



## PRODUCT INFORMATION

IA3109

2269EC

Please note that in Immunoassay Premium Plus - Level 1, lot 2269EC, values with TBD are currently unavailable and will be updated in due course.

For any questions or queries, please contact [Technical.support@randox.com](mailto:Technical.support@randox.com)

CCS INC384

## IMMUNOASSAY PREMIUM PLUS - LEVEL I (IA PREMIUM PLUS I)

<b>CAT. NO.</b> IA3109	<b>GTIN:</b> 05055273207255	<b>SIZE</b> 12 x 5 ml
<b>CAT. NO.</b> IA3112	<b>GTIN:</b> 05055273207286	<b>SIZE</b> 4 x 5 ml
<b>LOT NO.</b> 2269EC	<b>EXPIRY:</b> 2026-05-28	

### INTENDED USE

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

**This device is for prescription use only.**

### SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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

Health and Safety Data Sheets are available on request.

### STORAGE AND STABILITY

**OPENED:** Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. C-Peptide is stable for 1 day at +2°C to +8°C. Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

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

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

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

### PREPARATION

Immunoassay Premium Plus is supplied lyophilized.

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

### MATERIALS PROVIDED

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

### MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

### VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).



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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	2.86	2.15	3.57	DIAsource ELISA
	ng/ml	0.947	0.712	1.18	
25-OH Vitamin D	nmol/l	154	116	193	Vitros ECi
	nmol/l	61.9	46.4	77.4	BioMerieux Vidas
	nmol/l	72.5	54.4	90.6	Beckman Dxl 600/800
	nmol/l	40.2	30.2	50.3	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	24.1	18.1	30.1	Roche Vitamin D Total II
	nmol/l	40.8	30.6	51.0	Abbott Alinity i
	nmol/l	36.1	27.1	45.1	Siemens Atellica IM
	nmol/l	32.1	24.1	40.1	Roche Vitamin D Total II e801
	nmol/l	28.4	21.3	35.5	Roche Vitamin D Total III
ACTH	pmol/l	5.06	3.80	6.33	Siemens Immulite 2000/2500
	pg/ml	23.0	17.3	28.7	
	pmol/l	8.53	6.40	10.7	Roche Cobas 4000/E411
	pg/ml	38.8	29.1	48.5	
	pmol/l	8.64	6.48	10.8	Roche Cobas e601/602
	pg/ml	39.3	29.5	49.1	
	pmol/l	7.80	5.85	9.75	Diasorin Liaison XL
	pg/ml	35.5	26.6	44.4	
pmol/l	8.21	6.16	10.3	Roche Cobas e402/e801	
pg/ml	37.3	28.0	46.6		
Alphafoetoprotein	KIU/l = IU/ml	9.43	7.54	11.3	Siemens Centaur XP/XPT/Classic
	ng/ml	11.4	9.12	13.7	
	KIU/l = IU/ml	7.86	6.29	9.43	Abbott Architect
	ng/ml	9.51	7.61	11.4	
	KIU/l = IU/ml	8.07	6.46	9.68	Beckman Dxl800
	ng/ml	9.76	7.82	11.7	
	KIU/l = IU/ml	9.04	7.23	10.8	Roche Cobas e601/602
	ng/ml	10.9	8.75	13.1	
	KIU/l = IU/ml	8.77	7.02	10.5	Roche Cobas 4000/E411
	ng/ml	10.6	8.49	12.7	
	KIU/l = IU/ml	9.63	7.70	11.6	Siemens Atellica IM
	ng/ml	11.7	9.32	14.1	
	KIU/l = IU/ml	7.96	6.37	9.55	Abbott Alinity i
ng/ml	9.63	7.71	11.6		
KIU/l = IU/ml	9.84	7.87	11.8	Roche Cobas e402/e801	
ng/ml	11.9	9.52	14.3		
Amikacin	µmol/l	6.40	5.12	7.68	Gravimetric
	µg/ml	3.75	3.00	4.50	
Androstenedione	nmol/l	4.98	3.74	6.23	Siemens Immulite 2000
	ng/ml	1.43	1.07	1.79	
Beta-2-microglobulin	µg/ml = mg/l	0.680	0.544	0.816	Abbott Architect

