

PRODUCT INFORMATION

IA3109

2341EC

Please note that in Immunoassay Premium Plus - Level 1, lot 2341EC, the value for T-Uptake is currently unavailable and will be updated in due course.

For any questions or queries, please contact Technical.services@randox.com

CCS INC767

PRODUCT INFORMATION

IA3109 / IA3112

Lot: 2341EC

Please note the concentration level of analyte DHEA-S is low in the lots listed above and therefore cannot be measured. For any queries regarding this, please contact technical.services@randox.com

qCCS 660

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. 2341EC	EXPIRY: 2026-11-28	

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 Radox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@radox.com.



Radox 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. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	1.82	1.37	2.28	DIAsource ELISA
	ng/ml	0.602	0.453	0.751	
25-OH Vitamin D	nmol/l	27.8	20.9	34.8	Abbott Architect (3L52)
	nmol/l	117	87.8	146	Vitros ECi
	nmol/l	40.3	30.2	50.4	BioMerieux Vidas
	nmol/l	25.7	19.3	32.1	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	26.2	19.7	32.8	Abbott Alinity i
	nmol/l	14.4	10.8	18.0	Siemens Atellica IM
	nmol/l	21.7	16.3	27.1	Roche Vitamin D Total II e801
ACTH	pmol/l	1.89	1.42	2.36	Siemens Immulite 2000/2500
	pg/ml	8.59	6.45	10.7	
	pmol/l	2.53	1.90	3.16	Roche Cobas e601/602
	pg/ml	11.5	8.64	14.4	
	pmol/l	2.99	2.24	3.74	Roche Cobas e402/e801
pg/ml	13.6	10.2	17.0		
Alphafoetoprotein	KIU/l = IU/ml	8.88	7.10	10.7	Vitros ECi
	ng/ml	10.7	8.59	12.8	
	KIU/l = IU/ml	9.54	7.63	11.4	Siemens Centaur XP/XPT/Classic
	ng/ml	11.5	9.23	13.8	
	KIU/l = IU/ml	8.25	6.60	9.90	Abbott Architect
	ng/ml	9.98	7.99	12.0	
	KIU/l = IU/ml	7.78	6.22	9.34	Beckman Dxl800
	ng/ml	9.41	7.53	11.3	
	KIU/l = IU/ml	8.68	6.94	10.4	Roche Cobas e601/602
	ng/ml	10.5	8.40	12.6	
	KIU/l = IU/ml	9.47	7.58	11.4	Roche Cobas 4000/E411
	ng/ml	11.5	9.17	13.8	
	KIU/l = IU/ml	9.91	7.93	11.9	Siemens Atellica IM
	ng/ml	12.0	9.60	14.4	
KIU/l = IU/ml	8.08	6.46	9.70	Abbott Alinity i	
ng/ml	9.78	7.82	11.7		
KIU/l = IU/ml	9.79	7.83	11.7	Roche Cobas e402/e801	
ng/ml	11.8	9.47	14.1		
Amikacin	µmol/l	6.40	5.12	7.68	Gravimetric
	µg/ml	3.75	3.00	4.50	
Androstenedione	nmol/l	1.05	0.788	1.31	Siemens Immulite 2000
	ng/ml	0.301	0.226	0.376	
Beta-2-microglobulin	µg/ml = mg/l	1.03	0.824	1.24	Siemens Immulite 2000/2500
	µg/ml = mg/l	1.00	0.800	1.20	Roche Cobas 6000/8000
C-Peptide	nmol/l	0.510	0.383	0.638	Roche Cobas e601/602
	ng/ml	1.54	1.16	1.92	
	nmol/l	0.520	0.390	0.650	Roche Cobas e402/e801
	ng/ml	1.57	1.18	1.96	

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
CA 15-3	U/ml	23.1	18.5	27.7	Siemens Centaur XP/XPT/Classic
	U/ml	24.9	19.9	29.9	Abbott Architect
	U/ml	24.2	19.4	29.0	Roche Cobas e601/602
	U/ml	24.9	19.9	29.9	Roche Cobas 4000/E411
	U/ml	25.2	20.2	30.2	Siemens Atellica IM
	U/ml	23.3	18.6	28.0	Roche Cobas e402/e801
	U/ml	24.4	19.5	29.3	Abbott Alinity i
CA 19-9	U/ml	22.4	17.9	26.9	BioMerieux Vidas
	U/ml	28.2	22.6	33.8	Siemens Centaur XP/XPT/Classic
	U/ml	32.7	26.2	39.2	Vitros ECi
	U/ml	51.7	41.4	62.0	Abbott Architect XR/XR2/XRL
	U/ml	17.9	14.3	21.5	Roche Cobas e601/602
	U/ml	18.6	14.9	22.3	Roche Cobas 4000/E411
	U/ml	34.3	27.4	41.2	Siemens Atellica IM
	U/ml	18.9	15.1	22.7	Roche Cobas e402/e801
	U/ml	53.3	42.6	64.0	Abbott Alinity XR/XR2/XRL
CA125	U/ml	25.1	20.1	30.1	BioMerieux Vidas
	U/ml	20.5	16.4	24.6	Vitros ECi
	U/ml	33.6	26.9	40.3	Abbott Architect
	U/ml	28.0	22.4	33.6	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	19.3	15.4	23.2	Beckman DxI800
	U/ml	22.5	18.0	27.0	Roche Cobas 4000/E411
	U/ml	22.2	17.8	26.6	Roche Cobas e601/602
	U/ml	32.8	26.2	39.4	Siemens Atellica IM
	U/ml	20.5	16.4	24.6	Roche Cobas e402/e801
	U/ml	33.7	27.0	40.4	Abbott Alinity i
Carbamazepine	µmol/l	16.0	12.8	19.2	Abbott Architect (CMIA)
	µg/ml	3.78	3.03	4.53	
	µmol/l	14.7	11.8	17.6	Roche Cobas 6000/8000
	µg/ml	3.48	2.79	4.17	
	µmol/l	15.4	12.3	18.5	Gravimetric
µg/ml	3.64	2.91	4.37		
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	4.17	3.34	5.00	BioMerieux Vidas
	ng/ml = µg/l	4.66	3.73	5.59	Vitros ECi
	ng/ml = µg/l	4.79	3.83	5.75	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.44	4.35	6.53	Abbott Architect
	ng/ml = µg/l	4.36	3.49	5.23	Beckman DxI800
	ng/ml = µg/l	4.27	3.42	5.12	Roche Cobas e601/602
	ng/ml = µg/l	4.55	3.64	5.46	Roche Cobas 4000/E411
	ng/ml = µg/l	5.10	4.08	6.12	Siemens Atellica IM
	ng/ml = µg/l	4.33	3.46	5.20	Roche Cobas e402/e801
	ng/ml = µg/l	5.58	4.46	6.70	Abbott Alinity i
Cortisol	nmol/l	163	122	204	Siemens Centaur XP/XPT/Classic
	µg/dl	5.87	4.39	7.35	
	nmol/l	206	155	258	Siemens Immulite 2000/2500
µg/dl	7.42	5.58	9.26		

