

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

<b>CAT. NO.</b> IA2640	<b>GTIN:</b> 05055273203868	<b>SIZE</b> 12 x 5 ml
<b>CAT. NO.</b> IA2633	<b>GTIN:</b> 05055273203837	<b>SIZE</b> 4 x 5 ml
<b>LOT NO.</b> 2277EC	<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.

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 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 - Level 3: 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](mailto:Technical.Services@randox.com).

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Rev. 12 Apr '24 me

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	44.5	33.4	55.6	DIAsource ELISA
	ng/ml	14.7	11.1	18.3	
	nmol/l	39.0	29.3	48.8	SNIBE Maglumi Analysers
	ng/ml	12.9	9.70	16.1	
25-OH Vitamin D	nmol/l	146	110	183	Siemens Centaur XP/XPT/Classic
	nmol/l	99.0	74.3	124	Roche Vitamin D Total
	nmol/l	110	82.5	138	Abbott Architect (3L52)
	nmol/l	174	131	218	Vitros ECi
	nmol/l	106	79.5	133	BioMerieux Vidas
	nmol/l	146	110	183	Beckman Dxl 600/800
	nmol/l	111	83.3	139	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	116	87.0	145	Abbott Alinity i
	nmol/l	148	111	185	Siemens Atellica IM
	nmol/l	101	75.8	126	Roche Vitamin D Total II e801
	nmol/l	97.3	73.0	122	Roche Vitamin D Total III
ACTH	pmol/l	50.2	37.7	62.8	Siemens Immulite 2000/2500
	pg/ml	228	171	285	
	pmol/l	35.8	26.9	44.8	Roche Cobas 4000/E411
	pg/ml	163	122	204	
	pmol/l	34.1	25.6	42.6	Roche Cobas e601/602
	pg/ml	155	116	194	
	pmol/l	51.6	38.7	64.5	Siemens Immulite 1000
Aldosterone	pmol/l	590	443	738	Diasorin Liaison XL
	pg/ml	213	160	266	
Alphafoetoprotein	KIU/l = IU/ml	183	146	220	Vitros ECi
	ng/ml	221	177	265	
	KIU/l = IU/ml	207	166	248	Siemens Centaur XP/XPT/Classic
	ng/ml	250	201	299	
	KIU/l = IU/ml	173	138	208	Abbott Architect
	ng/ml	209	167	251	
	KIU/l = IU/ml	167	134	200	Beckman Dxl800
	ng/ml	202	162	242	
	KIU/l = IU/ml	194	155	233	Roche Cobas e601/602
	ng/ml	235	188	282	
	KIU/l = IU/ml	199	159	239	Roche Cobas 4000/E411
	ng/ml	241	192	290	
	KIU/l = IU/ml	202	162	242	Siemens Atellica IM
	ng/ml	244	196	292	
	KIU/l = IU/ml	171	137	205	Abbott Alinity i
ng/ml	207	166	248		
KIU/l = IU/ml	191	153	229	Roche Cobas e402/e801	
ng/ml	231	185	277		

