	0.060	0.048	0.072	bioMerieux VIDAS TSH3 Ultrasensitive
	µU/ml = mIU/l	0.100	0.080	0.120	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	0.100	0.080	0.120	Siemens Centaur XP/XPT/Classic 3rd Generation
	µU/ml = mIU/l	0.090	0.072	0.108	Siemens Immulite 2000/2500
	µU/ml = mIU/l	0.120	0.096	0.144	Siemens Immulite 1000
	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Dxl800
	µU/ml = mIU/l	0.140	0.112	0.168	Roche Elecsys
	µU/ml = mIU/l	0.130	0.104	0.156	Diasorin Liaison
	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Access Fast TSH
	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	0.360	0.288	0.432	Tosoh Series
	µU/ml = mIU/l	0.100	0.080	0.120	Vitros ECi
	µU/ml = mIU/l	0.150	0.120	0.180	Immunotech IRMA
	µU/ml = mIU/l	0.140	0.112	0.168	Roche Cobas 4000/E411
	µU/ml = mIU/l	0.140	0.112	0.168	Roche Cobas e601/602
	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Dxl800 Hyper TSH
	µU/ml = mIU/l	0.120	0.096	0.144	SNIBE Maglumi Analysers
	µU/ml = mIU/l	0.100	0.080	0.120	Siemens Centaur XP/XPT/Classic TSH3-Ultra
µU/ml = mIU/l	0.100	0.080	0.120	Siemens Dimension Exl LOCI	
µU/ml = mIU/l	0.090	0.072	0.108	Siemens Centaur CP	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.090	0.072	0.108	Siemens Centaur CP TSH3-Ultra
	µU/ml = mIU/l	0.170	0.136	0.204	Mindray CL 8000i/6000i/2000i/1200i/1000i
	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Dxl 600/800 Access (3rd IS)
	µU/ml = mIU/l	0.150	0.120	0.180	Diasorin Liaison XL
	µU/ml = mIU/l	0.100	0.080	0.120	Siemens Atellica IM
	µU/ml = mIU/l	0.090	0.072	0.108	Abbott Alinity i
	µU/ml = mIU/l	0.120	0.096	0.144	Roche Cobas e402/e801
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	11.6	9.28	13.9	Abbott Architect
	IU/ml	0.012	0.009	0.015	
	mU/ml=IU/l	15.8	12.6	19.0	BioMerieux Vidas
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	14.6	11.7	17.5	Siemens Centaur XP/XPT/Classic
	IU/ml	0.015	0.012	0.018	
	mU/ml=IU/l	18.9	15.1	22.7	Siemens Dimension
	IU/ml	0.019	0.015	0.023	
	mU/ml=IU/l	22.5	18.0	27.0	Siemens Immulite 2000
	IU/ml	0.023	0.018	0.028	
	mU/ml=IU/l	21.3	17.0	25.6	Siemens Immulite 1000
	IU/ml	0.021	0.017	0.025	
	mU/ml=IU/l	13.2	10.6	15.8	Beckman Dxl800
	IU/ml	0.013	0.011	0.015	
	mU/ml=IU/l	12.1	9.68	14.5	Roche Cobas Core EIA
	IU/ml	0.012	0.010	0.014	
	mU/ml=IU/l	12.9	10.3	15.5	Beckman Access
	IU/ml	0.013	0.010	0.016	
	mU/ml=IU/l	17.3	13.8	20.8	Tosoh Series
	IU/ml	0.017	0.014	0.020	
	mU/ml=IU/l	17.5	14.0	21.0	Vitros ECi
	IU/ml	0.018	0.014	0.022	
	mU/ml=IU/l	8.75	7.00	10.5	Roche hCG STAT (Intact)
	IU/ml	0.009	0.007	0.011	
	mU/ml=IU/l	12.6	10.1	15.1	Roche hCG+Beta
	IU/ml	0.013	0.010	0.016	
	mU/ml=IU/l	18.2	14.6	21.8	SNIBE Maglumi Analysers
	IU/ml	0.018	0.015	0.021	
	mU/ml=IU/l	12.7	10.2	15.2	Beckman Access Total BhCG (5th IS)
	IU/ml	0.013	0.010	0.016	
mU/ml=IU/l	13.2	10.6	15.8	Beckman Dxl Total BhCG (5th IS)	
IU/ml	0.013	0.011	0.015		
mU/ml=IU/l	12.9	10.3	15.5	Siemens Centaur CP	
