

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. 2270EC	EXPIRY: 2026-04-28	

INTENDED USE

This product is intended for in vitro diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

The Abbott Architect CA19-9 assay utilises an antibody/antigen system based on the 1116-NA-19-9 antibody. There are reports that the formulation employed with this system may return elevated concentrations, when compared to other methods for samples expressing high levels of 1116-NA-19-9 reactive determinants.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. C-Peptide is stable for 1 day at +2°C to +8°C.

Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

ACTH should be tested immediately after the 30-minute reconstitution period. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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

MATERIALS PROVIDED

Immunoassay Premium Plus - Level 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. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	13.0	9.75	16.3	DIAsource ELISA
	ng/ml	4.30	3.23	5.37	
	nmol/l	11.4	8.55	14.3	SNIBE Maglumi Analysers
	ng/ml	3.77	2.83	4.71	
25-OH Vitamin D	nmol/l	97.9	73.4	122	Siemens Centaur XP/XPT/Classic
	nmol/l	63.4	47.6	79.3	Roche Vitamin D Total
	nmol/l	74.3	55.7	92.9	Abbott Architect (3L52)
	nmol/l	115	86.3	144	Vitros ECi
	nmol/l	81.5	61.1	102	BioMerieux Vidas
	nmol/l	89.3	67.0	112	Beckman Dxl 600/800
	nmol/l	75.9	56.9	94.9	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	59.0	44.3	73.8	Roche Vitamin D Total II
	nmol/l	77.3	58.0	96.6	Abbott Alinity i
	nmol/l	93.0	69.8	116	Siemens Atellica IM
	nmol/l	65.4	49.1	81.8	Roche Vitamin D Total II e801
	nmol/l	66.0	49.5	82.5	Roche Vitamin D Total III
ACTH	pmol/l	9.43	7.07	11.8	Siemens Immulite 2000/2500
	pg/ml	42.9	32.1	53.7	
	pmol/l	8.82	6.62	11.0	Roche Cobas 4000/E411
	pg/ml	40.1	30.1	50.1	
	pmol/l	8.96	6.72	11.2	Roche Cobas e601/602
	pg/ml	40.7	30.5	50.9	
	pmol/l	9.26	6.95	11.6	Siemens Immulite 1000
	pg/ml	42.1	31.6	52.6	
	pmol/l	13.1	9.83	16.4	Diasorin Liaison XL
	pg/ml	59.5	44.7	74.3	
Aldosterone	pmol/l	410	308	513	Diasorin Liaison XL
	pg/ml	148	111	185	
Alphafoetoprotein	KIU/l = IU/ml	43.9	35.1	52.7	Abbott Architect
	ng/ml	53.1	42.5	63.7	
	KIU/l = IU/ml	42.8	34.2	51.4	Beckman Dxl800
	ng/ml	51.8	41.4	62.2	
	KIU/l = IU/ml	47.9	38.3	57.5	Roche Cobas e601/602
	ng/ml	58.0	46.3	69.7	
	KIU/l = IU/ml	48.5	38.8	58.2	Roche Cobas 4000/E411
	ng/ml	58.7	46.9	70.5	
KIU/l = IU/ml	52.0	41.6	62.4	Siemens Atellica IM	
	ng/ml	62.9	50.3	75.5	
KIU/l = IU/ml	43.9	35.1	52.7	Abbott Alinity i	
	ng/ml	53.1	42.5	63.7	

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Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods	
			low	high		
Alphafoetoprotein	KIU/l = IU/ml	47.5	38.0	57.0	Roche Cobas e402/e801	
	ng/ml	57.5	46.0	69.0		
Amikacin	µmol/l	15.2	12.2	18.2	Gravimetric	
	µg/ml	8.90	7.14	10.7		
Androstenedione	nmol/l	13.9	10.4	17.4	Siemens Immulite 2000	
	ng/ml	3.99	2.98	5.00		
Beta-2-microglobulin	µg/ml = mg/l	2.58	2.06	3.10	Siemens Immulite 2000/2500	
	µg/ml = mg/l	2.96	2.37	3.55	Roche Cobas 6000/8000	
C-Peptide	nmol/l	1.820	1.370	2.280	Roche Cobas e601/602	
	ng/ml	5.49	4.14	6.84		
	nmol/l	1.920	1.440	2.400	Roche Cobas 4000/E411	
	ng/ml	5.80	4.35	7.25		
C-Peptide	nmol/l	1.710	1.280	2.140	Roche Cobas e402/e801	
	ng/ml	5.16	3.86	6.46		
	CA 15-3	U/ml	41.4	33.1	49.7	Siemens Centaur XP/XPT/Classic
		U/ml	44.0	35.2	52.8	Abbott Architect
U/ml		44.0	35.2	52.8	Roche Cobas e601/602	
U/ml		42.3	33.8	50.8	Roche Cobas 4000/E411	
U/ml		43.3	34.6	52.0	Siemens Atellica IM	
U/ml		43.2	34.6	51.8	Roche Cobas e402/e801	
CA 19-9	U/ml	42.6	34.1	51.1	Abbott Alinity i	
	U/ml	89.9	71.9	108	BioMerieux Vidas	
	U/ml	148	118	178	Vitros Eci	
	U/ml	126	101	151	Beckman Access	
	U/ml	121	96.8	145	Beckman DxI800	
	U/ml	223	178	268	Abbott Architect XR/XR2/XRL	
	U/ml	71.7	57.4	86.0	Roche Cobas e601/602	
	U/ml	73.4	58.7	88.1	Roche Cobas 4000/E411	
	U/ml	130	104	156	Siemens Atellica IM	
CA125	U/ml	75.5	60.4	90.6	Roche Cobas e402/e801	
	U/ml	214	171	257	Abbott Alinity XR/XR2/XRL	
	U/ml	98.6	78.9	118	BioMerieux Vidas	
	U/ml	90.3	72.2	108	Vitros Eci	
	U/ml	121	96.8	145	Abbott Architect	
	U/ml	98.1	78.5	118	Siemens Centaur XP/XPT/Classic CA125 II kit	
	U/ml	75.9	60.7	91.1	Beckman Access	
	U/ml	76.2	61.0	91.4	Beckman DxI800	
	U/ml	87.1	69.7	105	Roche Cobas 4000/E411	
	U/ml	86.5	69.2	104	Roche Cobas e601/602	
	U/ml	115	92.0	138	Siemens Atellica IM	
Carbamazepine	U/ml	80.2	64.2	96.2	Roche Cobas e402/e801	
	U/ml	122	97.6	146	Abbott Alinity i	
	µmol/l	39.7	31.8	47.6	Abbott Architect (CMIA)	
	µg/ml	9.39	7.52	11.3		
Carbamazepine	µmol/l	40.2	32.2	48.2	Roche Cobas 6000/8000	
	µg/ml	9.50	7.61	11.4		