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Cortisol	nmol/l	154	116	193	Vitros ECI
	µg/dl	5.54	4.18	6.90	
	nmol/l	236	177	295	Abbott Architect
	µg/dl	8.50	6.37	10.6	
	nmol/l	219	164	274	Beckman DxI800
	µg/dl	7.88	5.90	9.86	
	nmol/l	203	152	254	Roche Cobas e601/602
	µg/dl	7.31	5.47	9.15	
	nmol/l	206	155	258	Roche Cobas 4000/E411
	µg/dl	7.42	5.58	9.26	
	nmol/l	209	157	261	Roche Cobas 4000/e411 Gen II
	µg/dl	7.52	5.65	9.39	
	nmol/l	201	151	251	Roche Cobas e601/602 Gen II
	µg/dl	7.24	5.44	9.04	
	nmol/l	130	97.5	163	Siemens Atellica IM
	µg/dl	4.68	3.51	5.85	
Digoxin	nmol/l	196	147	245	Roche Cobas e402/e801
	µg/dl	7.06	5.29	8.83	
	nmol/l	198	149	248	Roche Cobas e801 Gen II
	µg/dl	7.13	5.36	8.90	
Ethosuximide	nmol/l	230	173	288	Abbott Alinity i
	µg/dl	8.28	6.23	10.3	
	nmol/l	0.570	0.456	0.684	Abbott Architect (CMIA)
	ng/ml	0.445	0.356	0.534	
Ferritin	nmol/l	0.810	0.648	0.972	Roche Cobas e402/e801
	ng/ml	0.633	0.506	0.760	
	nmol/l	0.896	0.720	1.08	Gravimetric
	ng/ml	0.700	0.560	0.840	
Folate	µmol/l	226	181	271	Gravimetric
	µg/ml	32.0	25.7	38.4	
Folate	ng/ml = µg/l	24.0	19.2	28.8	Roche Elecsys/Cobas e411
	ng/ml = µg/l	13.4	10.7	16.1	Beckman Access
	ng/ml = µg/l	15.3	12.2	18.4	Vitros ECI
	ng/ml = µg/l	15.4	12.3	18.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	23.5	18.8	28.2	Abbott Architect
	ng/ml = µg/l	24.8	19.8	29.8	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	14.1	11.3	16.9	Beckman DxI800
	ng/ml = µg/l	24.4	19.5	29.3	Abbott Alinity i
	ng/ml = µg/l	15.2	12.2	18.2	Siemens Atellica IM
Folate	ng/ml = µg/l	23.5	18.8	28.2	Roche Cobas e402/e801
	nmol/l	5.78	4.39	7.17	Siemens Immulite 2000
	ng/ml	2.55	1.94	3.16	
	nmol/l	5.88	4.47	7.29	Vitros ECI
Folate	ng/ml	2.59	1.97	3.21	
	nmol/l	8.60	6.54	10.7	Abbott Architect
	ng/ml	3.79	2.88	4.70	

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Folate	nmol/l	20.2	15.4	25.0	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	8.91	6.79	11.0	
	nmol/l	7.37	5.60	9.14	Beckman Dxl 600 / 800 - A98032
	ng/ml	3.25	2.47	4.03	
	nmol/l	6.99	5.31	8.67	Roche Folate III - 07559992
	ng/ml	3.08	2.34	3.82	
	nmol/l	22.6	17.2	28.0	Siemens Atellica IM
	ng/ml	9.97	7.59	12.4	
	nmol/l	7.93	6.03	9.83	Abbott Alinity i
	ng/ml	3.50	2.66	4.34	
	nmol/l	6.74	5.12	8.36	Roche Folate 07027290 e801
	ng/ml	2.97	2.26	3.68	
Free T3	pmol/l	4.91	3.68	6.14	Beckman Access
	ng/dl	0.319	0.239	0.399	
	pg/ml	3.20	2.40	4.00	
	pmol/l	9.73	7.30	12.2	Vitros ECI
	ng/dl	0.632	0.475	0.789	
	pg/ml	6.33	4.75	7.91	
	pmol/l	5.69	4.27	7.11	Siemens Centaur XP/XPT/Classic
	ng/dl	0.370	0.278	0.462	
	pg/ml	3.70	2.78	4.62	
	pmol/l	4.10	3.08	5.13	Abbott Architect, 2 point calibration
	ng/dl	0.267	0.200	0.334	
	pg/ml	2.67	2.01	3.33	
	pmol/l	4.69	3.52	5.86	Beckman Dxl800
	ng/dl	0.305	0.229	0.381	
	pg/ml	3.05	2.29	3.81	
	pmol/l	5.71	4.28	7.14	Roche Cobas 4000/E411
	ng/dl	0.371	0.278	0.464	
	pg/ml	3.72	2.79	4.65	
	pmol/l	5.56	4.17	6.95	Roche Cobas e601/602
	ng/dl	0.361	0.271	0.451	
	pg/ml	3.62	2.71	4.53	
	pmol/l	6.28	4.71	7.85	Siemens Atellica IM
	ng/dl	0.408	0.306	0.510	
	pg/ml	4.09	3.07	5.11	
pmol/l	3.93	2.95	4.91	Abbott Architect, 6 point calibration	
ng/dl	0.255	0.192	0.318		
pg/ml	2.56	1.92	3.20		
pmol/l	5.51	4.13	6.89	Roche Cobas e402/e801	
ng/dl	0.358	0.268	0.448		
pg/ml	3.59	2.69	4.49		
pmol/l	3.93	2.95	4.91	Abbott Alinity, 6 point cal	
ng/dl	0.255	0.192	0.318		
pg/ml	2.56	1.92	3.20		

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Free T4	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	16.9	12.7	21.1	Vitros ECi
	ng/dl	1.32	0.991	1.65	
	pg/ml	13.2	9.91	16.5	
	pmol/l	8.32	6.24	10.4	Siemens Centaur XP/XPT/Classic
	ng/dl	0.649	0.487	0.811	
	pg/ml	6.49	4.87	8.11	
	pmol/l	12.4	9.30	15.5	Siemens Immulite 2000/2500
	ng/dl	0.967	0.725	1.21	
	pg/ml	9.67	7.25	12.1	
	pmol/l	9.68	7.26	12.1	Abbott Architect
	ng/dl	0.755	0.566	0.944	
	pg/ml	7.55	5.66	9.44	
	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	13.4	10.1	16.8	Roche Cobas e601/602
	ng/dl	1.05	0.788	1.31	
	pg/ml	10.5	7.88	13.1	
	pmol/l	13.3	9.98	16.6	Roche Cobas 4000/E411
	ng/dl	1.04	0.778	1.30	
	pg/ml	10.4	7.78	13.0	
pmol/l	8.86	6.65	11.1	Siemens Atellica IM	
ng/dl	0.691	0.519	0.863		
pg/ml	6.91	5.19	8.63		
pmol/l	9.76	7.32	12.2	Abbott Alinity i	
ng/dl	0.761	0.571	0.951		
pg/ml	7.61	5.71	9.51		
pmol/l	14.0	10.5	17.5	Roche Cobas e402/e801	
ng/dl	1.09	0.819	1.36		
pg/ml	10.9	8.19	13.6		
FSH	mU/ml	5.59	4.47	6.71	BioMerieux Vidas
	mU/ml	4.68	3.74	5.62	Vitros ECi
	mU/ml	6.67	5.34	8.00	Siemens Centaur XP/XPT/Classic
	mU/ml	6.13	4.90	7.36	Siemens Immulite 2000/2500
	mU/ml	5.12	4.10	6.14	Abbott Architect
	mU/ml	6.24	4.99	7.49	Beckman Dxl800
	mU/ml	5.81	4.65	6.97	Roche Cobas 4000/E411
	mU/ml	5.75	4.60	6.90	Roche Cobas e601/602
	mU/ml	6.48	5.18	7.78	Siemens Atellica IM
	mU/ml	5.52	4.42	6.62	Abbott Alinity i
	mU/ml	5.65	4.52	6.78	Roche Cobas e402/e801
	Gentamicin	µmol/l	4.85	3.88	5.82
µg/ml		2.32	1.85	2.78	

