

PRODUCT INFORMATION

IA3110

2397EC

Please note that in Immunoassay Premium Plus - Level 2, lot 2397EC, the value for T-Uptake is currently unavailable and will be updated in due course.

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

CCS INC767

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

CAT. NO. IA3110	GTIN: 05055273207262	SIZE: 12 x 5 ml
CAT. NO. IA3112	GTIN: 05055273207286	SIZE: 4 x 5 ml
LOT NO. 2397EC	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 lyophilised.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Premium Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. 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,
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IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
17-OH-Progesterone	nmol/l	3.32	2.49	4.15	DIAsource RIA
	ng/ml	1.10	0.824	1.38	
	nmol/l	2.38	1.79	2.98	DIAsource ELISA
	ng/ml	0.788	0.592	0.984	
	nmol/l	2.04	1.53	2.55	SNIBE Maglumi Analysers
	ng/ml	0.675	0.506	0.844	
25-OH Vitamin D	nmol/l	87.0	65.3	109	Siemens Centaur XP/XPT/Classic
	nmol/l	56.6	42.5	70.8	Roche Vitamin D Total
	nmol/l	62.8	47.1	78.5	Abbott Architect (3L52)
	nmol/l	104	78.0	130	Vitros ECI
	nmol/l	73.8	55.4	92.3	BioMerieux Vidas
	nmol/l	72.2	54.2	90.3	Beckman Dxl 600/800
	nmol/l	63.2	47.4	79.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	64.6	48.5	80.8	Abbott Alinity i
	nmol/l	84.8	63.6	106	Siemens Atellica IM
	nmol/l	57.1	42.8	71.4	Roche Vitamin D Total II e801
	nmol/l	52.8	39.6	66.0	Roche Vitamin D Total III
ACTH	pmol/l	6.37	4.78	7.96	Siemens Immulite 2000/2500
	pg/ml	29.0	21.7	36.3	
	pmol/l	8.21	6.16	10.3	Roche Cobas 4000/E411
	pg/ml	37.3	28.0	46.6	
	pmol/l	7.62	5.72	9.53	Roche Cobas e601/602
	pg/ml	34.6	26.0	43.2	
	pmol/l	7.39	5.54	9.24	Roche Cobas e402/e801
	pg/ml	33.6	25.2	42.0	
Aldosterone	pmol/l	319	239	399	Diasorin Liaison XL
	pg/ml	115	86.2	144	
Alphafoetoprotein	KIU/l = IU/ml	53.3	42.6	64.0	Vitros ECI
	ng/ml	64.5	51.5	77.5	
	KIU/l = IU/ml	56.0	44.8	67.2	Siemens Centaur XP/XPT/Classic
	ng/ml	67.8	54.2	81.4	
	KIU/l = IU/ml	49.5	39.6	59.4	Abbott Architect
	ng/ml	59.9	47.9	71.9	
	KIU/l = IU/ml	50.4	40.3	60.5	Beckman Dxl800
	ng/ml	61.0	48.8	73.2	
	KIU/l = IU/ml	52.5	42.0	63.0	Roche Cobas e601/602
	ng/ml	63.5	50.8	76.2	
	KIU/l = IU/ml	56.2	45.0	67.4	Roche Cobas 4000/E411
	ng/ml	68.0	54.5	81.5	
	KIU/l = IU/ml	55.9	44.7	67.1	Siemens Atellica IM
	ng/ml	67.6	54.1	81.1	
	KIU/l = IU/ml	49.9	39.9	59.9	Abbott Alinity i
	ng/ml	60.4	48.3	72.5	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	54.5	43.6	65.4	Roche Cobas e402/e801
	ng/ml	65.9	52.8	79.0	
Amikacin	µmol/l	15.2	12.2	18.2	Gravimetric
	µg/ml	8.90	7.14	10.7	
Androstenedione	nmol/l	13.8	10.4	17.3	Siemens Immulite 2000
	ng/ml	3.96	2.98	4.94	
Beta-2-microglobulin	µg/ml = mg/l	2.27	1.82	2.72	Roche Cobas 6000/8000
C-Peptide	nmol/l	1.930	1.450	2.410	Roche Cobas e601/602
	ng/ml	5.83	4.38	7.28	
	nmol/l	1.910	1.430	2.390	Roche Cobas e402/e801
	ng/ml	5.77	4.32	7.22	
CA 15-3	U/ml	42.1	33.7	50.5	Siemens Centaur XP/XPT/Classic
	U/ml	48.9	39.1	58.7	Abbott Architect
	U/ml	46.7	37.4	56.0	Roche Cobas e601/602
	U/ml	49.1	39.3	58.9	Roche Cobas 4000/E411
	U/ml	44.8	35.8	53.8	Siemens Atellica IM
	U/ml	46.9	37.5	56.3	Roche Cobas e402/e801
	U/ml	44.0	35.2	52.8	Abbott Alinity i
CA 19-9	U/ml	69.1	55.3	82.9	BioMerieux Vidas
	U/ml	80.7	64.6	96.8	Siemens Centaur XP/XPT/Classic
	U/ml	181	145	217	Beckman Access
	U/ml	120	96.0	144	Abbott Architect XR/XR2/XRL
	U/ml	66.3	53.0	79.6	Roche Cobas e601/602
	U/ml	70.9	56.7	85.1	Roche Cobas 4000/E411
	U/ml	108	86.4	130	Siemens Atellica IM
	U/ml	70.3	56.2	84.4	Roche Cobas e402/e801
CA125	U/ml	123	98.4	148	Abbott Alinity XR/XR2/XRL
	U/ml	114	91.2	137	BioMerieux Vidas
	U/ml	100	80.0	120	Vitros ECI
	U/ml	142	114	170	Abbott Architect
	U/ml	110	88.0	132	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	83.1	66.5	100	Beckman Dxl800
	U/ml	105	84.0	126	Roche Cobas 4000/E411
	U/ml	103	82.4	124	Roche Cobas e601/602
	U/ml	135	108	162	Siemens Atellica IM
	U/ml	91.4	73.1	110	Roche Cobas e402/e801
Carbamazepine	U/ml	144	115	173	Abbott Alinity i
	µmol/l	38.8	31.0	46.6	Abbott Architect (CMIA)
	µg/ml	9.17	7.33	11.0	
	µmol/l	40.0	32.0	48.0	Roche Cobas 6000/8000
	µg/ml	9.46	7.56	11.4	
	µmol/l	38.5	30.8	46.2	Gravimetric
	µg/ml	9.10	7.28	10.9	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	24.6	19.7	29.5	BioMerieux Vidas
	ng/ml = µg/l	25.5	20.4	30.6	Vitros ECI