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Analyte	unit	Target	Range		methods
			low	high	
Carbamazepine	µmol/l	38.5	30.8	46.2	Gravimetric
	µg/ml	9.10	7.28	10.9	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	26.5	21.2	31.8	BioMerieux Vidas
	ng/ml = µg/l	25.4	20.3	30.5	Vitros ECi
	ng/ml = µg/l	25.1	20.1	30.1	Beckman Access
	ng/ml = µg/l	29.6	23.7	35.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	29.8	23.8	35.8	Abbott Architect
	ng/ml = µg/l	25.0	20.0	30.0	Beckman DxI800
	ng/ml = µg/l	22.6	18.1	27.1	Roche Cobas e601/602
	ng/ml = µg/l	24.6	19.7	29.5	Roche Cobas 4000/E411
	ng/ml = µg/l	29.3	23.4	35.2	Siemens Atellica IM
	ng/ml = µg/l	23.6	18.9	28.3	Roche Cobas e402/e801
ng/ml = µg/l	29.3	23.4	35.2	Abbott Alinity i	
Cortisol	nmol/l	743	557	929	Siemens Centaur XP/XPT/Classic
	µg/dl	26.7	20.1	33.3	
	nmol/l	587	440	734	Siemens Immulite 2000/2500
	µg/dl	21.1	15.8	26.4	
	nmol/l	582	437	728	Vitros ECi
	µg/dl	21.0	15.7	26.3	
	nmol/l	573	430	716	Abbott Architect
	µg/dl	20.6	15.5	25.7	
	nmol/l	593	445	741	Beckman DxI800
	µg/dl	21.3	16.0	26.6	
	nmol/l	678	509	848	Roche Cobas e601/602
	µg/dl	24.4	18.3	30.5	
	nmol/l	676	507	845	Roche Cobas 4000/E411
	µg/dl	24.3	18.3	30.3	
	nmol/l	646	485	808	Roche Cobas 4000/e411 Gen II
	µg/dl	23.3	17.5	29.1	
	nmol/l	640	480	800	Roche Cobas e601/602 Gen II
	µg/dl	23.0	17.3	28.7	
	nmol/l	786	590	983	Siemens Atellica IM
	µg/dl	28.3	21.2	35.4	
nmol/l	628	471	785	Roche Cobas e402/e801	
µg/dl	22.6	17.0	28.2		
nmol/l	633	475	791	Roche Cobas e801 Gen II	
µg/dl	22.8	17.1	28.5		
nmol/l	577	433	721	Abbott Alinity i	
µg/dl	20.8	15.6	26.0		
DHEA-S	µmol/l	11.2	8.96	13.4	Siemens Immulite 2000/2500
	µmol/l	12.2	9.76	14.6	Abbott Architect
	µmol/l	9.73	7.78	11.7	Beckman DxI800
	µmol/l	14.6	11.7	17.5	Roche Cobas 4000/E411
	µmol/l	14.1	11.3	16.9	Roche Cobas e601/602
	µmol/l	13.9	11.1	16.7	Roche Cobas e402/e801
	µmol/l	12.1	9.68	14.5	Abbott Alinity i

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Digoxin	nmol/l	3.35	2.68	4.02	Roche Cobas e402/e801
	ng/ml	2.62	2.09	3.15	
	nmol/l	2.71	2.17	3.25	Abbott Architect (CMIA)
	ng/ml	2.12	1.69	2.54	
	nmol/l	3.07	2.46	3.68	Gravimetric
Ethosuximide	µmol/l	360	288	432	Gravimetric
	µg/ml	51.0	40.8	61.3	
Ferritin	ng/ml = µg/l	96.0	76.8	115	BioMerieux Vidas
	ng/ml = µg/l	132	106	158	Roche Elecsys/Cobas e411
	ng/ml = µg/l	80.9	64.7	97.1	Beckman Access
	ng/ml = µg/l	79.1	63.3	94.9	Vitros ECi
	ng/ml = µg/l	87.7	70.2	105	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	131	105	157	Abbott Architect
	ng/ml = µg/l	128	102	154	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	76.5	61.2	91.8	Beckman Dxl800
	ng/ml = µg/l	117	93.6	140	Roche Cobas c501/502/503/701/702
	ng/ml = µg/l	134	107	161	Abbott Alinity i
	ng/ml = µg/l	86.1	68.9	103	Siemens Atellica IM
Folate	nmol/l	8.57	6.51	10.6	Siemens Immulite 2000
	ng/ml	3.78	2.87	4.69	
	nmol/l	7.39	5.62	9.16	Vitros ECi
	ng/ml	3.26	2.48	4.04	
	nmol/l	11.2	8.51	13.9	Abbott Architect
	ng/ml	4.94	3.75	6.13	
	nmol/l	25.8	19.6	32.0	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	11.4	8.64	14.2	
	nmol/l	13.5	10.3	16.7	Beckman Dxl 600 / 800 - A98032
	ng/ml	5.95	4.54	7.36	
	nmol/l	12.9	9.80	16.0	Roche Elecsys Folate
	ng/ml	5.69	4.32	7.06	
	nmol/l	13.1	9.96	16.2	Roche Folate III - 07559992
	ng/ml	5.78	4.39	7.17	
	nmol/l	21.8	16.6	27.0	Siemens Atellica IM
	ng/ml	9.61	7.32	11.9	
	nmol/l	12.5	9.50	15.5	Abbott Alinity i
ng/ml	5.51	4.19	6.83		
nmol/l	12.8	9.73	15.9	Roche Folate 07027290 e801	
ng/ml	5.64	4.29	6.99		
Free T3	pmol/l	10.7	8.03	13.4	Beckman Access
	ng/dl	0.696	0.522	0.870	
	pg/ml	6.97	5.23	8.71	
	pmol/l	30.8	23.1	38.5	Vitros ECi
	ng/dl	2.00	1.50	2.50	
	pg/ml	20.1	15.0	25.2	