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Growth Hormone (GH)	μU/ml	7.56	6.05	9.07	Siemens Immulite 2000/2500
	ng/ml	2.52	2.01	3.03	
	μU/ml	6.04	4.83	7.25	Roche Cobas e601/602
	ng/ml	2.01	1.61	2.41	
	μU/ml	5.40	4.32	6.48	Diasorin Liaison XL
	ng/ml	1.80	1.44	2.16	
Immunoglobulin E	μU/ml	6.33	5.06	7.60	Roche Cobas e402/e801
	ng/ml	2.11	1.68	2.54	
	KIU/I = IU/ml	187	150	224	BioMerieux Vidas
	KIU/I = IU/ml	222	178	266	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	218	174	262	Siemens Immulite 2000/2500
	KIU/I = IU/ml	211	169	253	Abbott Architect
Insulin	KIU/I = IU/ml	221	177	265	Roche Cobas 4000/E411
	KIU/I = IU/ml	211	169	253	Roche Cobas e601/602
	KIU/I = IU/ml	224	179	269	Roche Cobas e402/e801
	mU/l	1.35	1.01	1.69	Abbott Architect
	μU/ml	1.35	1.01	1.69	
	mU/l	1.45	1.09	1.81	Roche Cobas 4000/E411
	μU/ml	1.45	1.09	1.81	
	mU/l	1.59	1.19	1.99	Roche Cobas 6000/8000
Luteinising Hormone (LH)	μU/ml	1.59	1.19	1.99	
	mU/l	1.13	0.848	1.41	Beckman Dxl 600/800
	μU/ml	1.13	0.848	1.41	
	mU/l	1.50	1.13	1.88	Abbott Alinity i
	μU/ml	1.50	1.13	1.87	
	mU/ml	3.33	2.66	4.00	BioMerieux Vidas
	mU/ml	4.96	3.97	5.95	Vitros ECi
	mU/ml	2.97	2.38	3.56	Siemens Centaur XP/XPT/Classic
	mU/ml	6.87	5.50	8.24	Siemens Immulite 2000
	mU/ml	2.61	2.09	3.13	Abbott Architect
Oestradiol	mU/ml	2.56	2.05	3.07	Beckman Dxl800
	mU/ml	4.13	3.30	4.96	Roche Cobas 4000/E411
	mU/ml	4.34	3.47	5.21	Roche Cobas e601/602
	mU/ml	3.17	2.54	3.80	Siemens Atellica IM
	mU/ml	2.57	2.06	3.08	Abbott Alinity i
	mU/ml	4.53	3.62	5.44	Roche Cobas e402/e801
	pmol/l	228	182	274	Abbott Architect
	pg/ml	62.0	49.5	74.5	
	pmol/l	252	202	302	Roche Cobas e601/602 (Estradiol III)
	pg/ml	68.5	54.9	82.1	
Oestradiol	pmol/l	225	180	270	Roche Elecsys (Estradiol III)
	pg/ml	61.2	49.0	73.4	
	pmol/l	246	197	295	Roche Cobas 4000/E411 (Estradiol III)
	pg/ml	66.9	53.6	80.2	
	pmol/l	196	157	235	Beckman Dxl600/800 Sensitive B84493
	pg/ml	53.3	42.7	63.9	

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Oestradiol	pmol/l	254	203	305	Siemens Atellica IM
	pg/ml	69.1	55.2	83.0	
	pmol/l	219	175	263	Abbott Alinity i
	pg/ml	59.6	47.6	71.6	
	pmol/l	245	196	294	Roche Cobas e801 (Estradiol III)
	pg/ml	66.6	53.3	79.9	
Paracetamol	mmol/l	0.140	0.112	0.168	Roche Cobas c501/502/503/701/702
	mg/l	21.2	16.9	25.5	
	mmol/l	0.166	0.130	0.200	Gravimetric
	mg/l	25.1	19.7	30.3	
Phenobarbital	µmol/l	34.8	27.8	41.8	Siemens Immulite 2000/2500
	µg/ml	8.07	6.45	9.69	
	µmol/l	31.4	25.1	37.7	Beckman AU400/600/640/2700/5400
	µg/ml	7.28	5.82	8.74	
	µmol/l	33.9	27.1	40.7	Roche Cobas C303/501/502/503/701
	µg/ml	7.86	6.29	9.43	
Phenytoin	µmol/l	19.2	15.4	23.0	Abbott Architect
	µg/ml	4.85	3.89	5.81	
	µmol/l	19.3	15.4	23.2	Roche Cobas 6000/8000
	µg/ml	4.87	3.89	5.85	
	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	2.21	1.77	2.65	Siemens Immulite 2000/2500
	ng/ml	0.692	0.554	0.830	
	nmol/l	2.81	2.25	3.37	Abbott Architect
	ng/ml	0.880	0.704	1.06	
	nmol/l	3.11	2.49	3.73	Roche Cobas e601/602 (Prog. III)
	ng/ml	0.973	0.779	1.17	
	nmol/l	3.06	2.45	3.67	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	0.958	0.767	1.15	
	nmol/l	2.46	1.97	2.95	Abbott Alinity i
	ng/ml	0.770	0.617	0.923	
Prolactin	µU/ml	134	107	161	BioMerieux Vidas
	µU/ml	165	132	198	Vitros ECI
	µU/ml	124	99.0	149	Siemens Centaur XP/XPT/Classic
	µU/ml	138	110	166	Abbott Architect
	µU/ml	123	98.4	148	Beckman DxI800
	µU/ml	154	123	185	Roche Cobas 4000/E411