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	24.8	19.8	29.8	Beckman Access
	ng/ml = µg/l	29.3	23.4	35.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	29.7	23.8	35.6	Abbott Architect
	ng/ml = µg/l	25.1	20.1	30.1	Beckman Dxl800
	ng/ml = µg/l	23.5	18.8	28.2	Roche Cobas e601/602
	ng/ml = µg/l	23.6	18.9	28.3	Roche Cobas 4000/E411
	ng/ml = µg/l	29.5	23.6	35.4	Siemens Atellica IM
	ng/ml = µg/l	23.4	18.7	28.1	Roche Cobas e402/e801
	ng/ml = µg/l	30.0	24.0	36.0	Abbott Alinity i
Cortisol	nmol/l	744	558	930	Siemens Centaur XP/XPT/Classic
	µg/dl	26.8	20.1	33.5	
	nmol/l	556	417	695	Siemens Immulite 2000/2500
	µg/dl	20.0	15.0	25.0	
	nmol/l	564	423	705	Vitros ECI
	µg/dl	20.3	15.2	25.4	
	nmol/l	584	438	730	Abbott Architect
	µg/dl	21.0	15.8	26.2	
	nmol/l	594	446	743	Beckman Dxl800
	µg/dl	21.4	16.1	26.7	
	nmol/l	658	494	823	Roche Cobas e601/602
	µg/dl	23.7	17.8	29.6	
	nmol/l	652	489	815	Roche Cobas 4000/E411
	µg/dl	23.5	17.6	29.4	
	nmol/l	635	476	794	Roche Cobas 4000/e411 Gen II
	µg/dl	22.9	17.1	28.7	
	nmol/l	626	470	783	Roche Cobas e601/602 Gen II
	µg/dl	22.5	16.9	28.1	
	nmol/l	808	606	1010	Siemens Atellica IM
	µg/dl	29.1	21.8	36.4	
	nmol/l	612	459	765	Roche Cobas e402/e801
	µg/dl	22.0	16.5	27.5	
	nmol/l	624	468	780	Roche Cobas e801 Gen II
	µg/dl	22.5	16.8	28.2	
	nmol/l	583	437	729	Abbott Alinity i
	µg/dl	21.0	15.7	26.3	
DHEA-S	µmol/l	10.8	8.64	13.0	Siemens Immulite 2000/2500
	µmol/l	12.5	10.0	15.0	Abbott Architect
	µmol/l	10.1	8.08	12.1	Beckman Dxl800
	µmol/l	14.3	11.4	17.2	Roche Cobas 4000/E411
	µmol/l	13.6	10.9	16.3	Roche Cobas e601/602
	µmol/l	14.1	11.3	16.9	Roche Cobas e402/e801
	µmol/l	11.9	9.52	14.3	Abbott Alinity i
Digoxin	nmol/l	2.47	1.98	2.96	Abbott Architect (CMIA)
	ng/ml	1.93	1.55	2.31	
	nmol/l	2.92	2.34	3.50	Roche Cobas e402/e801
	ng/ml	2.28	1.83	2.73	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Digoxin	nmol/l	3.07	2.46	3.68	Gravimetric
	ng/ml	2.40	1.92	2.87	
Ethosuximide	µmol/l	360	288	432	Gravimetric
	µg/ml	51.0	40.8	61.3	
Ferritin	ng/ml = µg/l	95.7	76.6	115	Roche Elecsys/Cobas e411
	ng/ml = µg/l	55.0	44.0	66.0	Beckman Access
	ng/ml = µg/l	53.6	42.9	64.3	Vitros ECI
	ng/ml = µg/l	63.2	50.6	75.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	87.0	69.6	104	Abbott Architect