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Free T3	pmol/l	13.4	10.1	16.8	Siemens Centaur XP/XPT/Classic
	ng/dl	0.871	0.657	1.09	
	pg/ml	8.72	6.58	10.9	
	pmol/l	11.5	8.63	14.4	Abbott Architect, 2 point calibration
	ng/dl	0.748	0.561	0.935	
	pg/ml	7.49	5.62	9.36	
	pmol/l	9.68	7.26	12.1	Beckman Dxl800
	ng/dl	0.629	0.472	0.786	
	pg/ml	6.30	4.73	7.87	
	pmol/l	14.6	11.0	18.3	Roche Cobas 4000/E411
	ng/dl	0.949	0.715	1.18	
	pg/ml	9.50	7.16	11.8	
	pmol/l	14.7	11.0	18.4	Roche Cobas e601/602
	ng/dl	0.956	0.715	1.20	
	pg/ml	9.57	7.16	12.0	
	pmol/l	14.3	10.7	17.9	Siemens Atellica IM
	ng/dl	0.930	0.696	1.16	
	pg/ml	9.31	6.97	11.7	
	pmol/l	11.7	8.78	14.6	Abbott Architect, 6 point calibration
	ng/dl	0.761	0.571	0.951	
	pg/ml	7.62	5.72	9.52	
pmol/l	14.7	11.0	18.4	Roche Cobas e402/e801	
ng/dl	0.956	0.715	1.20		
pg/ml	9.57	7.16	12.0		
pmol/l	11.8	8.85	14.8	Abbott Alinity, 6 point cal	
ng/dl	0.767	0.575	0.959		
pg/ml	7.68	5.76	9.60		
Free T4	pmol/l	25.0	18.8	31.3	Beckman Access
	ng/dl	1.95	1.47	2.43	
	pg/ml	19.5	14.7	24.3	
	pmol/l	68.3	51.2	85.4	Vitros Eci
	ng/dl	5.33	3.99	6.67	
	pg/ml	53.3	39.9	66.7	
	pmol/l	21.8	16.4	27.3	Siemens Centaur XP/XPT/Classic
	ng/dl	1.70	1.28	2.12	
	pg/ml	17.0	12.8	21.2	
	pmol/l	31.2	23.4	39.0	Siemens Immulite 2000/2500
	ng/dl	2.43	1.83	3.03	
	pg/ml	24.3	18.3	30.3	
	pmol/l	22.8	17.1	28.5	Abbott Architect
	ng/dl	1.78	1.33	2.23	
	pg/ml	17.8	13.3	22.3	
	pmol/l	25.4	19.1	31.8	Beckman Dxl800
	ng/dl	1.98	1.49	2.47	
	pg/ml	19.8	14.9	24.7	
pmol/l	29.9	22.4	37.4	Roche Cobas e601/602	
ng/dl	2.33	1.75	2.91		
pg/ml	23.3	17.5	29.1		

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Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	29.3	22.0	36.6	Roche Cobas 4000/E411
	ng/dl	2.29	1.72	2.86	
	pg/ml	22.9	17.2	28.6	
	pmol/l	23.0	17.3	28.8	Siemens Atellica IM
	ng/dl	1.79	1.35	2.23	
	pg/ml	17.9	13.5	22.3	
	pmol/l	21.5	16.1	26.9	Abbott Alinity i
	ng/dl	1.68	1.26	2.10	
	pg/ml	16.8	12.6	21.0	
	pmol/l	30.9	23.2	38.6	Roche Cobas e402/e801
	ng/dl	2.41	1.81	3.01	
	pg/ml	24.1	18.1	30.1	
FSH	mU/ml	26.0	20.8	31.2	BioMerieux Vidas
	mU/ml	29.5	23.6	35.4	Beckman Access
	mU/ml	29.7	23.8	35.6	Siemens Centaur XP/XPT/Classic
	mU/ml	21.3	17.0	25.6	Siemens Immulite 2000/2500
	mU/ml	24.2	19.4	29.0	Abbott Architect
	mU/ml	26.8	21.4	32.2	Beckman DxI800
	mU/ml	25.4	20.3	30.5	Roche Cobas 4000/E411
	mU/ml	24.3	19.4	29.2	Roche Cobas e601/602
	mU/ml	26.8	21.4	32.2	Siemens Atellica IM
	mU/ml	24.7	19.8	29.6	Abbott Alinity i
	mU/ml	24.6	19.7	29.5	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	18.5	14.8	22.2	Siemens Immulite 2000/2500
	ng/ml	6.16	4.93	7.39	
	µU/ml	17.6	14.1	21.1	Roche Cobas e601/602
	ng/ml	5.86	4.70	7.02	
	µU/ml	15.4	12.3	18.5	Diasorin Liaison XL
	ng/ml	5.13	4.10	6.16	
	µU/ml	17.5	14.0	21.0	Roche Cobas e402/e801
ng/ml	5.83	4.66	7.00		
Immunoglobulin E	KIU/l = IU/ml	98.0	78.4	118	BioMerieux Vidas
	KIU/l = IU/ml	102	81.6	122	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	106	84.8	127	Siemens Immulite 2000/2500
	KIU/l = IU/ml	94.3	75.4	113	Abbott Architect
	KIU/l = IU/ml	120	96.0	144	Roche Cobas 4000/E411
	KIU/l = IU/ml	113	90.4	136	Roche Cobas e601/602
	KIU/l = IU/ml	113	90.4	136	Siemens Atellica IM
	KIU/l = IU/ml	121	96.8	145	Roche Cobas e402/e801
	KIU/l = IU/ml	88.7	71.0	106	Abbott Alinity
Insulin	mU/l	17.5	13.1	21.9	Siemens Centaur XP/XPT/Classic
	µU/ml	17.5	13.1	21.9	