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Beta-2-microglobulin	µg/ml = mg/l	0.750	0.600	0.900	Roche Cobas 6000/8000
C-Peptide	nmol/l	0.587	0.440	0.734	Roche Cobas e601/602
	ng/ml	1.77	1.33	2.21	
	nmol/l	0.580	0.435	0.725	Roche Cobas 4000/E411
	ng/ml	1.75	1.31	2.19	
	nmol/l	0.500	0.375	0.625	Abbott Architect
	ng/ml	1.51	1.13	1.89	
	nmol/l	0.566	0.425	0.708	Roche Cobas e402/e801
	ng/ml	1.71	1.28	2.14	
CA 15-3	nmol/l	0.499	0.374	0.624	Abbott Alinity i
	ng/ml	1.51	1.13	1.89	
	U/ml	21.3	17.0	25.6	Siemens Centaur XP/XPT/Classic
	U/ml	22.4	17.9	26.9	Abbott Architect
	U/ml	22.0	17.6	26.4	Roche Cobas e601/602
	U/ml	21.2	17.0	25.4	Roche Cobas 4000/E411
	U/ml	23.2	18.6	27.8	Siemens Atellica IM
	U/ml	22.5	18.0	27.0	Roche Cobas e402/e801
CA 19-9	U/ml	22.9	18.3	27.5	Abbott Alinity i
	U/ml	25.6	20.5	30.7	BioMerieux Vidas
	U/ml	35.3	28.2	42.4	Siemens Centaur XP/XPT/Classic
	U/ml	41.6	33.3	49.9	Vitros ECi
	U/ml	34.9	27.9	41.9	Beckman Access
	U/ml	33.3	26.6	40.0	Beckman DxI800
	U/ml	64.1	51.3	76.9	Abbott Architect XR/XR2/XRL
	U/ml	21.5	17.2	25.8	Roche Cobas e601/602
	U/ml	22.0	17.6	26.4	Roche Cobas 4000/E411
	U/ml	39.9	31.9	47.9	Siemens Atellica IM
	U/ml	22.3	17.8	26.8	Roche Cobas e402/e801
CA125	U/ml	63.5	50.8	76.2	Abbott Alinity XR/XR2/XRL
	U/ml	19.7	15.8	23.6	BioMerieux Vidas
	U/ml	18.6	14.9	22.3	Vitros ECi
	U/ml	27.3	21.8	32.8	Abbott Architect
	U/ml	22.8	18.2	27.4	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	17.4	13.9	20.9	Beckman Access
	U/ml	17.3	13.8	20.8	Beckman DxI800
	U/ml	18.3	14.6	22.0	Roche Cobas 4000/E411
	U/ml	18.6	14.9	22.3	Roche Cobas e601/602
	U/ml	26.6	21.3	31.9	Siemens Atellica IM
	U/ml	17.7	14.2	21.2	Roche Cobas e402/e801
Carbamazepine	U/ml	27.6	22.1	33.1	Abbott Alinity i
	µmol/l	18.0	14.4	21.6	Siemens Centaur XP/XPT/Classic
	µg/ml	4.26	3.40	5.12	
	µmol/l	15.5	12.4	18.6	Abbott Architect (CMIA)
	µg/ml	3.66	2.93	4.39	
	µmol/l	15.1	12.1	18.1	Roche Cobas 6000/8000
µg/ml	3.57	2.86	4.28		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Carbamazepine	µmol/l	15.4	12.3	18.5	Gravimetric
	µg/ml	3.64	2.91	4.37	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	3.18	2.54	3.82	BioMerieux Vidas
	ng/ml = µg/l	3.52	2.82	4.22	Vitros ECi
	ng/ml = µg/l	3.41	2.73	4.09	Beckman Access
	ng/ml = µg/l	3.94	3.15	4.73	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.22	3.38	5.06	Abbott Architect
	ng/ml = µg/l	3.51	2.81	4.21	Beckman Dxl800
	ng/ml = µg/l	3.64	2.91	4.37	Roche Cobas e601/602
	ng/ml = µg/l	3.71	2.97	4.45	Roche Cobas 4000/E411
	ng/ml = µg/l	3.92	3.14	4.70	Siemens Atellica IM
	ng/ml = µg/l	3.54	2.83	4.25	Roche Cobas e402/e801
Cortisol	ng/ml = µg/l	4.08	3.26	4.90	Abbott Alinity i
	nmol/l	166	125	208	Siemens Centaur XP/XPT/Classic
	µg/dl	5.98	4.50	7.46	
	nmol/l	184	138	230	Siemens Immulite 2000/2500
	µg/dl	6.62	4.97	8.27	
	nmol/l	138	104	173	Vitros ECi
	µg/dl	4.97	3.74	6.20	
	nmol/l	203	152	254	Abbott Architect
	µg/dl	7.31	5.47	9.15	
	nmol/l	193	145	241	Beckman Dxl800
	µg/dl	6.95	5.22	8.68	
	nmol/l	192	144	240	Roche Cobas e601/602
	µg/dl	6.91	5.18	8.64	
	nmol/l	197	148	246	Roche Cobas 4000/E411
	µg/dl	7.09	5.33	8.85	
	nmol/l	194	146	243	Roche Cobas 4000/e411 Gen II
	µg/dl	6.98	5.26	8.70	
	nmol/l	188	141	235	Roche Cobas e601/602 Gen II
	µg/dl	6.77	5.08	8.46	
	nmol/l	151	113	189	Siemens Atellica IM
µg/dl	5.44	4.07	6.81		
nmol/l	181	136	226	Roche Cobas e402/e801	
µg/dl	6.52	4.90	8.14		
nmol/l	181	136	226	Roche Cobas e801 Gen II	
µg/dl	6.52	4.90	8.14		
nmol/l	205	154	256	Abbott Alinity i	
µg/dl	7.38	5.54	9.22		
DHEA-S	µmol/l	1.67	1.34	2.00	Abbott Architect
	µmol/l	1.61	1.29	1.93	Beckman Dxl800
	µmol/l	2.27	1.82	2.72	Roche Cobas 4000/E411
	µmol/l	2.19	1.75	2.63	Roche Cobas e601/602
	µmol/l	2.10	1.68	2.52	Roche Cobas e402/e801
Digoxin	µmol/l	1.64	1.31	1.97	Abbott Alinity i
	nmol/l	0.570	0.456	0.684	Abbott Architect (CMIA)
	ng/ml	0.445	0.356	0.534	