	ng/ml = µg/l	94.8	75.8	114	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	53.8	43.0	64.6	Beckman Dxl800
	ng/ml = µg/l	90.7	72.6	109	Abbott Alinity i
	ng/ml = µg/l	60.3	48.2	72.4	Siemens Atellica IM
	ng/ml = µg/l	90.9	72.7	109	Roche Cobas e402/e801
Folate	nmol/l	11.3	8.59	14.0	Beckman Access
	ng/ml	4.98	3.79	6.17	
	nmol/l	7.27	5.53	9.01	Siemens Immulite 2000
	ng/ml	3.21	2.44	3.98	
	nmol/l	6.65	5.05	8.25	Vitros ECI
	ng/ml	2.93	2.23	3.63	
	nmol/l	9.97	7.58	12.4	Abbott Architect
	ng/ml	4.40	3.34	5.46	
	nmol/l	20.9	15.9	25.9	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	9.22	7.01	11.4	
	nmol/l	12.0	9.12	14.9	Beckman Dxl 600 / 800 - A98032
	ng/ml	5.29	4.02	6.56	
	nmol/l	10.2	7.75	12.6	Roche Folate III - 07559992
	ng/ml	4.50	3.42	5.58	
	nmol/l	20.7	15.7	25.7	Siemens Atellica IM
	ng/ml	9.13	6.92	11.3	
	nmol/l	10.6	8.06	13.1	Abbott Alinity i
	ng/ml	4.67	3.55	5.79	
	nmol/l	10.5	7.98	13.0	Roche Folate 07027290 e801
	ng/ml	4.63	3.52	5.74	
Free T3	pmol/l	10.3	7.73	12.9	Beckman Access
	ng/dl	0.670	0.502	0.838	
	pg/ml	6.71	5.03	8.39	
	pmol/l	30.4	22.8	38.0	Vitros ECI
	ng/dl	1.98	1.48	2.48	
	pg/ml	19.8	14.8	24.8	
	pmol/l	12.6	9.45	15.8	Siemens Centaur XP/XPT/Classic
	ng/dl	0.819	0.614	1.02	
	pg/ml	8.20	6.15	10.3	
	pmol/l	11.2	8.40	14.0	Abbott Architect, 2 point calibration
	ng/dl	0.728	0.546	0.910	
	pg/ml	7.29	5.47	9.11	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Free T3	pmol/l	9.12	6.84	11.4	Beckman Dxl800
	ng/dl	0.593	0.445	0.741	
	pg/ml	5.94	4.45	7.43	
	pmol/l	14.3	10.7	17.9	Roche Cobas 4000/E411
	ng/dl	0.930	0.696	1.16	
	pg/ml	9.31	6.97	11.7	
	pmol/l	14.0	10.5	17.5	Roche Cobas e601/602
	ng/dl	0.910	0.683	1.14	
	pg/ml	9.11	6.84	11.4	
	pmol/l	13.2	9.90	16.5	Siemens Atellica IM
	ng/dl	0.858	0.644	1.07	
	pg/ml	8.59	6.44	10.7	
	pmol/l	11.1	8.33	13.9	Abbott Architect, 6 point calibration
	ng/dl	0.722	0.541	0.903	
	pg/ml	7.23	5.42	9.04	
	pmol/l	14.0	10.5	17.5	Roche Cobas e402/e801
	ng/dl	0.910	0.683	1.14	
	pg/ml	9.11	6.84	11.4	
	pmol/l	11.3	8.48	14.1	Abbott Alinity, 6 point cal
	ng/dl	0.735	0.551	0.919	
	pg/ml	7.36	5.52	9.20	
Free T4	pmol/l	22.6	17.0	28.3	Beckman Access
	ng/dl	1.76	1.33	2.19	
	pg/ml	17.6	13.3	21.9	
	pmol/l	60.2	45.2	75.3	Vitros ECI
	ng/dl	4.70	3.53	5.87	
	pg/ml	47.0	35.3	58.7	
	pmol/l	20.4	15.3	25.5	Siemens Centaur XP/XPT/Classic
	ng/dl	1.59	1.19	1.99	
	pg/ml	15.9	11.9	19.9	