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Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Insulin	mU/l	13.8	10.4	17.3	Abbott Architect
	µU/ml	13.8	10.4	17.2	
	mU/l	19.1	14.3	23.9	Roche Cobas 4000/E411
	µU/ml	19.1	14.3	23.9	
	mU/l	18.0	13.5	22.5	Roche Cobas 6000/8000
	µU/ml	18.0	13.5	22.5	
	mU/l	14.4	10.8	18.0	Beckman Dxl 600/800
	µU/ml	14.4	10.8	18.0	
Luteinising Hormone (LH)	mU/ml	31.0	24.8	37.2	Beckman Access
	mU/ml	35.4	28.3	42.5	BioMerieux Vidas
	mU/ml	34.7	27.8	41.6	Siemens Centaur XP/XPT/Classic
	mU/ml	51.9	41.5	62.3	Siemens Immulite 2000
	mU/ml	29.9	23.9	35.9	Abbott Architect
	mU/ml	29.3	23.4	35.2	Beckman Dxl800
	mU/ml	38.9	31.1	46.7	Roche Cobas 4000/E411
	mU/ml	37.9	30.3	45.5	Roche Cobas e601/602
Oestradiol	mU/ml	35.5	28.4	42.6	Siemens Atellica IM
	mU/ml	28.3	22.6	34.0	Abbott Alinity i
	mU/ml	40.7	32.6	48.8	Roche Cobas e402/e801
	pmol/l	1997	1598	2396	BioMerieux Vidas
	pg/ml	543	435	651	
	pmol/l	795	636	954	Abbott Architect
	pg/ml	216	173	259	
	pmol/l	1252	1002	1502	Siemens Centaur XP/XPT/Classic Enhanced (eE2)
	pg/ml	341	273	409	
	pmol/l	954	763	1145	Roche Cobas e601/602 (Estradiol III)
	pg/ml	259	208	310	
	pmol/l	960	768	1152	Roche Elecsys (Estradiol III)
	pg/ml	261	209	313	
	pmol/l	957	766	1148	Roche Cobas 4000/E411 (Estradiol III)
	pg/ml	260	208	312	
	pmol/l	758	606	910	Beckman Dxl600/800 Sensitive B84493
pg/ml	206	165	247		
pmol/l	1369	1095	1643	Siemens Atellica IM	
pg/ml	372	298	446		
pmol/l	780	624	936	Abbott Alinity i	
pg/ml	212	170	254		
pmol/l	933	746	1120	Roche Cobas e801 (Estradiol III)	
pg/ml	254	203	305		
Paracetamol	mmol/l	0.310	0.248	0.372	Roche Cobas c501/502/503/701/702
	mg/l	46.9	37.5	56.3	
	mmol/l	0.348	0.280	0.420	Gravimetric
	mg/l	52.7	42.1	63.3	
Phenobarbital	µmol/l	79.9	63.9	95.9	Abbott Architect (CMIA)
	µg/ml	18.5	14.8	22.2	

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Phenobarbital	µmol/l	79.6	63.7	95.5	Siemens Immulite 2000/2500
	µg/ml	18.5	14.8	22.2	
	µmol/l	79.0	63.2	94.8	Beckman AU400/600/640/2700/5400
	µg/ml	18.3	14.7	21.9	
	µmol/l	75.7	60.6	90.8	Roche Cobas C303/501/502/503/701
	µg/ml	17.6	14.1	21.1	
Phenytoin	µmol/l	77.6	62.1	93.1	Gravimetric
	µg/ml	18.0	14.4	21.6	
	µmol/l	66.7	53.4	80.0	Abbott Architect
	µg/ml	16.8	13.5	20.1	
Phenytoin	µmol/l	70.3	56.2	84.4	Roche Cobas 6000/8000
	µg/ml	17.8	14.2	21.4	
	µmol/l	71.3	57.0	85.6	Gravimetric
Phenytoin	µg/ml	18.0	14.4	21.6	
	µmol/l	22.5	18.0	27.0	Gravimetric
Primidone	µg/ml	4.91	3.93	5.89	
	µmol/l	22.5	18.0	27.0	Gravimetric
Progesterone	nmol/l	31.7	25.4	38.0	BioMerieux Vidas
	ng/ml	9.92	7.95	11.9	
	nmol/l	24.9	19.9	29.9	Siemens Centaur XP/XPT/Classic
	ng/ml	7.79	6.23	9.35	
	nmol/l	24.6	19.7	29.5	Siemens Immulite 2000/2500
	ng/ml	7.70	6.17	9.23	
	nmol/l	29.3	23.4	35.2	Abbott Architect
	ng/ml	9.17	7.32	11.0	
	nmol/l	29.2	23.4	35.0	Beckman Dxl Prog Cal 33555
	ng/ml	9.14	7.32	11.0	
	nmol/l	32.7	26.2	39.2	Roche Cobas 4000/e411 (Prog. II)
	ng/ml	10.2	8.20	12.2	
	nmol/l	22.3	17.8	26.8	Beckman Dxl Prog DE Cal A80773
	ng/ml	6.98	5.57	8.39	
	nmol/l	31.9	25.5	38.3	Roche Cobas e601/602 (Prog. III)
	ng/ml	9.98	7.98	12.0	
	nmol/l	31.7	25.4	38.0	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	9.92	7.95	11.9	
Prolactin	nmol/l	26.3	21.0	31.6	Abbott Alinity i
	ng/ml	8.23	6.57	9.89	
	nmol/l	25.5	20.4	30.6	Siemens Atellica IM
	ng/ml	7.98	6.39	9.57	
	nmol/l	32.2	25.8	38.6	Roche Cobas e801 (Prog. III)
	ng/ml	10.1	8.08	12.1	
	µU/ml	666	533	799	BioMerieux Vidas
	µU/ml	494	395	593	Vitros ECI
	µU/ml	434	347	521	Siemens Centaur XP/XPT/Classic
	µU/ml	554	443	665	Abbott Architect
µU/ml	496	397	595	Beckman Dxl800	