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Amikacin	µmol/l	24.1	19.3	28.9	Gravimetric
	µg/ml	14.1	11.3	16.9	
Androstenedione	nmol/l	32.2	24.2	40.3	Siemens Immulite 2000
	ng/ml	9.24	6.95	11.5	
Beta-2-microglobulin	µg/ml = mg/l	6.61	5.29	7.93	Roche Cobas 6000/8000
C-Peptide	nmol/l	2.470	1.850	3.090	Roche Cobas e601/602
	ng/ml	7.46	5.59	9.33	
	nmol/l	2.390	1.790	2.990	Roche Cobas e402/e801
	ng/ml	7.22	5.40	9.04	
	nmol/l	2.170	1.630	2.710	Abbott Alinity i
Carbamazepine	µmol/l	71.3	57.0	85.6	Abbott Architect (CMIA)
	µg/ml	16.9	13.5	20.3	
	µmol/l	71.4	57.1	85.7	Roche Cobas 6000/8000
	µg/ml	16.9	13.5	20.3	
	µmol/l	72.2	57.8	86.6	Gravimetric
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	56.3	45.0	67.6	BioMerieux Vidas
	ng/ml = µg/l	53.8	43.0	64.6	Vitros ECI
	ng/ml = µg/l	53.0	42.4	63.6	Beckman Access
	ng/ml = µg/l	60.1	48.1	72.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	60.9	48.7	73.1	Abbott Architect
	ng/ml = µg/l	51.7	41.4	62.0	Beckman DxI800
	ng/ml = µg/l	45.7	36.6	54.8	Roche Cobas e601/602
	ng/ml = µg/l	49.0	39.2	58.8	Roche Cobas 4000/E411
	ng/ml = µg/l	57.7	46.2	69.2	Siemens Atellica IM
	ng/ml = µg/l	47.9	38.3	57.5	Roche Cobas e402/e801
Cortisol	ng/ml = µg/l	61.9	49.5	74.3	Abbott Alinity i
	nmol/l	1139	854	1424	Siemens Centaur XP/XPT/Classic
	µg/dl	41.0	30.7	51.3	
	nmol/l	844	633	1055	Siemens Immulite 2000/2500
	µg/dl	30.4	22.8	38.0	
	nmol/l	910	683	1138	Vitros ECI
	µg/dl	32.8	24.6	41.0	
	nmol/l	859	644	1074	Abbott Architect
	µg/dl	30.9	23.2	38.6	
	nmol/l	902	677	1128	Beckman DxI800
	µg/dl	32.5	24.4	40.6	
	nmol/l	1022	767	1278	Roche Cobas e601/602
	µg/dl	36.8	27.6	46.0	
	nmol/l	1101	826	1376	Roche Cobas 4000/E411
µg/dl	39.6	29.7	49.5		
nmol/l	942	707	1178	Roche Cobas 4000/e411 Gen II	
µg/dl	33.9	25.5	42.3		
nmol/l	954	716	1193	Roche Cobas e601/602 Gen II	
µg/dl	34.3	25.8	42.8		

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Analyte	unit	Target	Range		methods
			low	high	
Cortisol	nmol/l	1188	891	1485	Siemens Atellica IM
	µg/dl	42.8	32.1	53.5	
	nmol/l	944	708	1180	Roche Cobas e402/e801
	µg/dl	34.0	25.5	42.5	
	nmol/l	940	705	1175	Roche Cobas e801 Gen II
	µg/dl	33.8	25.4	42.2	
DHEA-S	nmol/l	860	645	1075	Abbott Alinity i
	µg/dl	31.0	23.2	38.8	
	µmol/l	17.1	13.7	20.5	Siemens Immulite 2000/2500
	µmol/l	18.8	15.0	22.6	Abbott Architect
	µmol/l	14.1	11.3	16.9	Beckman DxI800
	µmol/l	23.9	19.1	28.7	Roche Cobas 4000/E411
Digoxin	µmol/l	24.0	19.2	28.8	Roche Cobas e601/602
	µmol/l	23.1	18.5	27.7	Roche Cobas e402/e801
	µmol/l	19.2	15.4	23.0	Abbott Alinity i
	nmol/l	4.39	3.51	5.27	Abbott Architect (CMIA)
	ng/ml	3.43	2.74	4.12	
	nmol/l	5.10	4.08	6.12	Roche Cobas e402/e801
	ng/ml	3.98	3.19	4.77	
	nmol/l	5.12	4.10	6.14	Gravimetric
Ethosuximide	ng/ml	4.00	3.20	4.80	
	µg/ml	493	394	592	Gravimetric
Ferritin	µg/ml	69.9	55.9	83.9	
	ng/ml = µg/l	276	221	331	BioMerieux Vidas
	ng/ml = µg/l	355	284	426	Roche Elecsys/Cobas e411
	ng/ml = µg/l	229	183	275	Beckman Access
	ng/ml = µg/l	219	175	263	Vitros ECI
	ng/ml = µg/l	258	206	310	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	373	298	448	Abbott Architect
	ng/ml = µg/l	352	282	422	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = µg/l	226	181	271	Beckman DxI800
	ng/ml = µg/l	317	254	380	Roche Cobas c501/502/503/701/702
	ng/ml = µg/l	395	316	474	Abbott Alinity i
	ng/ml = µg/l	250	200	300	Siemens Atellica IM
Folate	ng/ml = µg/l	336	269	403	Roche Cobas e402/e801
	nmol/l	21.1	16.0	26.2	Beckman Access
	ng/ml	9.31	7.06	11.6	
	nmol/l	13.7	10.4	17.0	Siemens Immulite 2000
	ng/ml	6.04	4.59	7.49	
	nmol/l	11.8	8.97	14.6	Vitros ECI
	ng/ml	5.20	3.96	6.44	
	nmol/l	17.0	12.9	21.1	Abbott Architect
ng/ml	7.50	5.69	9.31		
Folate	nmol/l	40.2	30.6	49.8	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	17.7	13.5	21.9	