	pmol/l	28.7	21.5	35.9	Siemens Immulite 2000/2500
	ng/dl	2.24	1.68	2.80	
	pg/ml	22.4	16.8	28.0	
	pmol/l	21.0	15.8	26.3	Abbott Architect
	ng/dl	1.64	1.23	2.05	
	pg/ml	16.4	12.3	20.5	
	pmol/l	21.8	16.4	27.3	Beckman Dxl800
	ng/dl	1.70	1.28	2.12	
	pg/ml	17.0	12.8	21.2	
	pmol/l	27.3	20.5	34.1	Roche Cobas e601/602
	ng/dl	2.13	1.60	2.66	
	pg/ml	21.3	16.0	26.6	
	pmol/l	27.3	20.5	34.1	Roche Cobas 4000/E411
	ng/dl	2.13	1.60	2.66	
	pg/ml	21.3	16.0	26.6	
	pmol/l	20.4	15.3	25.5	Siemens Atellica IM
	ng/dl	1.59	1.19	1.99	
	pg/ml	15.9	11.9	19.9	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Free T4	pmol/l	20.3	15.2	25.4	Abbott Alinity i
	ng/dl	1.58	1.19	1.97	
	pg/ml	15.8	11.9	19.7	
	pmol/l	29.0	21.8	36.3	Roche Cobas e402/e801
	ng/dl	2.26	1.70	2.82	
	pg/ml	22.6	17.0	28.2	
FSH	mU/ml	26.0	20.8	31.2	BioMerieux Vidas
	mU/ml	19.3	15.4	23.2	Vitros ECI
	mU/ml	27.6	22.1	33.1	Siemens Centaur XP/XPT/Classic
	mU/ml	24.4	19.5	29.3	Siemens Immulite 2000/2500
	mU/ml	21.3	17.0	25.6	Abbott Architect
	mU/ml	28.1	22.5	33.7	Beckman Dxl800
	mU/ml	23.7	19.0	28.4	Roche Cobas 4000/E411
	mU/ml	23.1	18.5	27.7	Roche Cobas e601/602
	mU/ml	27.2	21.8	32.6	Siemens Atellica IM
	mU/ml	21.7	17.4	26.0	Abbott Alinity i
	mU/ml	22.6	18.1	27.1	Roche Cobas e402/e801
Gentamicin	µmol/l	8.16	6.53	9.79	Gravimetric
	µg/ml	3.90	3.12	4.68	
Growth Hormone (GH)	µU/ml	18.9	15.1	22.7	Siemens Immulite 2000/2500
	ng/ml	6.29	5.03	7.55	
	µU/ml	16.4	13.1	19.7	Roche Cobas e601/602
	ng/ml	5.46	4.36	6.56	
	µU/ml	14.2	11.4	17.0	Diasorin Liaison XL
	ng/ml	4.73	3.80	5.66	
	µU/ml	15.8	12.6	19.0	Roche Cobas e402/e801
Immunoglobulin E	ng/ml	5.26	4.20	6.32	
	KIU/l = IU/ml	131	105	157	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	120	96.0	144	Abbott Architect
	KIU/l = IU/ml	152	122	182	Roche Cobas 4000/E411
	KIU/l = IU/ml	144	115	173	Roche Cobas e601/602
Insulin	KIU/l = IU/ml	151	121	181	Roche Cobas e402/e801
	mU/l	3.65	2.74	4.56	Siemens Immulite 2000
	µU/ml	3.65	2.74	4.56	
	mU/l	11.0	8.25	13.8	Abbott Architect
	µU/ml	11.0	8.25	13.8	
	mU/l	15.0	11.3	18.8	Roche Cobas 4000/E411
	µU/ml	15.0	11.3	18.7	
	mU/l	14.7	11.0	18.4	Roche Cobas 6000/8000
	µU/ml	14.7	11.0	18.4	
Luteinising Hormone (LH)	mU/l	10.1	7.58	12.6	Abbott Alinity i
	µU/ml	10.1	7.58	12.6	
	mU/ml	30.5	24.4	36.6	BioMerieux Vidas
	mU/ml	44.1	35.3	52.9	Vitros ECI