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Prolactin	µU/ml	144	115	173	Roche Cobas e601/602
	µU/ml	114	91.2	137	Siemens Atellica IM
	µU/ml	142	114	170	Abbott Alinity i
	µU/ml	144	115	173	Roche Cobas e801 PRL II
PSA Free	ng/ml = µg/l	1.79	1.34	2.24	Abbott Architect
	ng/ml = µg/l	2.07	1.55	2.59	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	1.38	1.04	1.73	Roche Cobas 4000/E411
	ng/ml = µg/l	1.35	1.01	1.69	Roche Cobas e601/602
	ng/ml = µg/l	1.77	1.33	2.21	Abbott Alinity i
	ng/ml = µg/l	1.30	0.975	1.63	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	2.36	1.77	2.95	Beckman Access standardised to Hybritech
	ng/ml = µg/l	1.69	1.27	2.11	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.41	1.06	1.76	Abbott Architect
	ng/ml = µg/l	2.24	1.68	2.80	Beckman Dxl standardisd to Hybritech
	ng/ml = µg/l	1.87	1.40	2.34	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	1.85	1.39	2.31	Roche Cobas 4000/E411
	ng/ml = µg/l	1.92	1.44	2.40	Roche Cobas e601/602
	ng/ml = µg/l	1.85	1.39	2.31	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	1.83	1.37	2.29	Siemens Atellica IM
	ng/ml = µg/l	1.51	1.13	1.89	Abbott Alinity i
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	11.6	9.28	13.9	Abbott Architect
	nmol/l	11.1	8.88	13.3	Roche Cobas e801 - 413429
	nmol/l	11.2	8.96	13.4	Roche analysers - 413417/15
	nmol/l	11.4	9.12	13.7	Abbott Alinity i
T Uptake	%U	TBD	TBD	TBD	Siemens Immulite 2000
Testosterone	nmol/l	0.810	0.648	0.972	Siemens Immulite 2000/2500
	ng/ml	0.233	0.187	0.279	
	ng/dl	23.3	18.7	27.9	
	nmol/l	1.81	1.45	2.17	Abbott Architect
	ng/ml	0.521	0.418	0.624	
	ng/dl	52.1	41.8	62.4	
	nmol/l	1.40	1.12	1.68	Roche Cobas 4000/e411 Test II
	ng/ml	0.403	0.323	0.483	
	ng/dl	40.3	32.3	48.3	
	nmol/l	1.32	1.06	1.58	Roche Cobas e601/602 Test II
	ng/ml	0.380	0.305	0.455	
	ng/dl	38.0	30.5	45.5	
	nmol/l	1.82	1.46	2.18	Abbott Architect 2nd Generation
	ng/ml	0.524	0.420	0.628	
ng/dl	52.4	42.0	62.8		
nmol/l	1.53	1.22	1.84	Siemens Centaur TST II	
ng/ml	0.441	0.351	0.531		
ng/dl	44.1	35.1	53.1		

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	nmol/l	1.18	0.944	1.42	Siemens Atellica IM
	ng/ml	0.340	0.272	0.408	
	ng/dl	34.0	27.2	40.8	
	nmol/l	1.41	1.13	1.69	Roche Cobas e801 Test II
	ng/ml	0.406	0.325	0.487	
	ng/dl	40.6	32.5	48.7	
Theophylline	nmol/l	1.83	1.46	2.20	Abbott Alinity i
	ng/ml	0.527	0.420	0.634	
	ng/dl	52.7	42.0	63.4	
Theophylline	µmol/l	28.3	22.6	34.0	Gravimetric
	µg/ml	5.10	4.07	6.13	
Thyroglobulin	ng/ml	1.44	1.08	1.80	Siemens Immulite 2000
	ng/ml	4.53	3.40	5.66	Roche Cobas e601/602
	ng/ml	4.90	3.68	6.13	Abbott Architect 2000i
	ng/ml	4.61	3.46	5.76	Roche Cobas e601/602 Tg II
	ng/ml	4.35	3.26	5.44	Roche Cobas e801 Tg II
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.100	0.080	0.120	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	0.112	0.090	0.134	Vitros ECI
	µU/ml = mIU/l	0.108	0.086	0.130	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	0.109	0.087	0.131	Siemens Immulite 2000/2500
	µU/ml = mIU/l	0.100	0.080	0.120	Abbott Architect
	µU/ml = mIU/l	0.136	0.109	0.163	Roche Cobas 4000/E411
	µU/ml = mIU/l	0.136	0.109	0.163	Roche Cobas e601/602
	µU/ml = mIU/l	0.108	0.086	0.130	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	0.090	0.072	0.108	Beckman Dxl 600/800 Access (3rd IS)
	µU/ml = mIU/l	0.116	0.093	0.139	Siemens Atellica IM
	µU/ml = mIU/l	0.099	0.079	0.119	Abbott Alinity i
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	27.2	21.8	32.6	BioMerieux Vidas
	IU/ml	0.027	0.022	0.032	
	mU/ml=IU/l	35.8	28.6	43.0	Vitros ECI
	IU/ml	0.036	0.029	0.043	
	mU/ml=IU/l	7.10	5.68	8.52	Siemens Centaur XP/XPT/Classic
	IU/ml	0.007	0.006	0.008	
	mU/ml=IU/l	63.4	50.7	76.1	Siemens Immulite 2000
	IU/ml	0.063	0.051	0.075	
	mU/ml=IU/l	4.93	3.94	5.92	Abbott Architect
	IU/ml	0.005	0.004	0.006	
	mU/ml=IU/l	13.8	11.0	16.6	Roche hCG+Beta
	IU/ml	0.014	0.011	0.017	
	mU/ml=IU/l	6.29	5.03	7.55	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.006	0.005	0.007	
mU/ml=IU/l	5.89	4.71	7.07	Siemens Atellica IM	
IU/ml	0.006	0.005	0.007		

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Total Beta hCG	mU/ml=IU/l	5.16	4.13	6.19	Abbott Alinity i
	IU/ml	0.005	0.004	0.006	
	mU/ml=IU/l	13.8	11.0	16.6	Roche hCG+Beta e801
	IU/ml	0.014	0.011	0.017	
Total T3	nmol/l	1.04	0.780	1.30	Abbott Architect
	ng/ml	0.677	0.508	0.846	
	ng/dl	67.7	50.8	84.6	
	nmol/l	1.12	0.840	1.40	Vitros ECi
	ng/ml	0.729	0.547	0.911	
	ng/dl	72.9	54.7	91.1	
	nmol/l	1.56	1.17	1.95	Roche Cobas 4000/E411
	ng/ml	1.02	0.762	1.28	
	ng/dl	102	76.2	128	
	nmol/l	1.57	1.18	1.96	Roche Cobas e601/602
	ng/ml	1.02	0.768	1.27	
	ng/dl	102	76.8	127	
	nmol/l	1.04	0.780	1.30	Abbott Alinity i
	ng/ml	0.677	0.508	0.846	
	ng/dl	67.7	50.8	84.6	
	nmol/l	1.03	0.773	1.29	Siemens Atellica IM
ng/ml	0.671	0.503	0.839		
ng/dl	67.1	50.3	83.9		
nmol/l	1.53	1.15	1.91	Roche Cobas e402/e801	
ng/ml	0.996	0.749	1.24		
ng/dl	100	74.9	125		
Total T4	nmol/l	27.9	20.9	34.9	Vitros ECi
	µg/dl	2.18	1.63	2.73	
	ng/ml	21.8	16.3	27.3	
	nmol/l	21.1	15.8	26.4	Siemens Centaur XP/XPT/Classic
	µg/dl	1.65	1.23	2.07	
	ng/ml	16.5	12.3	20.7	
	nmol/l	24.7	18.5	30.9	Siemens Immulite 2000/2500
	µg/dl	1.93	1.44	2.42	
	ng/ml	19.3	14.4	24.2	
	nmol/l	36.4	27.3	45.5	Abbott Architect
	µg/dl	2.84	2.13	3.55	
	ng/ml	28.4	21.3	35.5	
	nmol/l	36.1	27.1	45.1	Roche Cobas 4000/E411
	µg/dl	2.82	2.11	3.53	
	ng/ml	28.2	21.1	35.3	
	nmol/l	36.4	27.3	45.5	Roche Cobas e601/602
µg/dl	2.84	2.13	3.55		
ng/ml	28.4	21.3	35.5		
nmol/l	32.5	24.4	40.6	Abbott Alinity i	
µg/dl	2.54	1.90	3.18		
ng/ml	25.4	19.0	31.8		