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Digoxin	nmol/l	0.870	0.696	1.04	Roche Cobas e402/e801
	ng/ml	0.679	0.544	0.814	
	nmol/l	0.896	0.720	1.08	Gravimetric
	ng/ml	0.700	0.560	0.840	
Ethosuximide	µmol/l	226	181	271	Gravimetric
	µg/ml	32.0	25.7	38.4	
Ferritin	ng/ml = µg/l	14.8	11.8	17.8	BioMerieux Vidas
	ng/ml = µg/l	21.9	17.5	26.3	Roche Elecsys/Cobas e411
	ng/ml = µg/l	13.1	10.5	15.7	Beckman Access
	ng/ml = µg/l	14.2	11.4	17.0	Vitros ECI
	ng/ml = µg/l	14.3	11.4	17.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	21.1	16.9	25.3	Abbott Architect
	ng/ml = µg/l	21.7	17.4	26.0	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	12.9	10.3	15.5	Beckman Dxl800
	ng/ml = µg/l	21.5	17.2	25.8	Roche Cobas c501/502/503/701/702
	ng/ml = µg/l	21.2	17.0	25.4	Abbott Alinity i
	ng/ml = µg/l	14.8	11.8	17.8	Siemens Atellica IM
ng/ml = µg/l	21.4	17.1	25.7	Roche Cobas e402/e801	
Folate	nmol/l	7.10	5.40	8.80	Beckman Access
	ng/ml	3.13	2.38	3.88	
	nmol/l	5.48	4.16	6.80	Siemens Immulite 2000
	ng/ml	2.42	1.83	3.01	
	nmol/l	5.24	3.98	6.50	Vitros ECI
	ng/ml	2.31	1.76	2.86	
	nmol/l	7.37	5.60	9.14	Abbott Architect
	ng/ml	3.25	2.47	4.03	
	nmol/l	18.2	13.8	22.6	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	8.03	6.09	9.97	
	nmol/l	7.06	5.37	8.75	Beckman Dxl 600 / 800 - A98032
	ng/ml	3.11	2.37	3.85	
	nmol/l	6.91	5.25	8.57	Roche Folate III - 07559992
	ng/ml	3.05	2.32	3.78	
	nmol/l	19.3	14.7	23.9	Siemens Atellica IM
	ng/ml	8.51	6.48	10.5	
	nmol/l	7.76	5.90	9.62	Abbott Alinity i
ng/ml	3.42	2.60	4.24		
nmol/l	6.03	4.58	7.48	Roche Folate 07027290 e801	
ng/ml	2.66	2.02	3.30		
Free T3	pmol/l	4.19	3.14	5.24	Beckman Access
	ng/dl	0.272	0.204	0.340	
	pg/ml	2.73	2.04	3.42	
	pmol/l	8.92	6.69	11.2	Vitros ECI
	ng/dl	0.580	0.435	0.725	
	pg/ml	5.81	4.36	7.26	
	pmol/l	4.75	3.56	5.94	Siemens Centaur XP/XPT/Classic
ng/dl	0.309	0.231	0.387		
pg/ml	3.09	2.32	3.86		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Free T3	pmol/l	3.21	2.41	4.01	Abbott Architect, 2 point calibration
	ng/dl	0.209	0.157	0.261	
	pg/ml	2.09	1.57	2.61	
	pmol/l	4.07	3.05	5.09	Beckman Dxl800
	ng/dl	0.265	0.198	0.332	
	pg/ml	2.65	1.99	3.31	
	pmol/l	4.91	3.68	6.14	Roche Cobas 4000/E411
	ng/dl	0.319	0.239	0.399	
	pg/ml	3.20	2.40	4.00	
	pmol/l	4.77	3.58	5.96	Roche Cobas e601/602
	ng/dl	0.310	0.233	0.387	
	pg/ml	3.11	2.33	3.89	
	pmol/l	5.28	3.96	6.60	Siemens Atellica IM
	ng/dl	0.343	0.257	0.429	
	pg/ml	3.44	2.58	4.30	
	pmol/l	3.31	2.48	4.14	Abbott Architect, 6 point calibration
	ng/dl	0.215	0.161	0.269	
	pg/ml	2.15	1.61	2.69	
pmol/l	4.70	3.53	5.88	Roche Cobas e402/e801	
ng/dl	0.306	0.229	0.383		