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Luteinising Hormone (LH)	mU/ml	30.4	24.3	36.5	Siemens Centaur XP/XPT/Classic
	mU/ml	25.1	20.1	30.1	Abbott Architect
	mU/ml	24.2	19.4	29.0	Beckman Dxl800
	mU/ml	34.3	27.4	41.2	Roche Cobas 4000/E411
	mU/ml	33.5	26.8	40.2	Roche Cobas e601/602
	mU/ml	31.4	25.1	37.7	Siemens Atellica IM
	mU/ml	24.9	19.9	29.9	Abbott Alinity i
	mU/ml	35.3	28.2	42.4	Roche Cobas e402/e801
Oestradiol	pmol/l	669	535	803	Abbott Architect
	pg/ml	182	146	218	
	pmol/l	740	592	888	Roche Cobas e601/602 (Estradiol III)
	pg/ml	201	161	241	
	pmol/l	726	581	871	Roche Cobas 4000/E411 (Estradiol III)
	pg/ml	197	158	236	
	pmol/l	701	561	841	Beckman Dxl600/800 Sensitive B84493
	pg/ml	191	153	229	
	pmol/l	1018	814	1222	Siemens Atellica IM
	pg/ml	277	221	333	
	pmol/l	670	536	804	Abbott Alinity i
	pg/ml	182	146	218	
Paracetamol	pmol/l	732	586	878	Roche Cobas e801 (Estradiol III)
	pg/ml	199	159	239	
	mmol/l	0.320	0.256	0.384	Roche Cobas c501/502/503/701/702
	mg/l	48.4	38.7	58.1	
Phenobarbital	mmol/l	0.348	0.280	0.420	Gravimetric
	mg/l	52.7	42.4	63.5	
	µmol/l	80.4	64.3	96.5	Siemens Immulite 2000/2500
	µg/ml	18.7	14.9	22.5	
	µmol/l	78.7	63.0	94.4	Beckman AU400/600/640/2700/5400
	µg/ml	18.3	14.6	22.0	
Phenytoin	µmol/l	77.2	61.8	92.6	Roche Cobas C303/501/502/503/701
	µg/ml	17.9	14.3	21.5	
	µmol/l	77.6	62.1	93.1	Gravimetric
	µg/ml	18.0	14.4	21.6	
	µmol/l	68.1	54.5	81.7	Abbott Architect
	µg/ml	17.2	13.8	20.6	
Primidone	µmol/l	65.0	52.0	78.0	Roche Cobas 6000/8000
	µg/ml	16.4	13.1	19.7	
	µmol/l	71.3	57.0	85.6	Gravimetric
	µg/ml	18.0	14.4	21.6	
Progesterone	µmol/l	22.5	18.0	27.0	Gravimetric
	µg/ml	4.91	3.93	5.89	
Progesterone	nmol/l	32.9	26.3	39.5	BioMerieux Vidas
	ng/ml	10.3	8.23	12.4	
	nmol/l	22.9	18.3	27.5	Siemens Centaur XP/XPT/Classic
	ng/ml	7.17	5.73	8.61	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Progesterone	nmol/l	25.4	20.3	30.5	Siemens Immulite 2000/2500
	ng/ml	7.95	6.35	9.55	
	nmol/l	28.8	23.0	34.6	Abbott Architect
	ng/ml	9.01	7.20	10.8	
	nmol/l	22.4	17.9	26.9	Beckman Dxl Prog DE Cal A80773
	ng/ml	7.01	5.60	8.42	
	nmol/l	32.3	25.8	38.8	Roche Cobas e601/602 (Prog. III)
	ng/ml	10.1	8.08	12.1	
	nmol/l	32.1	25.7	38.5	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	10.0	8.04	12.0	
	nmol/l	26.4	21.1	31.7	Abbott Alinity i
	ng/ml	8.26	6.60	9.92	
Prolactin	nmol/l	25.4	20.3	30.5	Siemens Atellica IM
	ng/ml	7.95	6.35	9.55	
	nmol/l	32.8	26.2	39.4	Roche Cobas e801 (Prog. III)
	ng/ml	10.3	8.20	12.4	
	µU/ml	658	526	790	BioMerieux Vidas
	µU/ml	538	430	646	Vitros ECI
	µU/ml	455	364	546	Siemens Centaur XP/XPT/Classic
	µU/ml	567	454	680	Abbott Architect
	µU/ml	522	418	626	Beckman Dxl800
	µU/ml	760	608	912	Roche Cobas 4000/E411
	µU/ml	727	582	872	Roche Cobas e601/602
	µU/ml	457	366	548	Siemens Atellica IM
PSA Free	µU/ml	611	489	733	Abbott Alinity i
	µU/ml	699	559	839	Roche Cobas e801 PRL II
	ng/ml = µg/l	13.9	10.4	17.4	Abbott Architect
	ng/ml = µg/l	11.8	8.85	14.8	Roche Cobas 4000/E411
	ng/ml = µg/l	11.3	8.48	14.1	Roche Cobas e601/602
PSA Total	ng/ml = µg/l	14.4	10.8	18.0	Abbott Alinity i
	ng/ml = µg/l	10.7	8.03	13.4	Roche Cobas e402/e801
	ng/ml = µg/l	17.7	13.3	22.1	Beckman Access standardised to Hybritech
	ng/ml = µg/l	13.2	9.90	16.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	10.7	8.03	13.4	Abbott Architect
	ng/ml = µg/l	16.9	12.7	21.1	Beckman Dxl standardised to Hybritech
	ng/ml = µg/l	13.1	9.83	16.4	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	15.3	11.5	19.1	Roche Cobas 4000/E411
	ng/ml = µg/l	14.7	11.0	18.4	Roche Cobas e601/602
	ng/ml = µg/l	14.8	11.1	18.5	Ortho Vitros 3600/5600/ECi PSA II
Salicylic Acid	ng/ml = µg/l	14.1	10.6	17.6	Siemens Atellica IM
	ng/ml = µg/l	10.9	8.18	13.6	Abbott Alinity i
SHBG	ng/ml = µg/l	14.1	10.6	17.6	Roche Cobas e402/e801
	nmol/l	36.5	29.2	43.8	Siemens Immulite 2000/2500
	nmol/l	39.4	31.5	47.3	Abbott Architect

