

PRODUCT INFORMATION

IA2638

2347EC

Please note that in Immunoassay Premium- Level 1, lot 2347EC, 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

IA2638 / IA2633

Lot: 2347EC

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 - LEVEL I (IA PREMIUM I)

CAT. NO. IA2638	GTIN: 05055273203844	SIZE 12 x 5 ml
CAT. NO. IA2633	GTIN: 05055273203837	SIZE 4 x 5 ml
LOT NO. 2347EC	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.

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 is supplied lyophilised.

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

MATERIALS PROVIDED

Immunoassay Premium - 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 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 - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC 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 - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
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	
CEA	ng/ml = µg/l	2.50	2.00	3.00	Roche Cobas e402/e801
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	
	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 Dxl800
	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	
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		
nmol/l	230	173	288	Abbott Alinity i	
µg/dl	8.28	6.23	10.3		
Digoxin	nmol/l	0.570	0.456	0.684	Abbott Architect (CMIA)
	ng/ml	0.445	0.356	0.534	
	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	
Ethosuximide	µmol/l	226	181	271	Gravimetric
	µg/ml	32.0	25.7	38.4	
Ferritin	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

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Ferritin	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
	ng/ml = µg/l	23.5	18.8	28.2	Roche Cobas e402/e801
Folate	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
	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	
	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 DxI 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 DxI800
	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		

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range						
Analyte	unit	Target	low	high	methods	
Free T3	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
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 DxI800	
		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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
FSH	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	Gravimetric
	µg/ml	2.32	1.85	2.78	
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	
	µU/ml	6.33	5.06	7.60	Roche Cobas e402/e801
Immunoglobulin E	KIU/l = IU/ml	187	150	224	BioMerieux Vidas
	KIU/l = IU/ml	222	178	266	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	218	174	262	Siemens Immulite 2000/2500
	KIU/l = IU/ml	211	169	253	Abbott Architect
	KIU/l = IU/ml	221	177	265	Roche Cobas 4000/E411
	KIU/l = IU/ml	211	169	253	Roche Cobas e601/602
	KIU/l = IU/ml	224	179	269	Roche Cobas e402/e801
Insulin	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
	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
Luteinising Hormone (LH)	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
	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

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Luteinising Hormone	mU/ml	4.53	3.62	5.44	Roche Cobas e402/e801
Oestradiol	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	
	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	
	pmol/l	254	203	305	Siemens Atellica IM
	pg/ml	69.1	55.2	83.0	
Paracetamol	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	
	mmol/l	0.140	0.112	0.168	Roche Cobas c501/502/503/701/702
	mg/l	21.2	16.9	25.5	
Phenobarbital	mmol/l	0.166	0.130	0.200	Gravimetric
	mg/l	25.1	19.7	30.3	
	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	
Phenytoin	µmol/l	33.9	27.1	40.7	Roche Cobas C303/501/502/503/701
	µg/ml	7.86	6.29	9.43	
	µmol/l	34.5	27.6	41.4	Gravimetric
	µg/ml	8.00	6.40	9.60	
	µmol/l	19.2	15.4	23.0	Abbott Architect
	µg/ml	4.85	3.89	5.81	
Primidone	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	
Progesterone	µmol/l	12.3	9.84	14.8	Gravimetric
	µg/ml	2.69	2.15	3.23	
	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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Progesterone	nmol/l	3.02	2.42	3.62	Siemens Atellica IM
	ng/ml	0.945	0.757	1.13	
	nmol/l	3.14	2.51	3.77	Roche Cobas e801 (Prog. III)
	ng/ml	0.983	0.786	1.18	
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
	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
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 DxI standardised to Hybritech
	ng/ml = µg/l	1.87	1.40	2.34	Beckman DxI800 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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	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	
	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		
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
	µU/ml = mIU/l	0.130	0.104	0.156	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	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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	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	
	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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range						
Analyte	unit	Target	low	high	methods	
Total T4	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
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		
µmol/l	243	194	292	Gravimetric		
	µg/ml	35.1	28.0		42.1	
Vancomycin	µmol/l	3.33	2.66	4.00	Abbott Architect (CMIA)	
	µg/ml	4.95	3.95	5.95		
	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 DxI800	
		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	

IMMUNOASSAY PREMIUM - LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Vitamin B12	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	