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

Cat. No. IA3109 / IA3112 Lot. No. 2341EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Total T4	nmol/l	29.2	21.9	36.5	Siemens Atellica IM
	µg/dl	2.28	1.71	2.85	
	ng/ml	22.8	17.1	28.5	
	nmol/l	34.6	26.0	43.3	Roche Cobas e402/e801
	µg/dl	2.70	2.03	3.37	
	ng/ml	27.0	20.3	33.7	
Valproic Acid	µmol/l	187	150	224	Abbott Architect (CMIA)
	µg/ml	27.0	21.6	32.4	
	µmol/l	215	172	258	Roche Cobas 6000/8000
	µg/ml	31.0	24.8	37.2	
Vancomycin	µmol/l	243	194	292	Gravimetric
	µg/ml	35.1	28.0	42.1	
	µmol/l	3.33	2.66	4.00	Abbott Architect (CMIA)
	µg/ml	4.95	3.95	5.95	
Vancomycin	µmol/l	3.17	2.54	3.80	Roche Cobas 6000/8000
	µg/ml	4.71	3.77	5.65	
	µmol/l	3.43	2.74	4.12	Gravimetric
	µg/ml	5.10	4.07	6.12	
Vitamin B12	pmol/l	123	98.4	148	Beckman Access
	pg/ml	167	133	201	
	pmol/l	144	115	173	Siemens Centaur XP/XPT/Classic
	pg/ml	195	156	234	
	pmol/l	128	102	154	Siemens Immulite 2000
	pg/ml	173	138	208	
	pmol/l	170	136	204	Abbott Architect
	pg/ml	230	184	276	
	pmol/l	156	125	187	Vitros Eci
	pg/ml	211	169	253	
	pmol/l	111	88.8	133	Beckman Dxl800
	pg/ml	150	120	180	
	pmol/l	229	183	275	Roche Cobas 4000/e411 Gen II
	pg/ml	310	248	372	
	pmol/l	184	147	221	Roche Cobas e601/602 Gen II
	pg/ml	249	199	299	
	pmol/l	145	116	174	Siemens Atellica IM
	pg/ml	196	157	235	
pmol/l	286	229	343	Abbott Alinity i	
pg/ml	388	310	466		
pmol/l	169	135	203	Roche Cobas e801 Gen II	
pg/ml	229	183	275		

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
17-OH-Progesterone	ng/ml	0.632	0.474	0.790	0.079	0.158	SNIBE Maglumi analysers
	nmol/l	1.91	1.43	2.39	0.240	0.480	
25-OH-Vitamin D	nmol/l	57.7	43.3	72.1	7.20	14.4	SNIBE Maglumi analysers
	nmol/l	44.7	33.5	55.9	5.60	11.2	SNIBE Maglumi Analysers II Vit D II
Aldosterone	pg/ml	44.7	33.5	55.9	5.60	11.2	SNIBE Maglumi Analysers II Aldosterone II
	pmol/l	124	93.0	155	15.5	31.0	
Alpha-fetoprotein	ng/ml	11.3	9.04	13.6	1.15	2.30	SNIBE Maglumi analysers
	KIU/l = IU/ml	9.30	7.44	11.2	0.950	1.90	
Androstenedione	ng/ml	0.373	0.280	0.466	0.047	0.093	SNIBE Maglumi analysers
	nmol/l	1.30	0.975	1.63	0.165	0.330	
Beta-2-Microglobulin	µg/ml = mg/l	0.684	0.547	0.821	0.069	0.137	SNIBE Maglumi analysers
C-Peptide	ng/ml	1.93	1.45	2.41	0.240	0.480	SNIBE Maglumi analysers
	nmol/l	0.639	0.479	0.799	0.080	0.160	
CA 125	U/ml	24.3	19.4	29.2	2.45	4.90	SNIBE Maglumi analysers
CA 15-3	U/ml	24.9	19.9	29.9	2.50	5.00	SNIBE Maglumi analysers
CA 19-9	U/ml	19.4	15.5	23.3	1.95	3.90	SNIBE Maglumi analysers
CEA	ng/ml = µg/l	5.20	4.16	6.24	0.520	1.04	SNIBE Maglumi analysers
Cortisol	nmol/l	323	242	404	40.5	81.0	SNIBE Maglumi analysers
	µg/dl	11.6	8.70	14.5	1.45	2.90	
Digoxin	ng/ml	0.334	0.267	0.401	0.034	0.067	SNIBE Maglumi analysers
	nmol/l	0.428	0.342	0.514	0.043	0.086	
Ferritin	ng/ml = µg/l	20.1	16.1	24.1	2.00	4.00	SNIBE Maglumi analysers
Folate	ng/ml	2.02	1.54	2.50	0.240	0.480	SNIBE Maglumi analysers
	nmol/l	4.59	3.49	5.69	0.550	1.10	
Free T3	ng/dl	0.228	0.171	0.285	0.029	0.057	SNIBE Maglumi analysers
	pg/ml	2.28	1.71	2.85	0.285	0.570	
	pmol/l	3.50	2.63	4.37	0.435	0.870	
Free T4	ng/dl	0.858	0.644	1.07	0.106	0.212	SNIBE Maglumi analysers
	pg/ml	8.58	6.44	10.7	1.06	2.12	
	pmol/l	11.0	8.25	13.8	1.40	2.80	
FSH	mU/ml	5.94	4.75	7.13	0.595	1.19	SNIBE Maglumi analysers
Growth Hormone (GH)	ng/ml	3.11	2.49	3.73	0.310	0.620	SNIBE Maglumi analysers
	µU/ml	9.34	7.47	11.2	0.930	1.86	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Immunoglobulin E	KIU/l = IU/ml	184	147	221	18.5	37.0	SNIBE Maglumi analysers
Insulin	mU/l	3.11	2.33	3.89	0.390	0.780	SNIBE Maglumi analysers
	µU/ml	3.11	2.33	3.89	0.390	0.780	
Luteinising Hormone (LH)	mU/ml	5.00	4.00	6.00	0.500	1.00	SNIBE Maglumi analysers
Oestradiol	pg/ml	68.3	54.6	82.0	6.85	13.7	SNIBE Maglumi analysers
	pmol/l	251	201	301	25.0	50.0	
Progesterone	ng/ml	0.432	0.346	0.518	0.043	0.086	SNIBE Maglumi analysers
	nmol/l	1.38	1.10	1.66	0.140	0.280	
Prolactin	µIU/mL	134	107	161	13.5	27.0	SNIBE Maglumi analysers
PSA Free	ng/ml = µg/l	1.03	0.773	1.29	0.130	0.260	SNIBE Maglumi analysers
PSA Total	ng/ml = µg/l	1.71	1.28	2.14	0.215	0.430	SNIBE Maglumi analysers
SHBG	nmol/l	14.5	11.6	17.4	1.45	2.90	SNIBE Maglumi analysers
Testosterone	ng/dl	28.2	22.6	33.8	2.80	5.60	SNIBE Maglumi analysers
	ng/ml	0.282	0.226	0.338	0.028	0.056	
	nmol/l	0.978	0.782	1.17	0.096	0.192	
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.138	0.110	0.166	0.014	0.028	SNIBE Maglumi analysers
Total Beta hCG	IU/ml	0.040	0.032	0.048	0.004	0.008	SNIBE Maglumi analysers
	mU/ml = IU/l	40.1	32.1	48.1	4.00	8.00	
Total T3	ng/dl	35.7	26.8	44.6	4.45	8.90	SNIBE Maglumi analysers
	ng/ml	0.358	0.269	0.447	0.045	0.089	
	nmol/l	0.550	0.413	0.687	0.069	0.137	
Total T4	ng/ml	29.4	22.1	36.7	3.65	7.30	SNIBE Maglumi analysers
	nmol/l	37.7	28.3	47.1	4.70	9.40	
	µg/dl	2.94	2.21	3.67	0.365	0.730	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	nmol/l	49.9	37.4	62.4	6.25	12.5	Lifotronic eCL8000
	nmol/l	48.7	36.5	60.9	6.10	12.2	Lifotronic eCL9000
Alpha-fetoprotein	ng/ml	12.6	10.1	15.1	1.25	2.50	Lifotronic eCL8000
	KIU/l = IU/ml	10.4	8.32	12.5	1.05	2.10	
	ng/ml	11.6	9.28	13.9	1.15	2.30	Lifotronic eCL9000
	KIU/l = IU/ml	9.56	7.65	11.5	0.970	1.94	
CEA	ng/ml = µg/l	3.94	3.15	4.73	0.395	0.790	Lifotronic eCL8000
	ng/ml = µg/l	3.04	2.43	3.65	0.305	0.610	Lifotronic eCL9000
Ferritin	ng/ml = µg/l	30.1	24.1	36.1	3.00	6.00	Lifotronic eCL8000
	ng/ml = µg/l	29.4	23.5	35.3	2.95	5.90	Lifotronic eCL9000
Free T3	ng/dl	0.265	0.199	0.331	0.033	0.066	Lifotronic eCL8000
	pg/ml	2.66	2.00	3.32	0.330	0.660	
	pmol/l	4.08	3.06	5.10	0.510	1.02	
	ng/dl	0.239	0.179	0.299	0.030	0.060	Lifotronic eCL9000
	pg/ml	2.40	1.80	3.00	0.300	0.600	
	pmol/l	3.68	2.76	4.60	0.460	0.920	
Free T4	ng/dl	0.897	0.673	1.12	0.112	0.223	Lifotronic eCL8000
	pg/ml	8.97	6.73	11.2	1.12	2.23	
	pmol/l	11.5	8.63	14.4	1.45	2.90	
	ng/dl	0.866	0.650	1.08	0.107	0.214	Lifotronic eCL9000
	pg/ml	8.66	6.50	10.8	1.07	2.14	
	pmol/l	11.1	8.33	13.9	1.40	2.80	
FSH	mU/ml	6.07	4.86	7.28	0.605	1.21	Lifotronic eCL8000
	mU/ml	5.15	4.12	6.18	0.515	1.03	Lifotronic eCL9000
Insulin	mU/l	1.63	1.30	1.96	0.165	0.330	Lifotronic eCL8000
	µU/ml	1.63	1.30	1.96	0.165	0.330	
	mU/l	1.55	1.24	1.86	0.155	0.310	Lifotronic eCL9000
	µU/ml	1.55	1.24	1.86	0.155	0.310	
Luteinising Hormone (LH)	mU/ml	4.46	3.57	5.35	0.445	0.890	Lifotronic eCL8000
	mU/ml	3.99	3.19	4.79	0.400	0.800	Lifotronic eCL9000