pg/ml	3.06	2.30	3.82		
pmol/l	3.30	2.48	4.13	Abbott Alinity, 6 point cal	
ng/dl	0.215	0.161	0.269		
pg/ml	2.15	1.61	2.69		
Free T4	pmol/l	10.8	8.10	13.5	Beckman Access
	ng/dl	0.842	0.632	1.05	
	pg/ml	8.42	6.32	10.5	
	pmol/l	16.9	12.7	21.1	Vitros ECI
	ng/dl	1.32	0.991	1.65	
	pg/ml	13.2	9.91	16.5	
	pmol/l	8.59	6.44	10.7	Siemens Centaur XP/XPT/Classic
	ng/dl	0.670	0.502	0.838	
	pg/ml	6.70	5.02	8.38	
	pmol/l	12.7	9.53	15.9	Siemens Immulite 2000/2500
	ng/dl	0.991	0.743	1.24	
	pg/ml	9.91	7.43	12.4	
	pmol/l	9.96	7.47	12.5	Abbott Architect
	ng/dl	0.777	0.583	0.971	
	pg/ml	7.77	5.83	9.71	
	pmol/l	10.7	8.03	13.4	Beckman Dxl800
	ng/dl	0.835	0.626	1.04	
	pg/ml	8.35	6.26	10.4	
pmol/l	14.2	10.7	17.8	Roche Cobas e601/602	
ng/dl	1.11	0.835	1.39		
pg/ml	11.1	8.35	13.9		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	14.0	10.5	17.5	Roche Cobas 4000/E411
	ng/dl	1.09	0.819	1.36	
	pg/ml	10.9	8.19	13.6	
	pmol/l	9.09	6.82	11.4	Siemens Atellica IM
	ng/dl	0.709	0.532	0.886	
	pg/ml	7.09	5.32	8.86	
	pmol/l	10.1	7.58	12.6	Abbott Alinity i
	ng/dl	0.788	0.591	0.985	
	pg/ml	7.88	5.91	9.85	
	pmol/l	14.6	11.0	18.3	Roche Cobas e402/e801
	ng/dl	1.14	0.858	1.42	
	pg/ml	11.4	8.58	14.2	
FSH	mU/ml	7.00	5.60	8.40	BioMerieux Vidas
	mU/ml	8.76	7.01	10.5	Siemens Centaur XP/XPT/Classic
	mU/ml	7.32	5.86	8.78	Siemens Immulite 2000/2500
	mU/ml	6.40	5.12	7.68	Abbott Architect
	mU/ml	7.44	5.95	8.93	Beckman DxI800
	mU/ml	7.38	5.90	8.86	Roche Cobas 4000/E411
	mU/ml	6.95	5.56	8.34	Roche Cobas e601/602
	mU/ml	7.65	6.12	9.18	Siemens Atellica IM
	mU/ml	6.73	5.38	8.08	Abbott Alinity i
	mU/ml	6.82	5.46	8.18	Roche Cobas e402/e801
Gentamicin	µmol/l	4.85	3.88	5.82	Gravimetric
	µg/ml	2.32	1.85	2.78	
Growth Hormone (GH)	µU/ml	4.15	3.32	4.98	Siemens Immulite 2000/2500
	ng/ml	1.38	1.11	1.65	
	µU/ml	4.28	3.42	5.14	Roche Cobas e601/602
	ng/ml	1.43	1.14	1.72	
	µU/ml	3.19	2.55	3.83	Diasorin Liaison XL
	ng/ml	1.06	0.849	1.27	
	µU/ml	4.32	3.46	5.18	Roche Cobas e402/e801
ng/ml	1.44	1.15	1.73		
Immunoglobulin E	KIU/l = IU/ml	224	179	269	BioMerieux Vidas
	KIU/l = IU/ml	257	206	308	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	261	209	313	Siemens Immulite 2000/2500
	KIU/l = IU/ml	245	196	294	Abbott Architect
	KIU/l = IU/ml	257	206	308	Roche Cobas 4000/E411
	KIU/l = IU/ml	248	198	298	Roche Cobas e601/602
	KIU/l = IU/ml	257	206	308	Siemens Atellica IM
	KIU/l = IU/ml	264	211	317	Roche Cobas e402/e801
	KIU/l = IU/ml	249	199	299	Abbott Alinity
Insulin	mU/l	2.39	1.79	2.99	Siemens Centaur XP/XPT/Classic
	µU/ml	2.39	1.79	2.99	
	mU/l	1.74	1.31	2.18	Abbott Architect
	µU/ml	1.74	1.31	2.17	