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM - LEVEL I
(IA PREMIUM I)
Cat No. IA2638 / IA2633
Lot No. 2347EC
GTIN: 05055273203844 / 05055273203837**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Insulin	mU/l	1.17	0.878 – 1.48	Beckman Access/LXi725
	µU/ml	1.17	0.878 – 1.48	

EC REP

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

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Method		Immunoassay Premium - Level 1 (IA PREMIUM 1)					
Lot. No: 2347EC Cat. No: IA2638 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	nmol/l	40.0	30.0	50.0	5.00	10.0	Maccura i 1000 / i 800
Alpha-fetoprotein	ng/ml	11.8	9.44	14.2	1.20	2.40	Maccura i 1000 / i 800
	KIU/l = IU/ml	9.77	7.82	11.7	0.965	1.93	
C-Peptide	ng/ml	1.12	0.840	1.40	0.140	0.280	Maccura i 1000 / i 800
	nmol/l	0.371	0.278	0.464	0.047	0.093	
CEA	ng/ml = µg/l	2.80	2.24	3.36	0.280	0.560	Maccura i 1000 / i 800
Ferritin	ng/ml = µg/l	20.4	16.3	24.5	2.05	4.10	Maccura i 1000 / i 800
Folate	ng/ml	4.98	3.78	6.18	0.600	1.20	Maccura i 1000 / i 800
	nmol/l	11.3	8.59	14.0	1.35	2.70	
Free T3	ng/dl	0.294	0.221	0.367	0.037	0.073	Maccura i 1000 / i 800
	pg/ml	2.94	2.21	3.67	0.365	0.730	
	pmol/l	4.52	3.39	5.65	0.565	1.13	
Free T4	ng/dl	0.881	0.661	1.10	0.110	0.219	Maccura i 1000 / i 800
	pg/ml	8.81	6.61	11.0	1.10	2.19	
	pmol/l	11.3	8.48	14.1	1.40	2.80	
FSH	mU/ml	5.79	4.63	6.95	0.580	1.16	Maccura i 1000 / i 800
Growth Hormone (GH)	ng/ml	3.40	2.72	4.08	0.340	0.680	Maccura i 1000 / i 800
	µU/ml	10.2	8.16	12.2	1.00	2.00	
Insulin	mU/l	1.44	1.08	1.80	0.180	0.360	Maccura i 1000 / i 800
	µU/ml	1.44	1.08	1.80	0.180	0.360	
Luteinising Hormone (LH)	mU/ml	3.87	3.10	4.64	0.385	0.770	Maccura i 1000 / i 800
Oestradiol	pg/ml	53.0	42.4	63.6	5.30	10.6	Maccura i 1000 / i 800
	pmol/l	195	156	234	19.5	39.0	
Progesterone	ng/ml	0.520	0.416	0.624	0.052	0.104	Maccura i 1000 / i 800
	nmol/l	1.66	1.33	1.99	0.165	0.330	
Prolactin	µIU/mL	145	116	174	14.5	29.0	Maccura i 1000 / i 800
PSA Free	ng/ml = µg/l	1.40	1.05	1.75	0.175	0.350	Maccura i 1000 / i 800
PSA Total	ng/ml = µg/l	1.52	1.14	1.90	0.190	0.380	Maccura i 1000 / i 800
Testosterone	ng/dl	36.1	28.9	43.3	3.60	7.20	Maccura i 1000 / i 800
	ng/ml	0.361	0.289	0.433	0.036	0.072	
	nmol/l	1.25	1.00	1.50	0.125	0.250	

Method		Immunoassay Premium - Level 1 (IA PREMIUM 1)					
Lot. No: 2347EC Cat. No: IA2638 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.154	0.123	0.185	0.016	0.031	Maccura i 1000 / i 800
Total Beta hCG	IU/ml	0.037	0.030	0.044	0.004	0.007	Maccura i 1000 / i 800
	mU/ml = IU/l	37.2	29.8	44.6	3.70	7.40	
Total T3	ng/dl	80.5	60.4	101	10.3	20.5	Maccura i 1000 / i 800
	ng/ml	0.807	0.605	1.01	0.102	0.203	
	nmol/l	1.24	0.930	1.55	0.155	0.310	
Total T4	ng/ml	23.9	17.9	29.9	3.00	6.00	Maccura i 1000 / i 800
	nmol/l	30.7	23.0	38.4	3.85	7.70	
	µg/dl	2.39	1.79	2.99	0.300	0.600	
Vitamin B12	pg/ml	180	144	216	18.0	36.0	Maccura i 1000 / i 800
	pmol/l	133	106	160	13.5	27.0	

IMMUNOASSAY PREMIUM - LEVEL I (IA PREMIUM I)

CAT. NO. IA2638	GTIN: 05055273203844	SIZE: 12 x 5 ml
CAT. NO. IA2633	GTIN: 05055273203837	SIZE: 4 x 5 ml
LOT NO. 2347EC	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.