IU/ml	0.013	0.010	0.016		
mU/ml=IU/l	10.9	8.72	13.1	Mindray CL Series	
IU/ml	0.011	0.009	0.013		
mU/ml=IU/l	11.4	9.12	13.7	Diasorin Liaison XL	
IU/ml	0.011	0.009	0.013		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods	
			low	high		
Total Beta hCG	mU/ml=IU/l	12.8	10.2	15.4	Siemens Atellica IM	
	IU/ml	0.013	0.010	0.016		
	mU/ml=IU/l	11.7	9.36	14.0	Abbott Alinity i	
	IU/ml	0.012	0.009	0.015		
	mU/ml=IU/l	12.1	9.68	14.5	Roche hCG+Beta e801	
	IU/ml	0.012	0.010	0.014		
	mU/ml=IU/l	21.3	17.0	25.6	Tosoh AIA-CL Series	
	IU/ml	0.021	0.017	0.025		
	Total T3	nmol/l	0.870	0.653	1.09	Abbott Architect
		ng/ml	0.566	0.425	0.707	
ng/dl		56.6	42.5	70.7		
nmol/l		0.680	0.510	0.850	BioMerieux Vidas	
ng/ml		0.443	0.332	0.554		
ng/dl		44.3	33.2	55.4		
nmol/l		0.810	0.608	1.01	Siemens Centaur XP/XPT/Classic	
ng/ml		0.527	0.396	0.658		
ng/dl		52.7	39.6	65.8		
nmol/l		0.620	0.465	0.775	Siemens Immulite 2000/2500	
ng/ml		0.404	0.303	0.505		
ng/dl		40.4	30.3	50.5		
nmol/l		1.16	0.870	1.45	Beckman DxI800	
ng/ml		0.755	0.566	0.944		
ng/dl		75.5	56.6	94.4		
nmol/l		1.37	1.03	1.71	Roche Elecsys	
ng/ml		0.892	0.671	1.11		
ng/dl		89.2	67.1	111		
nmol/l		1.22	0.915	1.53	Beckman Access	
ng/ml		0.794	0.596	0.992		
ng/dl		79.4	59.6	99.2		
nmol/l		0.820	0.615	1.03	Tosoh Series	
ng/ml		0.534	0.400	0.668		
ng/dl		53.4	40.0	66.8		
nmol/l		0.990	0.743	1.24	Vitros ECI	
ng/ml		0.644	0.484	0.804		
ng/dl		64.4	48.4	80.4		
nmol/l		1.33	0.998	1.66	Roche Cobas 4000/E411	
ng/ml		0.866	0.650	1.08		
ng/dl		86.6	65.0	108		
nmol/l	0.790	0.593	0.988	Immunotech RIA		
ng/ml	0.514	0.386	0.642			
ng/dl	51.4	38.6	64.2			
nmol/l	1.35	1.01	1.69	Roche Cobas e601/602		
ng/ml	0.879	0.658	1.10			
ng/dl	87.9	65.8	110			
nmol/l	0.750	0.563	0.938	Mindray CL Series		
ng/ml	0.488	0.367	0.609			
ng/dl	48.8	36.7	60.9			

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods	
			low	high		
Total T3	nmol/l	1.00	0.750	1.25	Diasorin Liaison XL	
	ng/ml	0.651	0.488	0.814		
	ng/dl	65.1	48.8	81.4		
	nmol/l	0.870	0.653	1.09	Abbott Alinity i	
		ng/ml	0.566	0.425		0.707
		ng/dl	56.6	42.5		70.7
	nmol/l	0.830	0.623	1.04	Siemens Atellica IM	
		ng/ml	0.540	0.406		0.674
		ng/dl	54.0	40.6		67.4
	nmol/l	1.31	0.983	1.64	Roche Cobas e402/e801	
		ng/ml	0.853	0.640		1.07
		ng/dl	85.3	64.0		107
nmol/l	0.860	0.645	1.08	Tosoh AIA-CL Series		
	ng/ml	0.560	0.420		0.700	
	ng/dl	56.0	42.0		70.0	
Total T4	nmol/l	34.0	25.5	42.5	Abbott Architect	
	µg/dl	2.65	1.99	3.31		
	ng/ml	26.5	19.9	33.1		
	nmol/l	36.1	27.1	45.1	BioMerieux Vidas	
		µg/dl	2.82	2.11		3.53
		ng/ml	28.2	21.1		35.3
	nmol/l	26.7	20.0	33.4	Siemens Immulite 2000/2500	
		µg/dl	2.08	1.56		2.60
		ng/ml	20.8	15.6		26.0
	nmol/l	37.1	27.8	46.4	Roche Elecsys	
		µg/dl	2.89	2.17		3.61
		ng/ml	28.9	21.7		36.1
	nmol/l	21.4	16.1	26.8	Beckman Access	
		µg/dl	1.67	1.26		2.08
		ng/ml	16.7	12.6		20.8
	nmol/l	27.2	20.4	34.0	Tosoh Series	
		µg/dl	2.12	1.59		2.65
		ng/ml	21.2	15.9		26.5