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Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Range						
Analyte	unit	Target	low	high	methods	
Folate	nmol/l	20.3	15.4	25.2	Beckman Dxl 600 / 800 - A98032	
	ng/ml	8.95	6.79	11.1		
	nmol/l	21.7	16.5	26.9	Roche Folate III - 07559992	
	ng/ml	9.57	7.28	11.9		
	nmol/l	30.8	23.4	38.2	Siemens Atellica IM	
	ng/ml	13.6	10.3	16.9		
	nmol/l	18.9	14.4	23.4	Abbott Alinity i	
	ng/ml	8.33	6.35	10.3		
	nmol/l	21.5	16.3	26.7	Roche Folate 07027290 e801	
	ng/ml	9.48	7.19	11.8		
	Free T3	pmol/l	19.1	14.3	23.9	Beckman Access
		ng/dl	1.24	0.930	1.55	
pg/ml		12.4	9.31	15.5		
pmol/l		35.0	26.3	43.8	Vitros Eci	
ng/dl		2.28	1.71	2.85		
pg/ml		22.8	17.1	28.5		
pmol/l		23.0	17.3	28.8	Siemens Centaur XP/XPT/Classic	
ng/dl		1.50	1.12	1.88		
pg/ml		15.0	11.3	18.7		
pmol/l		23.7	17.8	29.6	Abbott Architect, 2 point calibration	
ng/dl		1.54	1.16	1.92		
pg/ml		15.4	11.6	19.2		
pmol/l		17.0	12.8	21.3	Beckman Dxl800	
ng/dl		1.11	0.832	1.39		
pg/ml		11.1	8.33	13.9		
pmol/l		27.9	20.9	34.9	Roche Cobas 4000/E411	
ng/dl		1.81	1.36	2.26		
pg/ml		18.2	13.6	22.8		
pmol/l		28.1	21.1	35.1	Roche Cobas e601/602	
ng/dl		1.83	1.37	2.29		
pg/ml		18.3	13.7	22.9		
pmol/l		25.9	19.4	32.4	Siemens Atellica IM	
ng/dl		1.68	1.26	2.10		
pg/ml		16.9	12.6	21.2		
pmol/l		23.3	17.5	29.1	Abbott Architect, 6 point calibration	
ng/dl		1.51	1.14	1.88		
pg/ml		15.2	11.4	19.0		
pmol/l		27.9	20.9	34.9	Roche Cobas e402/e801	
ng/dl		1.81	1.36	2.26		
pg/ml		18.2	13.6	22.8		
pmol/l		25.4	19.1	31.8	Abbott Alinity, 6 point cal	
ng/dl		1.65	1.24	2.06		
pg/ml		16.5	12.4	20.6		
Free T4		pmol/l	51.9	38.9	64.9	Beckman Access
		ng/dl	4.05	3.03	5.07	
		pg/ml	40.5	30.3	50.7	

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	89.8	67.4	112	Vitros ECI
	ng/dl	7.00	5.26	8.74	
	pg/ml	70.0	52.6	87.4	
	pmol/l	47.8	35.9	59.8	Siemens Centaur XP/XPT/Classic
	ng/dl	3.73	2.80	4.66	
	pg/ml	37.3	28.0	46.6	
	pmol/l	74.3	55.7	92.9	Siemens Immulite 2000/2500
	ng/dl	5.80	4.34	7.26	
	pg/ml	58.0	43.4	72.6	
	pmol/l	49.1	36.8	61.4	Abbott Architect
	ng/dl	3.83	2.87	4.79	
	pg/ml	38.3	28.7	47.9	
	pmol/l	55.9	41.9	69.9	Beckman Dxl800
	ng/dl	4.36	3.27	5.45	
	pg/ml	43.6	32.7	54.5	
	pmol/l	70.3	52.7	87.9	Roche Cobas e601/602
	ng/dl	5.48	4.11	6.85	
	pg/ml	54.8	41.1	68.5	
	pmol/l	68.4	51.3	85.5	Roche Cobas 4000/E411
	ng/dl	5.34	4.00	6.68	
	pg/ml	53.4	40.0	66.8	
pmol/l	51.6	38.7	64.5	Siemens Atellica IM	
ng/dl	4.02	3.02	5.02		
pg/ml	40.2	30.2	50.2		
pmol/l	43.6	32.7	54.5	Abbott Alinity i	
ng/dl	3.40	2.55	4.25		
pg/ml	34.0	25.5	42.5		
pmol/l	71.9	53.9	89.9	Roche Cobas e402/e801	
ng/dl	5.61	4.20	7.02		
pg/ml	56.1	42.0	70.2		
FSH	mU/ml	65.8	52.6	79.0	BioMerieux Vidas
	mU/ml	50.1	40.1	60.1	Vitros ECI
	mU/ml	81.8	65.4	98.2	Siemens Centaur XP/XPT/Classic
	mU/ml	57.5	46.0	69.0	Siemens Immulite 2000/2500
	mU/ml	56.1	44.9	67.3	Abbott Architect
	mU/ml	60.4	48.3	72.5	Beckman Dxl800
	mU/ml	60.2	48.2	72.2	Roche Cobas 4000/E411
	mU/ml	56.5	45.2	67.8	Roche Cobas e601/602
	mU/ml	72.4	57.9	86.9	Siemens Atellica IM
	mU/ml	54.9	43.9	65.9	Abbott Alinity i
	mU/ml	57.3	45.8	68.8	Roche Cobas e402/e801
Gentamicin	µmol/l	11.7	9.36	14.0	Gravimetric
	µg/ml	5.59	4.47	6.69	
Growth Hormone (GH)	µU/ml	47.2	37.8	56.6	Siemens Immulite 2000/2500
	ng/ml	15.7	12.6	18.8	
	µU/ml	43.9	35.1	52.7	Roche Cobas e601/602
	ng/ml	14.6	11.7	17.5	