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Progesterone	ng/ml	0.604	0.483	0.725	0.061	0.121	Lifotronic eCL8000
	nmol/l	1.93	1.54	2.32	0.195	0.390	
	ng/ml	0.567	0.454	0.680	0.057	0.113	Lifotronic eCL9000
	nmol/l	1.81	1.45	2.17	0.180	0.360	
Prolactin	µIU/mL	164	131	197	16.5	33.0	Lifotronic eCL8000
	µIU/mL	180	144	216	18.0	36.0	Lifotronic eCL9000
PSA Free	ng/ml = µg/l	1.91	1.43	2.39	0.240	0.480	Lifotronic eCL8000
	ng/ml = µg/l	1.63	1.22	2.04	0.205	0.410	Lifotronic eCL9000
PSA Total	ng/ml = µg/l	1.94	1.46	2.42	0.240	0.480	Lifotronic eCL8000
	ng/ml = µg/l	1.85	1.39	2.31	0.230	0.460	Lifotronic eCL9000
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.202	0.162	0.242	0.020	0.040	Lifotronic eCL8000
	µU/ml = mIU/l	0.164	0.131	0.197	0.017	0.033	Lifotronic eCL9000
Total Beta hCG	IU/ml	0.045	0.036	0.054	0.005	0.009	Lifotronic eCL8000
	mU/ml = IU/l	45.1	36.1	54.1	4.50	9.00	
	IU/ml	0.043	0.034	0.052	0.005	0.009	Lifotronic eCL9000
	mU/ml = IU/l	42.6	34.1	51.1	4.25	8.50	
Total T3	ng/dl	81.8	61.4	102	10.1	20.2	Lifotronic eCL8000
	ng/ml	0.820	0.615	1.03	0.105	0.210	
	nmol/l	1.26	0.945	1.58	0.160	0.320	
	ng/dl	73.4	55.1	91.7	9.15	18.3	Lifotronic eCL9000
	ng/ml	0.736	0.552	0.920	0.092	0.184	
	nmol/l	1.13	0.848	1.41	0.140	0.280	
Total T4	ng/ml	26.3	19.7	32.9	3.30	6.60	Lifotronic eCL8000
	nmol/l	33.7	25.3	42.1	4.20	8.40	
	µg/dl	2.63	1.97	3.29	0.330	0.660	
	ng/ml	26.4	19.8	33.0	3.30	6.60	Lifotronic eCL9000
	nmol/l	33.9	25.4	42.4	4.25	8.50	
	µg/dl	2.64	1.98	3.30	0.330	0.660	

Method

Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)

Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28

Size: 12 x 5 ml / 4 x 5 ml

Range

Analyte	Unit	Target	Low	High	1SD	2SD	Method
Vitamin B12	pg/ml	179	143	215	18.0	36.0	Lifotronic eCL8000
	pmol/l	132	106	158	13.0	26.0	
	pg/ml	196	157	235	19.5	39.0	Lifotronic eCL9000
	pmol/l	145	116	174	14.5	29.0	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	nmol/l	47.4	35.6	59.2	5.90	11.8	DiaSorin Liaison
	nmol/l	49.2	36.9	61.5	6.15	12.3	DiaSorin Liaison XL
Aldosterone	pg/ml	10.8	8.10	13.5	1.35	2.70	DiaSorin Liaison
	pmol/l	29.9	22.4	37.4	3.75	7.50	
Beta-2-Microglobulin	µg/ml = mg/l	0.742	0.594	0.890	0.074	0.148	DiaSorin Liaison XL
C-Peptide	ng/ml	1.69	1.27	2.11	0.210	0.420	DiaSorin Liaison XL
	nmol/l	0.559	0.419	0.699	0.070	0.140	
CA 125	U/ml	29.1	23.3	34.9	2.90	5.80	DiaSorin Liaison XL
CA 15-3	U/ml	24.1	19.3	28.9	2.40	4.80	DiaSorin Liaison XL
CA 19-9	U/ml	23.3	18.6	28.0	2.35	4.70	DiaSorin Liaison XL
CEA	ng/ml = µg/l	4.68	3.74	5.62	0.470	0.940	DiaSorin Liaison XL
Cortisol	nmol/l	264	198	330	33.0	66.0	DiaSorin Liaison XL
	µg/dl	9.50	7.13	11.9	1.20	2.40	
DHEA-S	µmol/l	0.043	0.034	0.052	0.005	0.009	DiaSorin Liaison XL
Ferritin	ng/ml = µg/l	18.4	14.7	22.1	1.85	3.70	DiaSorin Liaison XL
Free T3	ng/dl	0.284	0.213	0.355	0.036	0.071	DiaSorin Liaison XL
	pg/ml	2.84	2.13	3.55	0.355	0.710	
	pmol/l	4.37	3.28	5.46	0.545	1.09	
Free T4	ng/dl	0.928	0.696	1.16	0.116	0.232	DiaSorin Liaison XL
	pg/ml	9.28	6.96	11.6	1.16	2.32	
	pmol/l	11.9	8.93	14.9	1.50	3.00	
FSH	mU/ml	8.43	6.74	10.1	0.835	1.67	DiaSorin Liaison XL
Growth Hormone (GH)	ng/ml	1.70	1.36	2.04	0.170	0.340	DiaSorin Liaison XL
	µU/ml	5.11	4.09	6.13	0.510	1.02	
Insulin	mU/l	1.54	1.16	1.92	0.190	0.380	DiaSorin Liaison XL
	µU/ml	1.54	1.16	1.92	0.190	0.380	
Luteinising Hormone (LH)	mU/ml	4.64	3.71	5.57	0.465	0.930	DiaSorin Liaison
	mU/ml	4.56	3.65	5.47	0.455	0.910	DiaSorin Liaison XL
Oestradiol	pg/ml	46.0	36.8	55.2	4.60	9.20	DiaSorin Liaison XL
	pmol/l	169	135	203	17.0	34.0	
Progesterone	ng/ml	0.513	0.410	0.616	0.052	0.103	DiaSorin Liaison XL
	nmol/l	1.64	1.31	1.97	0.165	0.330	
Prolactin	µIU/mL	147	118	176	14.5	29.0	DiaSorin Liaison
	µIU/mL	139	111	167	14.0	28.0	DiaSorin Liaison XL
PSA Total	ng/ml = µg/l	1.66	1.25	2.07	0.205	0.410	DiaSorin Liaison XL

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Testosterone	ng/dl	16.8	13.4	20.2	1.70	3.40	DiaSorin Liaison XL
	ng/ml	0.168	0.134	0.202	0.017	0.034	
	nmol/l	0.583	0.466	0.700	0.059	0.117	
Thyroid Stimulating Hormone	μU/ml = mIU/l	0.176	0.141	0.211	0.018	0.035	DiaSorin Liaison
	μU/ml = mIU/l	0.197	0.158	0.236	0.020	0.039	DiaSorin Liaison XL
Total Beta hCG	IU/ml	0.005	0.004	0.006	0.001	0.001	DiaSorin Liaison XL
	mU/ml = IU/l	5.33	4.26	6.40	0.535	1.07	
Total T3	ng/dl	68.8	51.6	86.0	8.60	17.2	DiaSorin Liaison XL
	ng/ml	0.690	0.518	0.862	0.086	0.172	
	nmol/l	1.06	0.795	1.33	0.135	0.270	
Total T4	ng/ml	29.2	21.9	36.5	3.65	7.30	DiaSorin Liaison XL
	nmol/l	37.5	28.1	46.9	4.70	9.40	
	μg/dl	2.93	2.20	3.66	0.365	0.730	
Vitamin B12	pg/ml	145	116	174	14.5	29.0	DiaSorin Liaison XL
	pmol/l	107	85.6	128	10.5	21.0	

Method		Immunoassay Premium Plus - Level 1 (IA PREMIUM PLUS 1)					
Lot. No: 2341EC Cat. No: IA3109 / IA3112 Expiry: 2026-11-28							
Size: 12 x 5 ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
CA 125	U/ml	18.4	14.7	22.1	1.85	3.70	Siemens/DPC Immulite 2000/2500
CA 15-3	U/ml	23.6	18.9	28.3	2.35	4.70	Siemens/DPC Immulite 2000/2500
CA 19-9	U/ml	22.7	18.2	27.2	2.25	4.50	Siemens/DPC Immulite 2000/2500
Amikacin	µg/ml	3.73	2.98	4.48	0.375	0.750	EMIT
	µmol/l	6.37	5.10	7.64	0.635	1.27	
Vancomycin	µg/ml	4.42	3.54	5.30	0.440	0.880	EMIT
	µmol/l	2.98	2.38	3.58	0.300	0.600	
PSA Free	ng/ml = µg/l	1.84	1.38	2.30	0.230	0.460	Tisenc ACCRE 90
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.404	0.323	0.485	0.041	0.081	Tisenc ACCRE 90

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. 2341EC	EXPIRY: 2026-11-28	

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.



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. 2341EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
25-OH Vitamin D	ng/ml	8.07	5.49	10.65	Wiener Lab CLIA Series & Mindray Vitamin D Total II CL 8000i/6000i/2000i/1200i/1000i
		8.07	5.49	10.65	Wiener Lab CLIA Series & Mindray Vitamin D Total II CL 900i/920i/960i/980i
Alphafoetoprotein	ng/ml	10.3	7.52	13.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		10.3	7.52	13.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA125	U/ml	38.7	28.2	49.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		38.7	28.2	49.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 15-3	U/ml	13.7	10.0	17.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		13.7	10.0	17.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 19-9	U/ml	17.0	12.4	21.5	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		17.0	12.4	21.5	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Carcinoembryonic Antigen (CEA)	ng/ml	3.83	2.79	4.86	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		3.83	2.79	4.86	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Cortisol	µg/dL	7.48	5.09	9.87	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		7.48	5.09	9.87	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
C-Peptide	ng/mL	1.18	0.802	1.56	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		1.18	0.802	1.56	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
DHEA-S	µg/dL	<2.00			Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		<2.00			Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Ferritin	ng/mL	18.3	13.4	23.3	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		18.3	13.4	23.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
FSH	mIU/mL	6.54	4.45	8.63	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101
		6.54	4.45	8.63	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101
		5.46	3.71	7.20	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401
		5.46	3.71	7.20	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401
Total Beta hCG	mIU/mL	5.12	3.48	6.76	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i
		5.14	3.50	6.78	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i
		59.2	40.2	78.1	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i
		62.5	42.5	82.5	Wiener Lab CLIA Series & Mindray hCG2 CL 900i