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
SHBG	nmol/l	35.3	28.2	42.4	Roche Cobas e801 - 413429
	nmol/l	36.4	29.1	43.7	Roche analysers - 413417/15
	nmol/l	40.5	32.4	48.6	Abbott Alinity i
T Uptake	%U	TBD	TBD	TBD	Siemens Immulite 2000
Testosterone	nmol/l	13.5	10.8	16.2	Siemens Immulite 2000/2500
	ng/ml	3.89	3.11	4.67	
	ng/dl	389	311	467	
	nmol/l	12.1	9.68	14.5	Abbott Architect
	ng/ml	3.48	2.79	4.17	
	ng/dl	348	279	417	
	nmol/l	11.1	8.88	13.3	Beckman Dxl800
	ng/ml	3.20	2.56	3.84	
	ng/dl	320	256	384	
	nmol/l	12.8	10.2	15.4	Roche Cobas 4000/e411 Test II
	ng/ml	3.69	2.94	4.44	
	ng/dl	369	294	444	
	nmol/l	12.9	10.3	15.5	Roche Cobas e601/602 Test II
	ng/ml	3.72	2.97	4.47	
	ng/dl	372	297	447	
	nmol/l	11.5	9.20	13.8	Abbott Architect 2nd Generation
	ng/ml	3.31	2.65	3.97	
	ng/dl	331	265	397	
	nmol/l	13.4	10.7	16.1	Siemens Centaur TST II
	ng/ml	3.86	3.08	4.64	
	ng/dl	386	308	464	
	nmol/l	13.1	10.5	15.7	Siemens Atellica IM
	ng/ml	3.77	3.02	4.52	
	ng/dl	377	302	452	
	nmol/l	12.7	10.2	15.2	Roche Cobas e801 Test II
	ng/ml	3.66	2.94	4.38	
	ng/dl	366	294	438	
	nmol/l	12.4	9.92	14.9	Abbott Alinity i
	ng/ml	3.57	2.86	4.28	
	ng/dl	357	286	428	
Theophylline	µmol/l	83.8	67.0	101	Gravimetric
	µg/ml	15.1	12.1	18.2	
Thyroglobulin	ng/ml	15.4	11.6	19.3	Siemens Immulite 2000
	ng/ml	36.2	27.2	45.3	Roche Cobas e601/602
	ng/ml	40.7	30.5	50.9	Abbott Architect 2000i
	ng/ml	35.7	26.8	44.6	Roche Cobas e601/602 Tg II
	ng/ml	35.7	26.8	44.6	Roche Cobas e801 Tg II
	ng/ml	38.1	28.6	47.6	Abbott Alinity i
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.33	1.86	2.80	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	2.31	1.85	2.77	Vitros Eci
	µU/ml = mIU/l	2.23	1.78	2.68	Siemens Immulite 2000/2500
	µU/ml = mIU/l	1.96	1.57	2.35	Abbott Architect

