

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

CAT. NO.	IA2639	GTIN:	05055273203851	SIZE	12 x 5 ml
CAT. NO.	IA2633	GTIN:	05055273203837	SIZE	4 x 5 ml
LOT NO.	2276EC	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.

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.

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 - 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 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,
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Rev. 12 Apr '24 me

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
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	
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	
	nmol/l	1.710	1.280	2.140	Roche Cobas e402/e801
	ng/ml	5.16	3.86	6.46	
Carbamazepine	µmol/l	39.7	31.8	47.6	Abbott Architect (CMIA)
	µg/ml	9.39	7.52	11.3	
	µmol/l	40.2	32.2	48.2	Roche Cobas 6000/8000
	µg/ml	9.50	7.61	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	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 Dxl800
	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 Dxl800
	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	

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Range					
Analyte	unit	Target	low	high	methods
Cortisol	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	
DHEA-S	nmol/l	577	433	721	Abbott Alinity i
	µg/dl	20.8	15.6	26.0	
	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
Digoxin	µmol/l	12.1	9.68	14.5	Abbott Alinity i
	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
	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	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 DxI800
	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
	ng/ml = µg/l	124	99.0	149	Roche Cobas e402/e801
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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Folate	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	
Free T3	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	
	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	
	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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Free T4	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	
	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 Dxl800
	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	

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Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Growth Hormone (GH)	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/I = IU/ml	98.0	78.4	118	BioMerieux Vidas
	KIU/I = IU/ml	102	81.6	122	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	106	84.8	127	Siemens Immulite 2000/2500
	KIU/I = IU/ml	94.3	75.4	113	Abbott Architect
	KIU/I = IU/ml	120	96.0	144	Roche Cobas 4000/E411
	KIU/I = IU/ml	113	90.4	136	Roche Cobas e601/602
	KIU/I = IU/ml	113	90.4	136	Siemens Atellica IM
	KIU/I = IU/ml	121	96.8	145	Roche Cobas e402/e801
	KIU/I = IU/ml	88.7	71.0	106	Abbott Alinity
Insulin	mU/I	17.5	13.1	21.9	Siemens Centaur XP/XPT/Classic
	µU/ml	17.5	13.1	21.9	
	mU/I	13.8	10.4	17.3	Abbott Architect
	µU/ml	13.8	10.4	17.2	
	mU/I	19.1	14.3	23.9	Roche Cobas 4000/E411
	µU/ml	19.1	14.3	23.9	
	mU/I	18.0	13.5	22.5	Roche Cobas 6000/8000
	µU/ml	18.0	13.5	22.5	
	mU/I	14.4	10.8	18.0	Beckman Dxl 600/800
	µU/ml	14.4	10.8	18.0	
	mU/I	12.7	9.53	15.9	Abbott Alinity i
	µU/ml	12.7	9.53	15.9	
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
	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
Oestradiol	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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Oestradiol	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
Paracetamol	pg/ml	212	170	254	
	pmol/l	933	746	1120	Roche Cobas e801 (Estradiol III)
	pg/ml	254	203	305	
	mmol/l	0.310	0.248	0.372	Roche Cobas c501/502/503/701/702
Phenobarbital	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	
	µmol/l	79.9	63.9	95.9	Abbott Architect (CMIA)
	µg/ml	18.5	14.8	22.2	
	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
Phenytoin	µg/ml	17.6	14.1	21.1	
	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	
	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
Primidone	µg/ml	18.0	14.4	21.6	
	µmol/l	22.5	18.0	27.0	Gravimetric
Progesterone	µg/ml	4.91	3.93	5.89	
	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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Progesterone	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	
	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	
Prolactin	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
	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 standardised 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

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
SHBG	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	
	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
	ng/ml	36.6	27.5	45.8	Abbott Alinity i
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

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Thyroid Stimulating Hormone	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	
	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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Total T3	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	
	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	

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Valproic Acid	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	
	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	