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 is supplied lyophilised.

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

MATERIALS PROVIDED

Immunoassay Premium - 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 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

Rev. 19 Nov '24 me

IMMUNOASSAY PREMIUM LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5ml / 4 x 5ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
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
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
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

IMMUNOASSAY PREMIUM LEVEL 1 (IA PREMIUM 1)

Cat. No. IA2638 / IA2633 Lot. No. 2347EC Size 12 x 5ml / 4 x 5ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
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
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

Method		Immunoassay Premium - Level 1 (IA PREMIUM 1)					
Lot. No: 2347EC Cat. No: IA2638 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
1-25-(OH) ₂ Vitamin D	pmol/l	218	153	283	32.5	65.0	DiaSorin Liaison XL
25-OH-Vitamin D	nmol/l	71.1	53.3	88.9	8.90	17.8	DiaSorin Liaison
	nmol/l	68.9	51.7	86.1	8.60	17.2	DiaSorin Liaison XL
ACTH	pg/ml	50.5	37.9	63.1	6.30	12.6	DiaSorin Liaison XL
	pmol/l	11.1	8.33	13.9	1.40	2.80	
Aldosterone	pg/ml	110	82.5	138	14.0	28.0	DiaSorin Liaison
	pmol/l	305	229	381	38.0	76.0	
	pg/ml	121	90.8	151	15.0	30.0	DiaSorin Liaison XL
	pmol/l	336	252	420	42.0	84.0	
Alpha-fetoprotein	ng/ml	61.4	49.1	73.7	6.15	12.3	DiaSorin Liaison
	KIU/l = IU/ml	50.7	40.6	60.8	5.05	10.1	
	ng/ml	64.5	51.6	77.4	6.45	12.9	DiaSorin Liaison XL
	KIU/l = IU/ml	53.3	42.6	64.0	5.35	10.7	
Androstenedione	ng/ml	1.92	1.44	2.40	0.240	0.480	DiaSorin Liaison XL
	nmol/l	6.68	5.01	8.35	0.835	1.67	
Beta-2-Microglobulin	µg/ml = mg/l	1.99	1.59	2.39	0.200	0.400	DiaSorin Liaison XL
C-Peptide	ng/ml	6.40	4.80	8.00	0.800	1.60	DiaSorin Liaison XL
	nmol/l	2.12	1.59	2.65	0.265	0.530	
Cortisol	nmol/l	722	542	902	90.0	180	DiaSorin Liaison XL
	µg/dl	26.0	19.5	32.5	3.25	6.50	
DHEA-S	µmol/l	10.2	8.16	12.2	1.00	2.00	DiaSorin Liaison XL
Ferritin	ng/ml = µg/l	85.8	68.6	103	8.60	17.2	DiaSorin Liaison XL
Free T3	ng/dl	1.02	0.765	1.28	0.130	0.260	DiaSorin Liaison XL
	pg/ml	10.2	7.65	12.8	1.30	2.60	
	pmol/l	15.7	11.8	19.6	1.95	3.90	
Free T4	ng/dl	2.67	2.00	3.34	0.335	0.670	DiaSorin Liaison XL
	pg/ml	26.7	20.0	33.4	3.35	6.70	
	pmol/l	34.2	25.7	42.7	4.25	8.50	
FSH	mU/ml	33.7	27.0	40.4	3.35	6.70	DiaSorin Liaison XL
Growth Hormone (GH)	ng/ml	4.63	3.70	5.56	0.465	0.930	DiaSorin Liaison XL
	µU/ml	13.9	11.1	16.7	1.40	2.80	