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.62	2.10	3.14	Roche Cobas 4000/E411
	µU/ml = mIU/l	2.60	2.08	3.12	Roche Cobas e601/602
	µU/ml = mIU/l	2.43	1.94	2.92	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	2.12	1.70	2.54	Beckman Dxl 600/800 Access (3rd IS)
	µU/ml = mIU/l	2.43	1.94	2.92	Siemens Atellica IM
	µU/ml = mIU/l	1.92	1.54	2.30	Abbott Alinity i
	µU/ml = mIU/l	2.46	1.97	2.95	Roche Cobas e402/e801
Tobramycin	µmol/l	7.16	5.73	8.59	Gravimetric
	µg/ml	3.35	2.68	4.02	
Total Beta hCG	mU/ml=IU/l	86.8	69.4	104	Vitros ECI
	IU/ml	0.087	0.069	0.105	
	mU/ml=IU/l	5.79	4.63	6.95	Siemens Centaur XP/XPT/Classic
	IU/ml	0.006	0.005	0.007	
	mU/ml=IU/l	179	143	215	Siemens Immulite 2000
	IU/ml	0.179	0.143	0.215	
	mU/ml=IU/l	5.32	4.26	6.38	Abbott Architect
	IU/ml	0.005	0.004	0.006	
	mU/ml=IU/l	33.8	27.0	40.6	Roche hCG+Beta
	IU/ml	0.034	0.027	0.041	
	mU/ml=IU/l	6.73	5.38	8.08	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.007	0.005	0.009	
	mU/ml=IU/l	5.79	4.63	6.95	Siemens Atellica IM
	IU/ml	0.006	0.005	0.007	
Total T3	mU/ml=IU/l	5.34	4.27	6.41	Abbott Alinity i
	IU/ml	0.005	0.004	0.006	
	mU/ml=IU/l	33.1	26.5	39.7	Roche hCG+Beta e801
	IU/ml	0.033	0.027	0.039	
	nmol/l	3.91	2.93	4.89	Siemens Centaur XP/XPT/Classic
	ng/ml	2.55	1.91	3.19	
	ng/dl	255	191	319	
	nmol/l	3.07	2.30	3.84	Abbott Architect
	ng/ml	2.00	1.50	2.50	
	ng/dl	200	150	250	
	nmol/l	4.12	3.09	5.15	Vitros ECI
	ng/ml	2.68	2.01	3.35	
	ng/dl	268	201	335	
	nmol/l	3.90	2.93	4.88	Roche Cobas 4000/E411
	ng/ml	2.54	1.91	3.17	
	ng/dl	254	191	317	
	nmol/l	3.89	2.92	4.86	Roche Cobas e601/602
	ng/ml	2.53	1.90	3.16	
	ng/dl	253	190	316	
	nmol/l	3.20	2.40	4.00	Abbott Alinity i
	ng/ml	2.08	1.56	2.60	
	ng/dl	208	156	260	
	nmol/l	4.15	3.11	5.19	Siemens Atellica IM
	ng/ml	2.70	2.02	3.38	
	ng/dl	270	202	338	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Total T3	nmol/l	4.14	3.11	5.18	Roche Cobas e402/e801
	ng/ml	2.70	2.02	3.38	
	ng/dl	270	202	338	
Total T4	nmol/l	113	84.8	141	Vitros ECI
	µg/dl	8.81	6.61	11.0	
	ng/ml	88.1	66.1	110	
	nmol/l	112	84.0	140	Beckman Access
	µg/dl	8.74	6.55	10.9	
	ng/ml	87.4	65.5	109	
	nmol/l	113	84.8	141	Siemens Centaur XP/XPT/Classic
	µg/dl	8.81	6.61	11.0	
	ng/ml	88.1	66.1	110	
	nmol/l	107	80.3	134	Siemens Immulite 2000/2500
	µg/dl	8.35	6.26	10.4	
	ng/ml	83.5	62.6	104	
	nmol/l	105	78.8	131	Abbott Architect
	µg/dl	8.19	6.15	10.2	
	ng/ml	81.9	61.5	102	
	nmol/l	106	79.5	133	Roche Cobas 4000/E411
	µg/dl	8.27	6.20	10.3	
	ng/ml	82.7	62.0	103	
	nmol/l	102	76.5	128	Roche Cobas e601/602
	µg/dl	7.96	5.97	9.95	
	ng/ml	79.6	59.7	100	
	nmol/l	108	81.0	135	Abbott Alinity i
	µg/dl	8.42	6.32	10.5	
	ng/ml	84.2	63.2	105	
	nmol/l	122	91.5	153	Siemens Atellica IM
	µg/dl	9.52	7.14	11.9	
	ng/ml	95.2	71.4	119	
	nmol/l	100	75.0	125	Roche Cobas e402/e801
	µg/dl	7.80	5.85	9.75	
	ng/ml	78.0	58.5	97.5	
Valproic Acid	µmol/l	617	494	740	Abbott Architect (CMIA)
	µg/ml	89.0	71.3	107	
	µmol/l	603	482	724	Roche Cobas 6000/8000
	µg/ml	87.0	69.6	104	
	µmol/l	597	478	716	Abbott Alinity (PETINA)
	µg/ml	86.1	69.0	103	
Vancomycin	µmol/l	638	510	766	Gravimetric
	µg/ml	92.1	73.6	111	
	µmol/l	7.81	6.25	9.37	Abbott Architect (CMIA)
	µg/ml	11.6	9.29	13.9	
	µmol/l	6.32	5.06	7.58	Roche Cobas 6000/8000
	µg/ml	9.39	7.52	11.3	