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot No. 2341EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-11-28

Range						
Analyte	unit	Target	low	high	methods	
Insulin	µIU/mL	2.13	1.55	2.71	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		2.09	1.53	2.65	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
Luteinising Hormone (LH)	mIU/mL	4.40	3.21	5.59	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		4.40	3.21	5.59	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
Oestradiol	pg/mL	57.3	38.9	75.6	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501	
		57.3	38.9	75.6	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501	
		94.2	64.1	124	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001	
		94.2	64.1	124	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001	
Progesterone	ng/mL	0.866	0.589	1.14	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		0.866	0.589	1.14	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
		0.670	0.456	0.885	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i	
		0.670	0.456	0.885	Wiener Lab CLIA Series & Mindray PROG II CL 900i	
Prolactin	ng/mL	7.91	5.77	10.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		7.91	5.77	10.0	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
PSA Free	ng/mL	1.71	1.25	2.17	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		1.71	1.25	2.17	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
PSA Total	ng/mL	1.91	1.40	2.43	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i	
		1.97	1.44	2.50	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i	
Free T3	pg/mL	3.12	2.27	3.96	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X	
		2.94	2.15	3.74	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X	
		3.00	2.19	3.82	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00	
		3.00	2.19	3.82	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00	

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot No. 2341EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Total T3	ng/mL	0.624	0.455	0.792	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		0.624	0.455	0.792	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		0.640	0.467	0.812	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		0.640	0.467	0.812	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Free T4	ng/dL	0.825	0.602	1.05	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		0.825	0.602	1.05	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		1.10	0.802	1.40	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		1.10	0.802	1.40	Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T4	µg/dL	2.05	1.40	2.71	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		2.05	1.40	2.71	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		2.37	1.73	3.01	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		2.37	1.73	3.01	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00
Testosterone	ng/mL	0.286	0.194	0.377	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		0.286	0.194	0.377	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		<0.10			Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		<0.10			Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		0.371	0.252	0.490	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		0.371	0.252	0.490	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Thyroid Stimulating Hormone	µIU/mL	0.179	0.131	0.228	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		0.177	0.130	0.225	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		0.102	0.075	0.130	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		0.102	0.075	0.130	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00
Vitamin B12	pg/mL	248	181	314	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		248	181	314	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i

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. 2341EC	EXPIRY: 2026-11-28	

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. 2341EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	ng/ml	10.3	7.52	13.1	SYS Lumina ci/Infinity ci
		10.3	7.52	13.1	SYS Aurora
CA125	U/ml	38.7	28.2	49.1	SYS Lumina ci/Infinity ci
		38.7	28.2	49.1	SYS Aurora
CA153	U/ml	13.7	10.0	17.4	SYS Lumina ci/Infinity ci
		13.7	10.0	17.4	SYS Aurora
CA199	U/ml	17.0	12.4	21.5	SYS Lumina ci/Infinity ci
		17.0	12.4	21.5	SYS Aurora
CEA	ng/ml	3.83	2.79	4.86	SYS Lumina ci/Infinity ci
		3.83	2.79	4.86	SYS Aurora
Cortisol	µg/dL	7.48	5.09	9.87	SYS Lumina ci/Infinity ci
		7.48	5.09	9.87	SYS Aurora
C-Peptide	ng/mL	1.18	0.802	1.56	SYS Lumina ci/Infinity ci
		1.18	0.802	1.56	SYS Aurora
DHEA-S	µg/dL	<2.00			SYS Lumina ci/Infinity ci
		<2.00			SYS Aurora
Ferritin	ng/mL	18.3	13.4	23.3	SYS Lumina ci/Infinity ci
		18.3	13.4	23.3	SYS Aurora
FSH	mIU/mL	5.46	3.71	7.20	SYS Lumina ci/Infinity ci
		5.46	3.71	7.20	SYS Aurora
HCG	mIU/mL	5.12	3.48	6.76	SYS Lumina ci/Infinity ci hCG
		5.14	3.50	6.78	SYS Aurora hCG
		59.2	40.2	78.1	SYS Lumina ci/Infinity ci hCG II
		62.5	42.5	82.5	SYS Aurora hCG II
Insulin	µIU/mL	2.13	1.55	2.71	SYS Lumina ci/Infinity ci
		2.09	1.53	2.65	SYS Aurora
Luteinising Hormone (LH)	mIU/mL	4.40	3.21	5.59	SYS Lumina ci/Infinity ci
		4.40	3.21	5.59	SYS Aurora

IMMUNOASSAY PREMIUM PLUS LEVEL 1 (IA PREMIUM PLUS 1)					
Cat. No. IA3109 / IA3112		Lot No. 2341EC	Size: 12 x 5ml / 4 x 5ml		Expiry: 2026-11-28
Analyte	unit	Target	Range		methods
			low	high	
Oestradiol	pg/mL	94.2	64.1	124	SYS Lumina ci/Infinity ci
		94.2	64.1	124	SYS Aurora
Progesterone	ng/mL	0.866	0.589	1.14	SYS Lumina ci/Infinity ci PROG
		0.866	0.589	1.14	SYS Aurora PROG
		0.670	0.456	0.885	SYS Lumina ci/Infinity ci PROG II
		0.670	0.456	0.885	SYS Aurora PROG II
Prolactin	ng/mL	7.91	5.77	10.0	SYS Lumina ci/Infinity ci
		7.91	5.77	10.0	SYS Aurora
PSA Free	ng/mL	1.71	1.25	2.17	SYS Lumina ci/Infinity ci
		1.71	1.25	2.17	SYS Aurora
PSA Total	ng/mL	1.91	1.40	2.43	SYS Lumina ci/Infinity ci
		1.97	1.44	2.50	SYS Aurora
Free T3	pg/mL	3.00	2.19	3.82	SYS Lumina ci/Infinity ci
		3.00	2.19	3.82	SYS Aurora
Total T3	ng/mL	0.640	0.467	0.812	SYS Lumina ci/Infinity ci
		0.640	0.467	0.812	SYS Aurora
Free T4	ng/dL	1.10	0.802	1.40	SYS Lumina ci/Infinity ci
		1.10	0.802	1.40	SYS Aurora
Total T4	µg/dL	2.37	1.73	3.01	SYS Lumina ci/Infinity ci
		2.37	1.73	3.01	SYS Aurora
Testosterone	ng/mL	0.286	0.194	0.377	SYS Lumina ci/Infinity ci TESTO
		0.286	0.194	0.377	SYS Aurora TESTO
		0.371	0.252	0.490	SYS Lumina ci/Infinity ci TESTO II
		0.371	0.252	0.490	SYS Aurora TESTO II
Thyroglobulin	ng/mL	0.660	0.449	0.871	SYS Lumina ci/Infinity ci Item Code:221309934050/221309934100
		0.660	0.449	0.871	SYS Aurora Item Code:221309934050/221309934100
Thyroid Stimulating Hormone	µIU/mL	0.102	0.075	0.130	SYS Lumina ci/Infinity ci
		0.102	0.075	0.130	SYS Aurora
Vitamin B12	pg/mL	248	181	314	SYS Lumina ci/Infinity ci
		248	181	314	SYS Aurora