Method		Immunoassay Premium - Level 2 (IA PREMIUM 2)					
Lot. No: 2276EC Cat. No: IA2639 Expiry: 2026-04-28							
Size: 12 x 5ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	nmol/l	76.4	57.3	95.5	9.55	19.1	DiaSorin Liaison
	nmol/l	73.2	54.9	91.5	9.15	18.3	DiaSorin Liaison XL
Alpha-fetoprotein	ng/ml	54.9	43.9	65.9	5.50	11.0	DiaSorin Liaison
	KIU/l = IU/ml	45.4	36.3	54.5	4.55	9.10	
	ng/ml	58.1	46.5	69.7	5.80	11.6	DiaSorin Liaison XL
	KIU/l = IU/ml	48.0	38.4	57.6	4.80	9.60	
Androstenedione	ng/ml	1.88	1.41	2.35	0.235	0.470	DiaSorin Liaison XL
	nmol/l	6.56	4.92	8.20	0.820	1.64	
Beta-2-Microglobulin	µg/ml = mg/l	2.94	2.35	3.53	0.295	0.590	DiaSorin Liaison
	µg/ml = mg/l	2.63	2.10	3.16	0.265	0.530	DiaSorin Liaison XL
C-Peptide	ng/ml	5.89	4.42	7.36	0.735	1.47	DiaSorin Liaison
	nmol/l	1.95	1.46	2.44	0.245	0.490	
	ng/ml	6.01	4.51	7.51	0.750	1.50	DiaSorin Liaison XL
	nmol/l	1.99	1.49	2.49	0.250	0.500	
CEA	ng/ml = µg/l	24.1	19.3	28.9	2.40	4.80	DiaSorin Liaison XL
Cortisol	nmol/l	638	479	797	79.5	159	DiaSorin Liaison
	µg/dl	23.0	17.3	28.7	2.85	5.70	
	nmol/l	694	521	867	86.5	173	DiaSorin Liaison XL
	µg/dl	25.0	18.8	31.2	3.10	6.20	
DHEA-S	µmol/l	9.85	7.88	11.8	0.975	1.95	DiaSorin Liaison
	µmol/l	8.56	6.85	10.3	0.870	1.74	DiaSorin Liaison XL
Ferritin	ng/ml = µg/l	111	88.8	133	11.0	22.0	DiaSorin Liaison
	ng/ml = µg/l	127	102	152	12.5	25.0	DiaSorin Liaison XL
Folate	ng/ml	2.50	1.90	3.10	0.300	0.600	DiaSorin Liaison XL
	nmol/l	5.66	4.30	7.02	0.680	1.36	
Free T3	ng/dl	0.988	0.741	1.24	0.126	0.252	DiaSorin Liaison
	pg/ml	9.90	7.43	12.4	1.25	2.50	
	pmol/l	15.2	11.4	19.0	1.90	3.80	

Method		Immunoassay Premium - Level 2 (IA PREMIUM 2)					
Lot. No: 2276EC Cat. No: IA2639 Expiry: 2026-04-28							
Size: 12 x 5ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Free T3	ng/dl	1.06	0.795	1.33	0.135	0.270	DiaSorin Liaison XL
	pg/ml	10.6	7.95	13.3	1.35	2.70	
	pmol/l	16.3	12.2	20.4	2.05	4.10	
Free T4	ng/dl	2.85	2.14	3.56	0.355	0.710	DiaSorin Liaison
	pg/ml	28.5	21.4	35.6	3.55	7.10	
	pmol/l	36.5	27.4	45.6	4.55	9.10	
	ng/dl	2.85	2.14	3.56	0.355	0.710	DiaSorin Liaison XL
	pg/ml	28.5	21.4	35.6	3.55	7.10	
	pmol/l	36.6	27.5	45.7	4.55	9.10	
FSH	mU/ml	34.8	27.8	41.8	3.50	7.00	DiaSorin Liaison
	mU/ml	38.4	30.7	46.1	3.85	7.70	DiaSorin Liaison XL
Growth Hormone (GH)	ng/ml	5.33	4.26	6.40	0.535	1.07	DiaSorin Liaison
	µU/ml	16.0	12.8	19.2	1.60	3.20	
Insulin	mU/l	19.2	14.4	24.0	2.40	4.80	DiaSorin Liaison
	µU/ml	19.2	14.4	24.0	2.40	4.80	
	mU/l	18.5	13.9	23.1	2.30	4.60	DiaSorin Liaison XL
	µU/ml	18.5	13.9	23.1	2.30	4.60	
Luteinising Hormone (LH)	mU/ml	44.1	35.3	52.9	4.40	8.80	DiaSorin Liaison
	mU/ml	45.2	36.2	54.2	4.50	9.00	DiaSorin Liaison XL
Oestradiol	pg/ml	199	159	239	20.0	40.0	DiaSorin Liaison
	pmol/l	733	586	880	73.5	147	
	pg/ml	190	152	228	19.0	38.0	DiaSorin Liaison XL
	pmol/l	698	558	838	70.0	140	
Progesterone	ng/ml	9.01	7.21	10.8	0.895	1.79	DiaSorin Liaison XL
	nmol/l	28.8	23.0	34.6	2.90	5.80	
Prolactin	µIU/mL	605	484	726	60.5	121	DiaSorin Liaison
	µIU/mL	608	486	730	61.0	122	DiaSorin Liaison XL
PSA Free	ng/ml = µg/l	11.0	8.25	13.8	1.40	2.80	DiaSorin Liaison XL
PSA Total	ng/ml = µg/l	11.9	8.93	14.9	1.50	3.00	DiaSorin Liaison
	ng/ml = µg/l	12.1	9.08	15.1	1.50	3.00	DiaSorin Liaison XL
Testosterone	ng/dl	234	187	281	23.5	47.0	DiaSorin Liaison XL
	ng/ml	2.34	1.87	2.81	0.235	0.470	
	nmol/l	8.11	6.49	9.73	0.810	1.62	
Thyroglobulin	ng/ml	36.6	27.5	45.7	4.55	9.10	DiaSorin Liaison XL