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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods	
			low	high		
Insulin	mU/l	1.85	1.39	2.31	Roche Cobas 4000/E411	
	µU/ml	1.85	1.39	2.31		
	mU/l	1.94	1.46	2.43	Roche Cobas 6000/8000	
	µU/ml	1.94	1.46	2.42		
	mU/l	1.45	1.09	1.81	Beckman Dxl 600/800	
	µU/ml	1.45	1.09	1.81		
	mU/l	1.75	1.31	2.19	Abbott Alinity i	
	µU/ml	1.75	1.31	2.19		
	Luteinising Hormone (LH)	mU/ml	2.33	1.86	2.80	BioMerieux Vidas
		mU/ml	2.14	1.71	2.57	Siemens Centaur XP/XPT/Classic
		mU/ml	4.26	3.41	5.11	Siemens Immulite 2000
		mU/ml	1.75	1.40	2.10	Abbott Architect
mU/ml		1.77	1.42	2.12	Beckman Dxl800	
mU/ml		3.07	2.46	3.68	Roche Cobas 4000/E411	
mU/ml		3.08	2.46	3.70	Roche Cobas e601/602	
mU/ml		2.16	1.73	2.59	Siemens Atellica IM	
mU/ml		1.72	1.38	2.06	Abbott Alinity i	
mU/ml		3.23	2.58	3.88	Roche Cobas e402/e801	
Oestradiol	pmol/l	318	254	382	BioMerieux Vidas	
	pg/ml	86.5	69.1	104		
	pmol/l	178	142	214	Abbott Architect	
	pg/ml	48.4	38.6	58.2		
	pmol/l	150	120	180	Siemens Centaur XP/XPT/Classic Enhanced (eE2)	
	pg/ml	40.8	32.6	49.0		
	pmol/l	233	186	280	Roche Cobas e601/602 (Estradiol III)	
	pg/ml	63.4	50.6	76.2		
	pmol/l	213	170	256	Roche Cobas 4000/E411 (Estradiol III)	
	pg/ml	57.9	46.2	69.6		
	pmol/l	121	96.8	145	Beckman Dxl600/800 Sensitive B84493	
	pg/ml	32.9	26.3	39.5		
	pmol/l	169	135	203	Siemens Atellica IM	
	pg/ml	46.0	36.7	55.3		
pmol/l	177	142	212	Abbott Alinity i		
pg/ml	48.1	38.6	57.6			
pmol/l	216	173	259	Roche Cobas e801 (Estradiol III)		
pg/ml	58.8	47.1	70.5			
Paracetamol	mmol/l	0.150	0.120	0.180	Roche Cobas c501/502/503/701/702	
	mg/l	22.7	18.2	27.2		
	mmol/l	0.166	0.130	0.200	Gravimetric	
	mg/l	25.1	19.7	30.3		
Phenobarbital	µmol/l	36.1	28.9	43.3	Siemens Immulite 2000/2500	
	µg/ml	8.38	6.70	10.1		
	µmol/l	31.5	25.2	37.8	Beckman AU400/600/640/2700/5400	
	µg/ml	7.31	5.85	8.77		
	µmol/l	32.6	26.1	39.1	Roche Cobas C303/501/502/503/701	
	µg/ml	7.56	6.06	9.06		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Phenobarbital	µmol/l	34.5	27.6	41.4	Gravimetric
	µg/ml	8.00	6.40	9.60	
Phenytoin	µmol/l	18.8	15.0	22.6	Abbott Architect
	µg/ml	4.75	3.79	5.71	
	µmol/l	18.3	14.6	22.0	Roche Cobas 6000/8000
	µg/ml	4.62	3.69	5.55	
	µmol/l	20.2	16.2	24.2	Gravimetric
Primidone	µmol/l	12.3	9.84	14.8	Gravimetric
	µg/ml	2.69	2.15	3.23	
Progesterone	nmol/l	2.62	2.10	3.14	Siemens Centaur XP/XPT/Classic
	ng/ml	0.820	0.657	0.983	
	nmol/l	2.71	2.17	3.25	Siemens Immulite 2000/2500
	ng/ml	0.848	0.679	1.02	
	nmol/l	3.02	2.42	3.62	Abbott Architect
	ng/ml	0.945	0.757	1.13	
	nmol/l	1.13	0.904	1.36	Beckman Dxl Prog DE Cal A80773
	ng/ml	0.354	0.283	0.425	
	nmol/l	3.35	2.68	4.02	Roche Cobas e601/602 (Prog. III)
	ng/ml	1.05	0.839	1.26	
	nmol/l	3.25	2.60	3.90	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	1.02	0.814	1.23	
	nmol/l	2.66	2.13	3.19	Abbott Alinity i
	ng/ml	0.833	0.667	0.999	
Prolactin	µU/ml	126	101	151	BioMerieux Vidas
	µU/ml	168	134	202	Vitros ECi
	µU/ml	127	102	152	Siemens Centaur XP/XPT/Classic
	µU/ml	141	113	169	Abbott Architect
	µU/ml	124	99.0	149	Beckman DxI800
	µU/ml	156	125	187	Roche Cobas 4000/E411
	µU/ml	147	118	176	Roche Cobas e601/602
	µU/ml	117	93.6	140	Siemens Atellica IM
	µU/ml	144	115	173	Abbott Alinity i
	µU/ml	145	116	174	Roche Cobas e801 PRL II
PSA Free	ng/ml = µg/l	1.55	1.16	1.94	Abbott Architect
	ng/ml = µg/l	1.87	1.40	2.34	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	1.13	0.848	1.41	Roche Cobas 4000/E411
	ng/ml = µg/l	1.23	0.923	1.54	Roche Cobas e601/602
	ng/ml = µg/l	1.58	1.19	1.98	Siemens Atellica IM
	ng/ml = µg/l	1.56	1.17	1.95	Abbott Alinity i
	ng/ml = µg/l	1.20	0.900	1.50	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	1.96	1.47	2.45	Beckman Access standardised to Hybritech