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Prolactin	µU/ml	697	558	836	Roche Cobas 4000/E411
	µU/ml	642	514	770	Roche Cobas e601/602
	µU/ml	407	326	488	Siemens Atellica IM
	µU/ml	579	463	695	Abbott Alinity i
	µU/ml	634	507	761	Roche Cobas e801 PRL II
PSA Free	ng/ml = µg/l	12.0	9.00	15.0	Abbott Architect
	ng/ml = µg/l	12.5	9.38	15.6	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	9.67	7.25	12.1	Roche Cobas 4000/E411
	ng/ml = µg/l	9.37	7.03	11.7	Roche Cobas e601/602
	ng/ml = µg/l	11.8	8.85	14.8	Siemens Atellica IM
	ng/ml = µg/l	11.8	8.85	14.8	Abbott Alinity i
	ng/ml = µg/l	9.06	6.80	11.3	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	13.7	10.3	17.1	Beckman Access standardised to Hybritech
	ng/ml = µg/l	11.2	8.40	14.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	9.56	7.17	12.0	Abbott Architect
	ng/ml = µg/l	15.5	11.6	19.4	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	13.5	10.1	16.9	Beckman Dxl standardisd to Hybritech
	ng/ml = µg/l	10.5	7.88	13.1	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	13.4	10.1	16.8	Roche Cobas 4000/E411
	ng/ml = µg/l	13.0	9.75	16.3	Roche Cobas e601/602
	ng/ml = µg/l	13.3	9.98	16.6	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	12.3	9.23	15.4	Siemens Atellica IM
	ng/ml = µg/l	9.74	7.31	12.2	Abbott Alinity i
	ng/ml = µg/l	12.5	9.38	15.6	Roche Cobas e402/e801
Salicylic Acid	mmol/l	1.22	0.980	1.46	Gravimetric
	mg/dl	16.9	13.5	20.2	
SHBG	nmol/l	36.3	29.0	43.6	Siemens Immulite 2000/2500
	nmol/l	40.6	32.5	48.7	Abbott Architect
	nmol/l	36.1	28.9	43.3	Roche Cobas e801 - 413429
	nmol/l	38.3	30.6	46.0	Roche analysers - 413417/15
	nmol/l	41.5	33.2	49.8	Abbott Alinity i
T Uptake	%U	31.9	26.2	37.6	Siemens Immulite 2000
Testosterone	nmol/l	17.4	13.9	20.9	Siemens Immulite 2000/2500
	ng/ml	5.01	4.00	6.02	
	ng/dl	501	400	602	
	nmol/l	16.3	13.0	19.6	Abbott Architect
	ng/ml	4.69	3.74	5.64	
	ng/dl	469	374	564	
	nmol/l	13.5	10.8	16.2	Beckman Dxl800
	ng/ml	3.89	3.11	4.67	
	ng/dl	389	311	467	
	nmol/l	16.9	13.5	20.3	Roche Cobas 4000/e411 Test II
	ng/ml	4.87	3.89	5.85	
	ng/dl	487	389	585	
	nmol/l	16.9	13.5	20.3	Roche Cobas e601/602 Test II
ng/ml	4.87	3.89	5.85		
ng/dl	487	389	585		