	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	37.6	28.2	47.0	Roche Cobas 4000/E411	
		µg/dl	2.93	2.20		3.66
		ng/ml	29.3	22.0		36.6
nmol/l	36.9	27.7	46.1	Roche Cobas e601/602		
	µg/dl	2.88	2.16		3.60	
	ng/ml	28.8	21.6		36.0	
nmol/l	33.3	25.0	41.6	Immunotech IRMA		
	µg/dl	2.60	1.95		3.25	
	ng/ml	26.0	19.5		32.5	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Total T4	nmol/l	37.3	28.0	46.6	SNIBE Maglumi Analysers
	µg/dl	2.91	2.18	3.64	
	ng/ml	29.1	21.8	36.4	
	nmol/l	27.9	20.9	34.9	Siemens Centaur CP
	µg/dl	2.18	1.63	2.73	
	ng/ml	21.8	16.3	27.3	
	nmol/l	26.3	19.7	32.9	Mindray CL Series
	µg/dl	2.05	1.54	2.56	
	ng/ml	20.5	15.4	25.6	
	nmol/l	35.9	26.9	44.9	Diasorin Liaison XL
	µg/dl	2.80	2.10	3.50	
	ng/ml	28.0	21.0	35.0	
	nmol/l	33.3	25.0	41.6	Abbott Alinity i
	µg/dl	2.60	1.95	3.25	
	ng/ml	26.0	19.5	32.5	
	nmol/l	27.2	20.4	34.0	Siemens Atellica IM
	µg/dl	2.12	1.59	2.65	
	ng/ml	21.2	15.9	26.5	
nmol/l	34.1	25.6	42.6	Roche Cobas e402/e801	
µg/dl	2.66	2.00	3.32		
ng/ml	26.6	20.0	33.2		
nmol/l	36.5	27.4	45.6	Tosoh AIA-CL Series	
µg/dl	2.85	2.14	3.56		
ng/ml	28.5	21.4	35.6		
Valproic Acid	µmol/l	161	129	193	Abbott Architect (CMIA)
	µg/ml	23.2	18.6	27.8	
	µmol/l	203	162	244	Siemens Centaur XP/XPT/Classic
	µg/ml	29.3	23.4	35.2	
	µmol/l	195	156	234	Siemens Dimension
	µg/ml	28.1	22.5	33.7	
	µmol/l	182	146	218	Siemens Immulite 2000/2500
	µg/ml	26.3	21.1	31.5	
	µmol/l	192	154	230	Roche Integra
	µg/ml	27.7	22.2	33.2	
	µmol/l	189	151	227	Roche Cobas 6000/8000
	µg/ml	27.3	21.8	32.8	
	µmol/l	208	166	250	Beckman AU400/600/640/2700/5400
	µg/ml	30.0	24.0	36.0	
	µmol/l	164	131	197	Abbott Architect (PETINA)
	µg/ml	23.7	18.9	28.5	
	µmol/l	193	154	232	Siemens Atellica CH
	µg/ml	27.8	22.2	33.4	
µmol/l	163	130	196	Abbott Alinity (CMIA)	
µg/ml	23.5	18.8	28.2		
µmol/l	168	134	202	Abbott Alinity (PETINA)	
µg/ml	24.2	19.3	29.1		

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
Valproic Acid	µmol/l	243	194	292	Gravimetric
	µg/ml	35.1	28.0	42.1	
Vancomycin	µmol/l	3.45	2.76	4.14	Roche Integra
	µg/ml	5.13	4.10	6.16	
	µmol/l	3.93	3.14	4.72	Ortho Vitros Microslide Systems
	µg/ml	5.84	4.67	7.01	
	µmol/l	3.49	2.79	4.19	Abbott Architect (CMIA)
	µg/ml	5.19	4.15	6.23	
	µmol/l	2.48	1.98	2.98	Siemens Centaur XP/XPT/Classic
	µg/ml	3.68	2.94	4.42	
	µmol/l	3.21	2.57	3.85	Siemens Dimension
	µg/ml	4.77	3.82	5.72	
	µmol/l	3.31	2.65	3.97	Roche Cobas 6000/8000
	µg/ml	4.92	3.94	5.90	
	µmol/l	3.38	2.70	4.06	Abbott Architect (PETINA)
	µg/ml	5.02	4.01	6.03	
	µmol/l	3.00	2.40	3.60	EMIT
	µg/ml	4.46	3.57	5.35	
	µmol/l	3.50	2.80	4.20	Siemens Atellica CH
	µg/ml	5.20	4.16	6.24	
	µmol/l	3.85	3.08	4.62	Abbott Alinity (CMIA)
	µg/ml	5.72	4.58	6.86	
µmol/l	3.65	2.92	4.38	Abbott Alinity (PETINA)	
µg/ml	5.42	4.34	6.50		
µmol/l	3.43	2.74	4.12	Gravimetric	
µg/ml	5.10	4.07	6.12		
Vitamin B12	pmol/l	170	136	204	Abbott Architect
	pg/ml	230	184	276	
	pmol/l	165	132	198	Siemens Centaur XP/XPT/Classic
	pg/ml	224	179	269	