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods	
			low	high		
PSA Total	ng/ml = µg/l	1.54	1.16	1.93	Siemens Centaur XP/XPT/Classic	
	ng/ml = µg/l	1.28	0.960	1.60	Abbott Architect	
	ng/ml = µg/l	2.01	1.51	2.51	Beckman Access standardised to WHO IRP96/670	
	ng/ml = µg/l	1.87	1.40	2.34	Beckman Dxl standardisd to Hybritech	
	ng/ml = µg/l	1.58	1.19	1.98	Beckman Dxl800 standardised to WHO IRP96/670	
	ng/ml = µg/l	1.71	1.28	2.14	Roche Cobas 4000/E411	
	ng/ml = µg/l	1.78	1.34	2.23	Roche Cobas e601/602	
	ng/ml = µg/l	1.72	1.29	2.15	Ortho Vitros 3600/5600/ECi PSA II	
	ng/ml = µg/l	1.62	1.22	2.03	Siemens Atellica IM	
	ng/ml = µg/l	1.36	1.02	1.70	Abbott Alinity i	
Salicylic Acid	ng/ml = µg/l	1.67	1.25	2.09	Roche Cobas e402/e801	
	mmol/l	0.260	0.208	0.312	Roche Cobas c501/502/503	
	mg/dl	3.59	2.87	4.31		
	mmol/l	0.286	0.230	0.340	Gravimetric	
SHBG	mg/dl	3.95	3.18	4.70		
	nmol/l	11.7	9.36	14.0	Siemens Immulite 2000/2500	
	nmol/l	12.5	10.0	15.0	Abbott Architect	
	nmol/l	11.8	9.44	14.2	Roche Cobas e801 - 413429	
	nmol/l	12.0	9.60	14.4	Roche analysers - 413417/15	
T Uptake	nmol/l	13.9	11.1	16.7	Abbott Alinity i	
	%U	TBD	TBD	TBD	Siemens Immulite 2000	
	Testosterone	nmol/l	1.03	0.824	1.24	Siemens Immulite 2000/2500
		ng/ml	0.297	0.237	0.357	
		ng/dl	29.7	23.7	35.7	
nmol/l		1.94	1.55	2.33	Abbott Architect	
ng/ml		0.559	0.446	0.672		
ng/dl		55.9	44.6	67.2		
nmol/l		1.18	0.944	1.42	Beckman Dxl800	
ng/ml		0.340	0.272	0.408		
ng/dl		34.0	27.2	40.8		
nmol/l		1.60	1.28	1.92	Roche Cobas 4000/e411 Test II	
ng/ml		0.461	0.369	0.553		
ng/dl		46.1	36.9	55.3		
nmol/l		1.57	1.26	1.88	Roche Cobas e601/602 Test II	
ng/ml	0.452	0.363	0.541			
ng/dl	45.2	36.3	54.1			
nmol/l	1.93	1.54	2.32	Abbott Architect 2nd Generation		
ng/ml	0.556	0.444	0.668			
ng/dl	55.6	44.4	66.8			
nmol/l	1.22	0.976	1.46	Siemens Centaur TST II		
ng/ml	0.351	0.281	0.421			
ng/dl	35.1	28.1	42.1			
nmol/l	1.20	0.960	1.44	Siemens Atellica IM		
ng/ml	0.346	0.276	0.416			
ng/dl	34.6	27.6	41.6			
nmol/l	1.64	1.31	1.97	Roche Cobas e801 Test II		
ng/ml	0.472	0.377	0.567			
ng/dl	47.2	37.7	56.7			