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Growth Hormone (GH)	µU/ml	41.3	33.0	49.6	Diasorin Liaison XL
	ng/ml	13.8	11.0	16.6	
	µU/ml	46.0	36.8	55.2	Roche Cobas e402/e801
	ng/ml	15.3	12.3	18.3	
Immunoglobulin E	KIU/I = IU/ml	499	399	599	BioMerieux Vidas
	KIU/I = IU/ml	531	425	637	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	533	426	640	Siemens Immulite 2000/2500
	KIU/I = IU/ml	457	366	548	Abbott Architect
	KIU/I = IU/ml	552	442	662	Roche Cobas 4000/E411
	KIU/I = IU/ml	530	424	636	Roche Cobas e601/602
	KIU/I = IU/ml	530	424	636	Siemens Atellica IM
	KIU/I = IU/ml	548	438	658	Roche Cobas e402/e801
Insulin	mU/l	29.1	21.8	36.4	Siemens Centaur XP/XPT/Classic
	µU/ml	29.1	21.8	36.4	
	mU/l	9.74	7.31	12.2	Siemens Immulite 2000
	µU/ml	9.74	7.31	12.2	
	mU/l	22.9	17.2	28.6	Abbott Architect
	µU/ml	22.9	17.2	28.6	
	mU/l	30.8	23.1	38.5	Roche Cobas 4000/E411
	µU/ml	30.8	23.1	38.5	
	mU/l	30.1	22.6	37.6	Roche Cobas 6000/8000
	µU/ml	30.1	22.6	37.6	
	mU/l	25.8	19.4	32.3	Beckman Dxl 600/800
	µU/ml	25.8	19.4	32.2	
Luteinising Hormone (LH)	mU/ml	50.8	40.6	61.0	BioMerieux Vidas
	mU/ml	64.6	51.7	77.5	Vitros ECi
	mU/ml	48.8	39.0	58.6	Siemens Centaur XP/XPT/Classic
	mU/ml	68.1	54.5	81.7	Siemens Immulite 2000
	mU/ml	43.6	34.9	52.3	Abbott Architect
	mU/ml	40.5	32.4	48.6	Beckman DxI800
	mU/ml	57.1	45.7	68.5	Roche Cobas 4000/E411
	mU/ml	56.6	45.3	67.9	Roche Cobas e601/602
	mU/ml	52.8	42.2	63.4	Siemens Atellica IM
	mU/ml	42.8	34.2	51.4	Abbott Alinity i
	mU/ml	57.7	46.2	69.2	Roche Cobas e402/e801
	Oestradiol	pmol/l	3519	2815	4223
pg/ml		957	766	1148	
pmol/l		1280	1024	1536	Abbott Architect
pg/ml		348	279	417	
pmol/l		2587	2070	3104	Siemens Centaur XP/XPT/Classic Enhanced (eE2)
pg/ml		704	563	845	
	pmol/l	1558	1246	1870	Roche Cobas e601/602 (Estradiol III)
	pg/ml	424	339	509	