	pmol/l	124	99.0	149	Siemens Immulite 2000
	pg/ml	168	134	202	
	pmol/l	114	91.2	137	Beckman DxI800
	pg/ml	154	124	184	
	pmol/l	202	162	242	Roche Elecsys
	pg/ml	274	220	328	
	pmol/l	122	97.6	146	Beckman Access
	pg/ml	165	132	198	
	pmol/l	199	159	239	Tosoh Series
	pg/ml	270	215	325	
	pmol/l	158	126	190	Vitros ECI
	pg/ml	214	171	257	
	pmol/l	141	113	169	Siemens Dimension
	pg/ml	191	153	229	
	pmol/l	92.7	74.2	111	SNIBE Maglumi Analysers
	pg/ml	126	101	151	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot. No. 2229EC Size 12 x 5ml / 4 x 5ml Expiry 2025-12-28

Range					
Analyte	unit	Target	low	high	methods
Vitamin B12	pmol/l	204	163	245	Roche Cobas 4000/e411 Gen II
	pg/ml	276	221	331	
	pmol/l	185	148	222	Roche Cobas e601/602 Gen II
	pg/ml	251	201	301	
	pmol/l	185	148	222	Mindray CL Series
	pg/ml	251	201	301	
	pmol/l	110	88.0	132	Diasorin Liaison XL
	pg/ml	149	119	179	
	pmol/l	188	150	226	Siemens Atellica IM
	pg/ml	255	203	307	
	pmol/l	224	179	269	Abbott Alinity i
	pg/ml	304	243	365	
	pmol/l	173	138	208	Roche Cobas e801 Gen II
	pg/ml	234	187	281	

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.	2229EC	EXPIRY:	2025-12-28		

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

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IMMUNOASSAY PREMIUM PLUS - LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot No. 2229EC Size: 12 x 5ml / 4 x 5ml Expiry: 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
25-OH Vitamin D	nmol/l	123	92.3	154	Vitros Eci
Alpha-fetoprotein	KIU/l = IU/ml	10.3	8.24	12.4	Vitros Eci
CA 125	U/ml	16.3	13.0	19.6	Vitros Eci
CA 15-3	U/ml	19.9	15.9	23.9	Vitros Eci
CA 19-9	U/ml	38.2	30.6	45.8	Vitros Eci
C-Peptide	nmol/l	0.670	0.503	0.838	Vitros Eci
	ng/ml	2.02	1.52	2.52	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	3.34	2.67	5.68	Vitros Eci
Cortisol	nmol/l	147	110	184	Vitros Eci
	µg/dl	5.29	3.96	6.62	
Ferritin	ng/ml = µg/l	14.0	11.2	16.8	Vitros Eci
Folate	nmol/l	4.59	3.49	5.69	Vitros Eci
	ng/ml	2.02	1.54	2.50	
Free T3	pmol/l	7.67	5.75	9.59	Vitros Eci
	ng/dl	0.499	0.374	0.624	
	pg/ml	4.99	3.74	6.24	
Free T4	pmol/l	15.5	11.6	19.4	Vitros Eci
	ng/dl	1.21	0.905	1.52	
	pg/ml	12.1	9.05	15.2	
FSH	mU/ml	6.24	4.99	7.49	Vitros Eci
Insulin	mU/l	1.20	0.900	1.50	Vitros Eci
	µU/ml	1.20	0.900	1.50	
Luteinising Hormone (LH)	mU/ml	4.63	3.70	5.56	Vitros Eci
Oestradiol	pmol/l	71.4	57.1	85.7	Vitros Eci
	pg/ml	19.4	15.5	23.3	
Progesterone	nmol/l	2.4	1.92	2.88	Vitros Eci
	ng/ml	0.751	0.601	0.901	
Prolactin	µU/ml	184	147	221	Vitros Eci
PSA Free	ng/ml = µg/l	1.04	0.780	1.30	Ortho Vitros 3600/5600/ECi PSA II
PSA Total	ng/ml = µg/l	1.66	1.25	2.08	Vitros Eci
Testosterone	nmol/l	0.820	0.656	0.984	Vitros Eci
	ng/ml	0.236	0.189	0.283	
	ng/dl	23.6	18.9	28.3	
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.100	0.080	0.120	Vitros Eci
Total Beta hCG	mU/ml=IU/l	17.5	14.0	21.0	Vitros Eci
	IU/ml	0.018	0.014	0.022	
Vitamin B12	pmol/l	158	126	190	Vitros Eci
	pg/ml	214	171	257	