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	nmol/l	2.06	1.65	2.47	Abbott Alinity i
	ng/ml	0.593	0.475	0.711	
	ng/dl	59.3	47.5	71.1	
Theophylline	µmol/l	28.3	22.6	34.0	Gravimetric
	µg/ml	5.10	4.07	6.13	
Thyroglobulin	ng/ml	2.32	1.74	2.90	Beckman Dxl800
	ng/ml	2.76	2.07	3.45	Roche Cobas e601/602
	ng/ml	2.60	1.95	3.25	Abbott Architect 2000i
	ng/ml	2.70	2.03	3.38	Roche Cobas e601/602 Tg II
	ng/ml	2.60	1.95	3.25	Roche Cobas 4000/E411 TGII
	ng/ml	2.61	1.96	3.26	Roche Cobas e801 Tg II
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.087	0.070	0.104	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	0.071	0.057	0.085	Siemens Immulite 2000/2500
	µU/ml = mIU/l	0.078	0.062	0.094	Abbott Architect
	µU/ml = mIU/l	0.117	0.094	0.140	Roche Cobas 4000/E411
	µU/ml = mIU/l	0.112	0.090	0.134	Roche Cobas e601/602
	µU/ml = mIU/l	0.089	0.071	0.107	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	0.073	0.058	0.088	Beckman Dxl 600/800 Access (3rd IS)
	µU/ml = mIU/l	0.089	0.071	0.107	Siemens Atellica IM
	µU/ml = mIU/l	0.082	0.066	0.098	Abbott Alinity i
	µU/ml = mIU/l	0.109	0.087	0.131	Roche Cobas e402/e801
Tobramycin	µmol/l	4.17	3.34	5.00	Gravimetric
	µg/ml	1.95	1.56	2.34	
Total Beta hCG	mU/ml=IU/l	15.7	12.6	18.8	BioMerieux Vidas
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	17.8	14.2	21.4	Vitros ECi
	IU/ml	0.018	0.014	0.022	
	mU/ml=IU/l	17.0	13.6	20.4	Siemens Centaur XP/XPT/Classic
	IU/ml	0.017	0.014	0.020	
	mU/ml=IU/l	22.4	17.9	26.9	Siemens Immulite 2000
	IU/ml	0.022	0.018	0.026	
	mU/ml=IU/l	15.4	12.3	18.5	Abbott Architect
	IU/ml	0.015	0.012	0.018	
	mU/ml=IU/l	14.8	11.8	17.8	Roche hCG+Beta
	IU/ml	0.015	0.012	0.018	
	mU/ml=IU/l	16.4	13.1	19.7	Beckman Access Total BhCG (5th IS)
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	16.1	12.9	19.3	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	17.5	14.0	21.0	Siemens Atellica IM
	IU/ml	0.018	0.014	0.022	
mU/ml=IU/l	15.3	12.2	18.4	Abbott Alinity i	
IU/ml	0.015	0.012	0.018		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml=IU/l	14.4	11.5	17.3	Roche hCG+Beta e801
	IU/ml	0.014	0.012	0.016	
Total T3	nmol/l	0.820	0.615	1.03	Siemens Centaur XP/XPT/Classic
	ng/ml	0.534	0.400	0.668	
	ng/dl	53.4	40.0	66.8	
	nmol/l	0.840	0.630	1.05	Abbott Architect
	ng/ml	0.547	0.410	0.684	
	ng/dl	54.7	41.0	68.4	
	nmol/l	0.910	0.683	1.14	Vitros ECi
	ng/ml	0.592	0.445	0.739	
	ng/dl	59.2	44.5	73.9	
	nmol/l	1.35	1.01	1.69	Roche Cobas 4000/E411
	ng/ml	0.879	0.658	1.10	
	ng/dl	87.9	65.8	110	
	nmol/l	1.29	0.968	1.61	Roche Cobas e601/602
	ng/ml	0.840	0.630	1.05	
	ng/dl	84.0	63.0	105	
	nmol/l	0.860	0.645	1.08	Abbott Alinity i
	ng/ml	0.560	0.420	0.700	
	ng/dl	56.0	42.0	70.0	
	nmol/l	0.780	0.585	0.975	Siemens Atellica IM
	ng/ml	0.508	0.381	0.635	
ng/dl	50.8	38.1	63.5		
nmol/l	1.28	0.960	1.60	Roche Cobas e402/e801	
ng/ml	0.833	0.625	1.04		
ng/dl	83.3	62.5	104		
Total T4	nmol/l	27.5	20.6	34.4	Vitros ECi
	µg/dl	2.15	1.61	2.69	
	ng/ml	21.5	16.1	26.9	
	nmol/l	21.4	16.1	26.8	Siemens Centaur XP/XPT/Classic
	µg/dl	1.67	1.26	2.08	
	ng/ml	16.7	12.6	20.8	
	nmol/l	28.6	21.5	35.8	Siemens Immulite 2000/2500
	µg/dl	2.23	1.68	2.78	
	ng/ml	22.3	16.8	27.8	
	nmol/l	35.6	26.7	44.5	Abbott Architect
	µg/dl	2.78	2.08	3.48	
	ng/ml	27.8	20.8	34.8	
	nmol/l	39.1	29.3	48.9	Roche Cobas 4000/E411
	µg/dl	3.05	2.29	3.81	
	ng/ml	30.5	22.9	38.1	
	nmol/l	37.8	28.4	47.3	Roche Cobas e601/602
	µg/dl	2.95	2.22	3.68	
	ng/ml	29.5	22.2	36.8	
	nmol/l	32.8	24.6	41.0	Abbott Alinity i
	µg/dl	2.56	1.92	3.20	
ng/ml	25.6	19.2	32.0		