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

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5 ml / 4 x 5 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Vancomycin	µmol/l	7.10	5.68	8.52	Gravimetric
	µg/ml	10.5	8.44	12.7	
Vitamin B12	pmol/l	332	266	398	Beckman Access
	pg/ml	450	360	540	
	pmol/l	436	349	523	Siemens Centaur XP/XPT/Classic
	pg/ml	591	473	709	
	pmol/l	431	345	517	Siemens Immulite 2000
	pg/ml	584	467	701	
	pmol/l	392	314	470	Abbott Architect
	pg/ml	531	425	637	
	pmol/l	402	322	482	Vitros Eci
	pg/ml	545	436	654	
	pmol/l	317	254	380	Beckman Dxl800
	pg/ml	430	344	516	
	pmol/l	441	353	529	Roche Cobas 4000/e411 Gen II
	pg/ml	598	478	718	
	pmol/l	439	351	527	Roche Cobas e601/602 Gen II
	pg/ml	595	476	714	
	pmol/l	452	362	542	Siemens Atellica IM
	pg/ml	612	491	733	
	pmol/l	394	315	473	Abbott Alinity i
	pg/ml	534	427	641	
	pmol/l	421	337	505	Roche Cobas e801 Gen II
	pg/ml	570	457	683	

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

CAT. NO. IA3110	GTIN: 05055273207262	SIZE: 12 x 5 ml
CAT. NO. IA3112	GTIN: 05055273207286	SIZE: 4 x 5 ml
LOT NO. 2397EC	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 lyophilised.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Premium Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. 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 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5ml / 4 x 5ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	ng/ml	60.1	43.9	76.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		60.1	43.9	76.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA125	U/ml	152	111	193	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		152	111	193	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 15-3	U/ml	26.5	19.4	33.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		26.5	19.4	33.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 19-9	U/ml	57.3	41.8	72.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		57.3	41.8	72.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Carcinoembryonic Antigen (CEA)	ng/ml	19.6	14.3	24.9	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		19.6	14.3	24.9	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Cortisol	µg/dL	22.9	15.6	30.2	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		22.9	15.6	30.2	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
C-Peptide	ng/mL	4.89	3.33	6.46	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		4.89	3.33	6.46	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
DHEA-S	µg/dL	462	314	610	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		462	314	610	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Ferritin	ng/mL	72.5	52.9	92.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		74.5	54.4	94.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
FSH	mIU/mL	27.1	18.4	35.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101
		27.1	18.4	35.7	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101
		23.0	15.6	30.3	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401
		23.0	15.6	30.3	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401
Total Beta hCG	mIU/mL	6.06	4.12	7.99	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i
		5.60	3.81	7.39	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i
		161	109	212	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i
		179	122	237	Wiener Lab CLIA Series & Mindray hCG2 CL 900i
Insulin	µIU/mL	14.9	10.9	18.9	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		15.2	11.1	19.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Luteinising Hormone (LH)	mIU/mL	36.1	26.3	45.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		35.7	26.1	45.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Oestradiol	pg/mL	234	159	309	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501
		234	159	309	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501
		275	187	362	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001
		275	187	362	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001
Progesterone	ng/mL	11.8	8.05	15.6	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		11.8	8.05	15.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
		9.44	6.42	12.5	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i
		9.44	6.42	12.5	Wiener Lab CLIA Series & Mindray PROG II CL 900i

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2397EC Size 12 x 5ml / 4 x 5ml Expiry 2026-11-28

		Range			methods
Analyte	unit	Target	low	high	
Prolactin	ng/mL	31.7	23.2	40.3	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		32.2	23.5	40.9	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Free	ng/mL	13.7	10.00	17.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		13.7	10.00	17.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Total	ng/mL	14.5	10.6	18.5	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		15.1	11.0	19.2	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Free T3	pg/mL	7.89	5.76	10.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X
		8.07	5.89	10.2	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X
		7.69	5.62	9.77	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00
		7.69	5.62	9.77	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00
Total T3	ng/mL	2.03	1.48	2.58	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		2.03	1.48	2.58	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		1.91	1.39	2.42	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		1.91	1.39	2.42	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Free T4	ng/dL	2.11	1.54	2.67	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		2.11	1.54	2.67	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		2.55	1.86	3.24	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		2.55	1.86	3.24	Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T4	µg/dL	9.07	6.16	12.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		9.07	6.16	12.0	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		8.44	6.16	10.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		8.44	6.16	10.7	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00
Testosterone	ng/mL	5.33	3.62	7.03	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		5.33	3.62	7.03	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		4.14	2.82	5.47	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		4.14	2.82	5.47	Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		3.42	2.33	4.52	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		3.42	2.33	4.52	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Thyroid Stimulating Hormone	µIU/mL	2.80	2.04	3.56	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		2.75	2.00	3.49	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		2.16	1.57	2.74	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		2.16	1.57	2.74	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00
Vitamin B12	pg/mL	610	445	774	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		599	437	761	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i