Method		Immunoassay Premium - Level 1 (IA PREMIUM 1)					
Lot. No: 2347EC Cat. No: IA2638 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Insulin	mU/l	15.6	11.7	19.5	1.95	3.90	DiaSorin Liaison XL
	µU/ml	15.6	11.7	19.5	1.95	3.90	
Luteinising Hormone (LH)	mU/ml	40.0	32.0	48.0	4.00	8.00	DiaSorin Liaison XL
Oestradiol	pg/ml	162	130	194	16.0	32.0	DiaSorin Liaison XL
	pmol/l	595	476	714	59.5	119	
Prolactin	µIU/mL	667	534	800	66.5	133	DiaSorin Liaison XL
PSA Free	ng/ml = µg/l	9.73	7.30	12.2	1.24	2.47	DiaSorin Liaison XL
PSA Total	ng/ml = µg/l	12.5	9.38	15.6	1.55	3.10	DiaSorin Liaison XL
Testosterone	ng/dl	202	162	242	20.0	40.0	DiaSorin Liaison XL
	ng/ml	2.02	1.62	2.42	0.200	0.400	
	nmol/l	7.00	5.60	8.40	0.700	1.40	
Thyroglobulin	ng/ml	23.8	17.9	29.7	2.95	5.90	DiaSorin Liaison XL
Thyroid Stimulating Hormone	µU/ml = mIU/l	3.22	2.58	3.86	0.320	0.640	DiaSorin Liaison XL
Total T4	ng/ml	67.2	50.4	84.0	8.40	16.8	DiaSorin Liaison XL
	nmol/l	86.1	64.6	108	11.0	21.9	
	µg/dl	6.72	5.04	8.40	0.840	1.68	
Vitamin B12	pg/ml	495	396	594	49.5	99.0	DiaSorin Liaison XL
	pmol/l	365	292	438	36.5	73.0	

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM - LEVEL I
(IA PREMIUM I)**

Cat No. IA2638 / IA2633

Lot No. 2347EC

GTIN: 05055273203844 / 05055273203837

COMPONENT	UNITS	TARGET	RANGE	METHOD
25-OH Vitamin D II	ng/ml	17.9	12.5 - 23.3	SNIBE Maglumi Analysers II
Alpha-fetoprotein	IU/ml	9.30	6.51 - 12.1	SNIBE Maglumi Analysers
Androstenedione	ng/ml	0.372	0.260 - 0.484	SNIBE Maglumi Analysers
Beta-2-microglobulin	µg/ml	0.684	0.479 - 0.889	SNIBE Maglumi Analysers
C-Peptide	ng/ml	1.93	1.35 - 2.51	SNIBE Maglumi Analysers
Cortisol	ng/ml	117	81.9 - 152	SNIBE Maglumi Analysers
Digoxin	ng/ml	0.334	0.234 - 0.434	SNIBE Maglumi Analysers
Ferritin	ng/ml	20.1	14.1 - 26.1	SNIBE Maglumi Analysers
Free T3	pg/ml	2.28	1.60 - 2.96	SNIBE Maglumi Analysers
Free T4	pg/ml	8.52	5.96 - 11.1	SNIBE Maglumi Analysers
FSH	mU/ml	5.94	4.16 - 7.72	SNIBE Maglumi Analysers
Growth Hormone (GH)	ng/ml	3.11	2.18 - 4.04	SNIBE Maglumi Analysers
Immunoglobulin E	IU/ml	184	129 - 239	SNIBE Maglumi Analysers
Oestradiol	pg/ml	68.3	47.8 - 88.8	SNIBE Maglumi Analysers
Luteinising Hormone (LH)	mU/ml	5.00	3.50 - 6.50	SNIBE Maglumi Analysers
Prolactin	µU/ml	134	93.8 - 174	SNIBE Maglumi Analysers
PSA Free	ng/ml	1.03	0.721 - 1.34	SNIBE Maglumi Analysers
PSA Total	ng/ml	1.71	1.20 - 2.22	SNIBE Maglumi Analysers
SHBG	nmol/l	14.5	10.2 - 18.9	SNIBE Maglumi Analysers
Thyroid Stimulating Hormone	µU/ml	0.138	0.097 - 0.179	SNIBE Maglumi Analysers
Total Beta hCG	mIU/ml	40.1	28.1 - 52.1	SNIBE Maglumi Analysers
Total T3	ng/ml	0.358	0.251 - 0.465	SNIBE Maglumi Analysers
Total T4	ng/ml	29.3	20.5 - 38.1	SNIBE Maglumi Analysers

EC REP

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14 Jan '25 me