Method		Immunoassay Premium - Level 2 (IA PREMIUM 2)					
Lot. No: 2276EC Cat. No: IA2639 Expiry: 2026-04-28							
Size: 12 x 5ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Thyroid Stimulating Hormone	µU/ml = mIU/l	3.18	2.54	3.82	0.320	0.640	DiaSorin Liaison
	µU/ml = mIU/l	3.17	2.54	3.80	0.315	0.630	DiaSorin Liaison XL
Total Beta hCG	IU/ml	0.030	0.024	0.036	0.003	0.006	DiaSorin Liaison XL
	mU/ml = IU/l	30.2	24.2	36.2	3.00	6.00	
Total T3	ng/dl	177	133	221	22.0	44.0	DiaSorin Liaison XL
	ng/ml	1.77	1.33	2.21	0.220	0.440	
	nmol/l	2.72	2.04	3.40	0.340	0.680	
Total T4	ng/ml	73.6	55.2	92.0	9.20	18.4	DiaSorin Liaison XL
	nmol/l	94.4	70.8	118	11.8	23.6	
	µg/dl	7.36	5.52	9.20	0.920	1.84	
Vitamin B12	pg/ml	587	470	704	58.5	117	DiaSorin Liaison XL
	pmol/l	433	346	520	43.5	87.0	

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM - LEVEL 2
(IA PREMIUM 2)**

Cat No. IA2639 / IA2633

Lot No. 2276EC

GTIN: 05055273203851 / 05055273203837

COMPONENT	UNITS	TARGET	RANGE	METHOD
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 II	nmol/l	88.4	61.9 – 115	SNIBE Maglumi Analysers
	ng/ml	35.4	24.8 – 46.0	
Alpha-fetoprotein	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	
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	

COMPONENT	UNITS	TARGET	RANGE	METHOD
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

29 Jan '25 me

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

CAT. NO.	IA2639	GTIN:	05055273203851	SIZE	12 x 5 ml
CAT. NO.	IA2633	GTIN:	05055273203837	SIZE	4 x 5 ml
LOT NO.	2276EC	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.

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.

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 - 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 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

(S). Rev, 18 Mar '25 me

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot No. 2276EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
25-OH Vitamin D	ng/ml	33.99	23.11	44.87	Wiener Lab CLIA Series & Mindray Vitamin D Total II CL 8000i/6000i/2000i/1200i/1000i
		33.99	23.11	44.87	Wiener Lab CLIA Series & Mindray Vitamin D Total II CL 900i/920i/960i/980i
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
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

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot No. 2276EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
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
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

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot No. 2276EC Size: 12 x 5ml / 4 x 5ml Expiry: 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
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