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods	
			low	high		
Testosterone	nmol/l	16.4	13.1	19.7	Abbott Architect 2nd Generation	
	ng/ml	4.72	3.77	5.67		
	ng/dl	472	377	567		
	nmol/l	16.9	13.5	20.3	Siemens Centaur TST II	
		ng/ml	4.87	3.89		5.85
		ng/dl	487	389		585
	nmol/l	17.2	13.8	20.6	Siemens Atellica IM	
		ng/ml	4.95	3.97		5.93
		ng/dl	495	397		593
	nmol/l	16.3	13.0	19.6	Roche Cobas e801 Test II	
		ng/ml	4.69	3.74		5.64
		ng/dl	469	374		564
nmol/l	16.8	13.4	20.2	Abbott Alinity i		
	ng/ml	4.84	3.86		5.82	
	ng/dl	484	386		582	
Theophylline	µmol/l	83.8	67.0	101	Gravimetric	
	µg/ml	15.1	12.1	18.2		
Thyroglobulin	ng/ml	18.0	13.5	22.5	Siemens Immulite 2000	
	ng/ml	32.2	24.2	40.3	Beckman Dxl800	
	ng/ml	35.1	26.3	43.9	Roche Cobas e601/602	
	ng/ml	37.4	28.1	46.8	Abbott Architect 2000i	
	ng/ml	34.6	26.0	43.3	Roche Cobas e601/602 Tg II	
	ng/ml	35.5	26.6	44.4	Roche Cobas 4000/E411 TGII	
	ng/ml	34.3	25.7	42.9	Roche Cobas e801 Tg II	
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.31	1.85	2.77	Beckman Access hyperTSH 3rd Generation	
	µU/ml = mIU/l	2.34	1.87	2.81	Vitros Eci	
	µU/ml = mIU/l	2.37	1.90	2.84	Siemens Centaur XP/XPT/Classic	
	µU/ml = mIU/l	2.11	1.69	2.53	Siemens Immulite 2000/2500	
	µU/ml = mIU/l	1.91	1.53	2.29	Abbott Architect	
	µU/ml = mIU/l	2.51	2.01	3.01	Roche Cobas 4000/E411	
	µU/ml = mIU/l	2.48	1.98	2.98	Roche Cobas e601/602	
	µU/ml = mIU/l	2.36	1.89	2.83	Siemens Centaur XP/XPT/Classic TSH3-Ultra	
	µU/ml = mIU/l	2.16	1.73	2.59	Beckman Dxl 600/800 Access (3rd IS)	
	µU/ml = mIU/l	2.36	1.89	2.83	Siemens Atellica IM	
	µU/ml = mIU/l	1.92	1.54	2.30	Abbott Alinity i	
	µU/ml = mIU/l	2.34	1.87	2.81	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	47.1	37.7	56.5	BioMerieux Vidas	
	IU/ml	0.047	0.038	0.056		
	mU/ml=IU/l	48.6	38.9	58.3	Vitros Eci	
	IU/ml	0.049	0.039	0.059		
mU/ml=IU/l	28.0	22.4	33.6	Siemens Centaur XP/XPT/Classic		
IU/ml	0.028	0.022	0.034			

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	58.0	46.4	69.6	Siemens Immulite 2000
	IU/ml	0.058	0.046	0.070	
	mU/ml=IU/l	27.4	21.9	32.9	Abbott Architect
	IU/ml	0.027	0.022	0.032	
	mU/ml=IU/l	30.2	24.2	36.2	Roche hCG+Beta
	IU/ml	0.030	0.024	0.036	
	mU/ml=IU/l	30.7	24.6	36.8	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.031	0.025	0.037	
	mU/ml=IU/l	31.0	24.8	37.2	Siemens Atellica IM
	IU/ml	0.031	0.025	0.037	
	mU/ml=IU/l	27.8	22.2	33.4	Abbott Alinity i
	IU/ml	0.028	0.022	0.034	
	mU/ml=IU/l	29.5	23.6	35.4	Roche hCG+Beta e801
	IU/ml	0.030	0.024	0.036	
Total T3	nmol/l	3.96	2.97	4.95	Siemens Centaur XP/XPT/Classic
	ng/ml	2.58	1.93	3.23	
	ng/dl	258	193	323	
	nmol/l	3.35	2.51	4.19	Abbott Architect
	ng/ml	2.18	1.63	2.73	
	ng/dl	218	163	273	
	nmol/l	4.28	3.21	5.35	Vitros Eci
	ng/ml	2.79	2.09	3.49	
	ng/dl	279	209	349	
	nmol/l	3.99	2.99	4.99	Roche Cobas 4000/E411
	ng/ml	2.60	1.95	3.25	
	ng/dl	260	195	325	
	nmol/l	4.09	3.07	5.11	Roche Cobas e601/602
	ng/ml	2.66	2.00	3.32	
	ng/dl	266	200	332	
	nmol/l	3.38	2.54	4.23	Abbott Alinity i
	ng/ml	2.20	1.65	2.75	
	ng/dl	220	165	275	
	nmol/l	4.11	3.08	5.14	Siemens Atellica IM
	ng/ml	2.68	2.01	3.35	
	ng/dl	268	201	335	
	nmol/l	4.24	3.18	5.30	Roche Cobas e402/e801
	ng/ml	2.76	2.07	3.45	
	ng/dl	276	207	345	
Total T4	nmol/l	122	91.5	153	Vitros Eci
	µg/dl	9.52	7.14	11.9	
	ng/ml	95.2	71.4	119	
	nmol/l	128	96.0	160	Beckman Access
	µg/dl	9.98	7.49	12.5	
	ng/ml	100	74.9	125	
	nmol/l	127	95.3	159	Siemens Centaur XP/XPT/Classic
	µg/dl	9.91	7.43	12.4	
	ng/ml	99.1	74.3	124	