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Range						
Analyte	unit	Target	low	high	methods	
Oestradiol	pmol/l	1571	1257	1885	Roche Cobas 4000/E411 (Estradiol III)	
	pg/ml	427	342	512		
	pmol/l	1300	1040	1560	Beckman Dxl600/800 Sensitive B84493	
	pg/ml	354	283	425		
	pmol/l	2859	2287	3431	Siemens Atellica IM	
	pg/ml	778	622	934		
	pmol/l	1260	1008	1512	Abbott Alinity i	
	pg/ml	343	274	412		
Paracetamol	mmol/l	0.470	0.376	0.564	Roche Cobas c501/502/503/701/702	
	mg/l	71.1	56.9	85.3		
	mmol/l	0.529	0.423	0.635	Gravimetric	
	mg/l	80.0	64.0	96.0		
Phenobarbital	µmol/l	114	91.2	137	Abbott Architect (CMIA)	
	µg/ml	26.4	21.2	31.6		
	µmol/l	126	101	151	Siemens Immulite 2000/2500	
	µg/ml	29.2	23.4	35.0		
	µmol/l	122	97.6	146	Beckman AU400/600/640/2700/5400	
	µg/ml	28.3	22.6	34.0		
Phenytoin	µmol/l	122	97.6	146	Roche Cobas C303/501/502/503/701	
	µg/ml	28.3	22.6	34.0		
	µmol/l	121	96.8	145	Gravimetric	
	µg/ml	28.1	22.5	33.6		
	Phenytoin	µmol/l	92.2	73.8	111	Abbott Architect
		µg/ml	23.3	18.6	28.0	
µmol/l		93.9	75.1	113	Roche Cobas 6000/8000	
µg/ml		23.7	19.0	28.4		
Primidone	µmol/l	99.8	79.8	120	Gravimetric	
	µg/ml	25.2	20.1	30.3		
Primidone	µmol/l	32.7	26.2	39.2	Gravimetric	
	µg/ml	7.14	5.72	8.56		
Progesterone	nmol/l	81.0	64.8	97.2	Siemens Centaur XP/XPT/Classic	
	ng/ml	25.4	20.3	30.5		
	nmol/l	80.7	64.6	96.8	Siemens Immulite 2000/2500	
	ng/ml	25.3	20.2	30.4		
	nmol/l	108	86.4	130	Abbott Architect	
	ng/ml	33.8	27.0	40.6		
	nmol/l	94.0	75.2	113	Beckman Dxl Prog DE Cal A80773	
	ng/ml	29.4	23.5	35.3		
	nmol/l	112	89.6	134	Roche Cobas e601/602 (Prog. III)	
	ng/ml	35.1	28.0	42.2		
Progesterone	nmol/l	111	88.8	133	Roche Cobas 4000/e411 (Prog. III)	
	ng/ml	34.7	27.8	41.6		
	nmol/l	101	80.8	121	Abbott Alinity i	
ng/ml	31.6	25.3	37.9			