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

Cat. No. IA3109 / IA3112 Lot. No. 2269EC Size 12 x 5ml / 4 x 5 ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Total T4	nmol/l	31.2	23.4	39.0	Siemens Atellica IM
	µg/dl	2.43	1.83	3.03	
	ng/ml	24.3	18.3	30.3	
	nmol/l	36.0	27.0	45.0	Roche Cobas e402/e801
	µg/dl	2.81	2.11	3.51	
	ng/ml	28.1	21.1	35.1	
Valproic Acid	µmol/l	217	174	260	Siemens Centaur XP/XPT/Classic
	µg/ml	31.3	25.1	37.5	
	µmol/l	162	130	194	Abbott Architect (CMIA)
	µg/ml	23.4	18.8	28.0	
	µmol/l	192	154	230	Roche Cobas 6000/8000
	µg/ml	27.7	22.2	33.2	
	µmol/l	148	118	178	Abbott Alinity (PETINA)
	µg/ml	21.4	17.0	25.8	
	µmol/l	243	194	292	Gravimetric
	µg/ml	35.1	28.0	42.1	
Vancomycin	µmol/l	3.61	2.89	4.33	Abbott Architect (CMIA)
	µg/ml	5.36	4.29	6.43	
	µmol/l	3.58	2.86	4.30	Roche Cobas 6000/8000
	µg/ml	5.32	4.25	6.39	
	µmol/l	3.43	2.74	4.12	Gravimetric
	µg/ml	5.10	4.07	6.12	
Vitamin B12	pmol/l	107	85.6	128	Beckman Access
	pg/ml	145	116	174	
	pmol/l	137	110	164	Siemens Centaur XP/XPT/Classic
	pg/ml	186	149	223	
	pmol/l	113	90.4	136	Siemens Immulite 2000
	pg/ml	153	122	184	
	pmol/l	140	112	168	Vitros ECi
	pg/ml	190	152	228	
	pmol/l	104	83.2	125	Beckman DxI800
	pg/ml	141	113	169	
	pmol/l	205	164	246	Roche Cobas 4000/e411 Gen II
	pg/ml	278	222	334	
	pmol/l	168	134	202	Roche Cobas e601/602 Gen II
	pg/ml	228	182	274	
	pmol/l	146	117	175	Siemens Atellica IM
	pg/ml	198	159	237	
pmol/l	158	126	190	Roche Cobas e801 Gen II	
pg/ml	214	171	257		