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Total T4	nmol/l	114	85.5	143	Siemens Immulite 2000/2500
	µg/dl	8.89	6.67	11.1	
	ng/ml	88.9	66.7	111	
	nmol/l	116	87.0	145	Abbott Architect
	µg/dl	9.05	6.79	11.3	
	ng/ml	90.5	67.9	113	
	nmol/l	115	86.3	144	Roche Cobas 4000/E411
	µg/dl	8.97	6.73	11.2	
	ng/ml	89.7	67.3	112	
	nmol/l	112	84.0	140	Roche Cobas e601/602
	µg/dl	8.74	6.55	10.9	
	ng/ml	87.4	65.5	109	
	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	138	104	173	Siemens Atellica IM	
µg/dl	10.8	8.11	13.5		
ng/ml	108	81.1	135		
nmol/l	106	79.5	133	Roche Cobas e402/e801	
µg/dl	8.27	6.20	10.3		
ng/ml	82.7	62.0	103		
Valproic Acid	µmol/l	525	420	630	Abbott Architect (CMIA)
	µg/ml	75.8	60.6	91.0	
	µmol/l	539	431	647	Roche Cobas 6000/8000
	µg/ml	77.8	62.2	93.4	
	µmol/l	525	420	630	Abbott Alinity (PETINA)
µg/ml	75.8	60.6	91.0		
µmol/l	638	510	766	Gravimetric	
µg/ml	92.1	73.6	111		
Vancomycin	µmol/l	8.17	6.54	9.80	Abbott Architect (CMIA)
	µg/ml	12.1	9.72	14.5	
	µmol/l	7.26	5.81	8.71	Roche Cobas 6000/8000
	µg/ml	10.8	8.63	13.0	
	µmol/l	7.10	5.68	8.52	Gravimetric
µg/ml	10.5	8.44	12.7		
Vitamin B12	pmol/l	366	293	439	Beckman Access
	pg/ml	496	397	595	
	pmol/l	473	378	568	Siemens Centaur XP/XPT/Classic
	pg/ml	641	512	770	
	pmol/l	431	345	517	Abbott Architect
	pg/ml	584	467	701	
	pmol/l	454	363	545	Vitros ECI
	pg/ml	615	492	738	
	pmol/l	353	282	424	Beckman Dxl800
pg/ml	478	382	574		

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

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Vitamin B12	pmol/l	482	386	578	Roche Cobas 4000/e411 Gen II
	pg/ml	653	523	783	
	pmol/l	484	387	581	Roche Cobas e601/602 Gen II
	pg/ml	656	524	788	
	pmol/l	487	390	584	Siemens Atellica IM
	pg/ml	660	528	792	
	pmol/l	455	364	546	Abbott Alinity i
	pg/ml	617	493	741	
	pmol/l	484	387	581	Roche Cobas e801 Gen II
	pg/ml	656	524	788	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112		Lot No. 2270EC		Size: 12 x 5ml / 4 x 5ml		Expiry: 2026-04-28	
Analyte	unit	Target	Range		methods		
			low	high			
17-OH-Progesterone	nmol/l	11.4	8.55	14.3	SNIBE Maglumi Analysers		
	ng/ml	3.77	2.83	4.71			
25-OH Vitamin D	nmol/l	88.4	61.9	115	SNIBE Maglumi Analysers II		
	ng/ml	35.4	24.8	46.0			
Alphafoetoprotein	KIU/l = IU/ml	46.8	32.8	60.8	SNIBE Maglumi Analysers		
	ng/ml	56.6	39.6	73.6			
Androstenedione	nmol/l	9.22	6.45	11.99	SNIBE Maglumi Analysers		
	ng/ml	2.64	1.85	3.43			
Beta-2-microglobulin	µg/ml = mg/l	2.46	1.72	3.20	SNIBE Maglumi Analysers		
C-Peptide	nmol/l	1.95	1.37	2.53	SNIBE Maglumi Analysers		
	ng/ml	5.88	4.12	7.64			
CA 15-3	U/ml	50.0	35.0	65.0	SNIBE Maglumi Analysers		
CA 19-9	U/ml	67.6	47.3	87.9	SNIBE Maglumi Analysers		
CA125	U/ml	83.6	58.5	109	SNIBE Maglumi Analysers		
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	24.9	17.4	32.4	SNIBE Maglumi Analysers		
Cortisol	nmol/l	695	487	903	SNIBE Maglumi Analysers		
	µg/dl	25.0	17.5	32.5			
DHEA-S	µmol/l	11.1	7.77	14.4	SNIBE Maglumi Analysers		
	µg/dl	408	286	530			
Digoxin	nmol/l	3.78	2.65	4.91	SNIBE Maglumi Analysers		
	ng/ml	2.95	2.07	3.84			
Ferritin	ng/ml = µg/l	130	91.0	169	SNIBE Maglumi Analysers		
Free T3	pmol/l	14.9	10.4	19.4	SNIBE Maglumi Analysers		
	ng/dl	0.973	0.681	1.26			
	pg/ml	9.73	6.81	12.6			
Free T4	pmol/l	33.1	23.2	43.0	SNIBE Maglumi Analysers		
	ng/dl	2.57	1.80	3.34			
	pg/ml	25.7	18.0	33.4			
FSH	mU/ml	26.1	18.3	33.9	SNIBE Maglumi Analysers		
Growth Hormone (GH)	µU/ml	23.5	16.5	30.5	SNIBE Maglumi Analysers		
	ng/ml	7.82	5.47	10.2			
Immunoglobulin E	KIU/l = IU/ml	93.2	65.2	121	SNIBE Maglumi Analysers		
Insulin	mU/l	17.3	12.1	22.5	SNIBE Maglumi Analysers		
	µU/ml	17.3	12.1	22.5			
Luteinising Hormone (LH)	mU/ml	46.1	32.3	59.9	SNIBE Maglumi Analysers		
Progesterone	nmol/l	29.0	20.3	37.7	SNIBE Maglumi Analysers		
	ng/ml	9.07	6.35	11.8			
Prolactin	µU/ml	564	395	733	SNIBE Maglumi Analysers		
PSA Free	ng/ml = µg/l	9.12	6.38	11.9	SNIBE Maglumi Analysers		
PSA Total	ng/ml = µg/l	11.2	7.84	14.6	SNIBE Maglumi Analysers		
SHBG	nmol/l	48.9	34.2	63.6	SNIBE Maglumi Analysers		
Testosterone	nmol/l	13.3	9.31	17.3	SNIBE Maglumi Analysers		
	ng/ml	3.82	2.67	4.97			
	ng/dl	383	268	498			
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.30	1.61	2.99	SNIBE Maglumi Analysers		
Total Beta hCG	mU/ml=IU/l	50.4	35.3	65.5	SNIBE Maglumi Analysers		
	IU/ml	0.050	0.035	0.065			
Total T3	nmol/l	3.21	2.25	4.17	SNIBE Maglumi Analysers		
	ng/ml	2.09	1.46	2.72			
	ng/dl	209	146	272			
Total T4	nmol/l	133	93	173	SNIBE Maglumi Analysers		
	µg/dl	10.4	7.28	13.5			
	ng/ml	104	72.8	135			

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

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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. 2270EC	EXPIRY: 2026-04-28	

INTENDED USE

This product is intended for *in vitro* diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

The Abbott Architect CA19-9 assay utilises an antibody/antigen system based on the 1116-NA-19-9 antibody. There are reports that the formulation employed with this system may return elevated concentrations, when compared to other methods for samples expressing high levels of 1116-NA-19-9 reactive determinants.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. C-Peptide is stable for 1 day at +2°C to +8°C.

Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

ACTH should be tested immediately after the 30-minute reconstitution period. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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

MATERIALS PROVIDED

Immunoassay Premium Plus - Level 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. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Cortisol	µg/dL	22.6	16.5	28.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		22.6	16.5	28.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
C-Peptide	ng/mL	4.50	3.29	5.72	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		4.50	3.29	5.72	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
DHEA-S	µg/dL	466	340	591	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		466	340	591	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Insulin	µIU/mL	18.2	12.4	24.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		20.1	13.6	26.5	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Alphafoetoprotein	ng/ml	55.6	40.6	70.6	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		55.6	40.6	70.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Carcinoembryonic Antigen (CEA)	ng/ml	19.3	14.1	24.5	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		19.3	14.1	24.5	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA125	U/ml	141	103	179	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		141	103	179	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 15-3	U/ml	25.6	17.4	33.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		25.6	17.4	33.8	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 19-9	U/ml	63.6	46.4	80.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		63.6	46.4	80.8	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Ferritin	ng/mL	119	87.2	152	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		119	87.2	152	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Free	ng/mL	12.1	8.83	15.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		12.1	8.83	15.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Total	ng/mL	12.6	9.19	16.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		12.6	9.19	16.0	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Oestradiol	pg/mL	314	229	398	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501
		314	229	398	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501
		354	241	467	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001
		354	241	467	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001
FSH	mIU/mL	29.2	21.3	37.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101
		29.2	21.3	37.0	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101
		25.3	15.2	35.4	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401
		25.3	15.2	35.4	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401
Total Beta hCG	mIU/mL	27.4	18.6	36.1	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i
		24.5	16.7	32.3	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i
		56.2	33.7	78.6	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i
		56.2	33.7	78.6	Wiener Lab CLIA Series & Mindray hCG2 CL 900i
Luteinising Hormone (LH)	mIU/mL	40.6	29.7	51.6	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		40.6	29.7	51.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Prolactin	ng/mL	29.8	20.3	39.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		29.8	20.3	39.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2270EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
Progesterone	ng/mL	11.7	8.56	14.9	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		11.7	8.56	14.9	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
		9.16	6.23	12.1	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i
		9.16	6.23	12.1	Wiener Lab CLIA Series & Mindray PROG II CL 900i
Testosterone	ng/mL	6.58	4.80	8.35	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		6.58	4.80	8.35	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		5.62	4.10	7.13	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		5.62	4.10	7.13	Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		4.31	2.93	5.69	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		4.31	2.93	5.69	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Folate	ng/mL	14.2	9.63	18.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		14.2	9.63	18.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Vitamin B12	pg/mL	689	469	910	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		689	469	910	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Free T3	pg/mL	7.96	5.41	10.5	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X
		7.96	5.41	10.5	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X
		7.96	5.41	10.5	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00
		7.96	5.41	10.5	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00
Free T4	ng/dL	2.27	1.54	2.99	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		2.27	1.54	2.99	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		2.76	2.02	3.51	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		2.76	2.02	3.51	Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T3	ng/mL	2.05	1.39	2.70	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		2.05	1.39	2.70	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		2.05	1.39	2.70	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		2.05	1.39	2.70	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Total T4	µg/dL	9.84	6.69	13.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		9.84	6.69	13.0	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		8.97	6.55	11.4	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		8.97	6.55	11.4	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00
Thyroid Stimulating Hormone	µIU/mL	2.84	2.07	3.61	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		2.84	2.07	3.61	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		2.12	1.55	2.69	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		2.12	1.55	2.69	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00

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

Lot. No.	2270EC	EXPIRY:	2026-04-28	Cat. No.	IA3110 / IA3112	
Analyte	unit	Target	low	high	Instrument	
Alpha-fetoprotein	U/ml	43.3	37.6	49.3	Siemens Immulite 2000/2500	
CA 125	U/ml	73.2	66.3	80.1	Siemens Immulite 2000/2500	
CA 15-3	U/ml	47.9	39.4	56.5	Siemens Immulite 2000/2500	
CA 19-9	U/ml	104	74	134	Siemens Immulite 2000/2500	
CEA	ng/dl	36.2	32.7	39.7	Siemens Immulite 2000/2500	
Ferritin	ng/dl	103	87	118	Siemens Immulite 2000/2500	
Oestradiol	pmol/l	1428	1234	1622	Siemens Immulite 2000/2500	
Prolactin	μU/ml	476	399	552	Siemens Immulite 2000/2500	
PSA Free	ng/dl	10.1	9.02	11.25	Siemens Immulite 2000/2500	
PSA Total	ng/dl	10.1	8.77	11.49	Siemens Immulite 2000/2500	
Free T3	pmol/l	11.2	8.90	13.42	Siemens Immulite 2000/2500	
Total T3	nmol/l	3.56	3.08	4.04	Siemens Immulite 2000/2500	
Vitamin B12	pmol/l	464	352	577	Siemens Immulite 2000/2500	