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Range					
Analyte	unit	Target	low	high	methods
Progesterone	nmol/l	92.7	74.2	111	Siemens Atellica IM
	ng/ml	29.0	23.2	34.8	
	nmol/l	112	89.6	134	Roche Cobas e801 (Prog. III)
	ng/ml	35.1	28.0	42.2	
Prolactin	µU/ml	1279	1023	1535	BioMerieux Vidas
	µU/ml	1015	812	1218	Vitros ECi
	µU/ml	923	738	1108	Siemens Centaur XP/XPT/Classic
	µU/ml	1159	927	1391	Abbott Architect
	µU/ml	997	798	1196	Beckman DxI800
	µU/ml	1457	1166	1748	Roche Cobas 4000/E411
	µU/ml	1376	1101	1651	Roche Cobas e601/602
	µU/ml	861	689	1033	Siemens Atellica IM
	µU/ml	1192	954	1430	Abbott Alinity i
PSA Free	ng/ml = µg/l	24.8	18.6	31.0	Abbott Architect
	ng/ml = µg/l	18.8	14.1	23.5	Roche Cobas 4000/E411
	ng/ml = µg/l	18.8	14.1	23.5	Roche Cobas e601/602
	ng/ml = µg/l	23.4	17.6	29.3	Siemens Atellica IM
	ng/ml = µg/l	24.3	18.2	30.4	Abbott Alinity i
	ng/ml = µg/l	18.0	13.5	22.5	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	28.2	21.2	35.3	Beckman Access standardised to Hybritech
	ng/ml = µg/l	23.1	17.3	28.9	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	19.2	14.4	24.0	Abbott Architect
	ng/ml = µg/l	28.8	21.6	36.0	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	27.2	20.4	34.0	Beckman DxI standardisd to Hybritech
	ng/ml = µg/l	22.5	16.9	28.1	Beckman DxI800 standardised to WHO IRP96/670
	ng/ml = µg/l	26.3	19.7	32.9	Roche Cobas 4000/E411
	ng/ml = µg/l	26.2	19.7	32.8	Roche Cobas e601/602
	ng/ml = µg/l	25.8	19.4	32.3	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	23.7	17.8	29.6	Siemens Atellica IM
	ng/ml = µg/l	19.1	14.3	23.9	Abbott Alinity i
Salicylic Acid	mmol/l	2.88	2.30	3.46	Gravimetric
	mg/dl	39.8	31.8	47.8	
SHBG	nmol/l	36.7	29.4	44.0	Siemens Immulite 2000/2500
	nmol/l	39.9	31.9	47.9	Abbott Architect
	nmol/l	34.6	27.7	41.5	Roche Cobas e801 - 413429
	nmol/l	35.8	28.6	43.0	Roche analysers - 413417/15
	nmol/l	39.5	31.6	47.4	Abbott Alinity i
T Uptake	%U	37.9	31.1	44.7	Siemens Immulite 2000
Testosterone	nmol/l	32.8	26.2	39.4	Siemens Immulite 2000/2500
	ng/ml	9.45	7.55	11.4	
	ng/dl	945	755	1135	
	nmol/l	28.2	22.6	33.8	Abbott Architect
	ng/ml	8.12	6.51	9.73	
	ng/dl	812	651	973	

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	nmol/l	23.6	18.9	28.3	Beckman DxI800
	ng/ml	6.80	5.44	8.16	
	ng/dl	680	544	816	
	nmol/l	28.8	23.0	34.6	Roche Cobas 4000/e411 Test II
	ng/ml	8.29	6.62	9.96	
	ng/dl	829	662	996	
	nmol/l	28.9	23.1	34.7	Roche Cobas e601/602 Test II
	ng/ml	8.32	6.65	9.99	
	ng/dl	832	665	999	
	nmol/l	28.1	22.5	33.7	Abbott Architect 2nd Generation
	ng/ml	8.09	6.48	9.70	
	ng/dl	809	648	970	
	nmol/l	25.1	20.1	30.1	Siemens Centaur TST II
	ng/ml	7.23	5.79	8.67	
	ng/dl	723	579	867	
nmol/l	26.5	21.2	31.8	Siemens Atellica IM	
ng/ml	7.63	6.11	9.15		
ng/dl	763	611	915		
nmol/l	28.4	22.7	34.1	Roche Cobas e801 Test II	
ng/ml	8.18	6.54	9.82		
ng/dl	818	654	982		
nmol/l	29.6	23.7	35.5	Abbott Alinity i	
ng/ml	8.52	6.83	10.2		
ng/dl	852	683	1021		
Theophylline	µmol/l	166	133	199	Gravimetric
	µg/ml	29.9	24.0	35.9	
Thyroglobulin	ng/ml	28.0	21.0	35.0	Siemens Immulite 2000
	ng/ml	52.3	39.2	65.4	Beckman DxI800
	ng/ml	63.3	47.5	79.1	Roche Cobas e601/602
	ng/ml	66.6	50.0	83.3	Abbott Architect 2000i
	ng/ml	63.1	47.3	78.9	Roche Cobas e601/602 Tg II
	ng/ml	61.4	46.1	76.8	Roche Cobas e801 Tg II
Thyroid Stimulating Hormone	µU/ml = mIU/l	21.9	17.5	26.3	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	26.5	21.2	31.8	Vitros ECI
	µU/ml = mIU/l	24.7	19.8	29.6	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	20.3	16.2	24.4	Siemens Immulite 2000/2500
	µU/ml = mIU/l	19.2	15.4	23.0	Abbott Architect
	µU/ml = mIU/l	21.9	17.5	26.3	Roche Cobas 4000/E411
	µU/ml = mIU/l	22.1	17.7	26.5	Roche Cobas e601/602
	µU/ml = mIU/l	24.6	19.7	29.5	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	20.4	16.3	24.5	Beckman DxI 600/800 Access (3rd IS)
	µU/ml = mIU/l	24.0	19.2	28.8	Siemens Atellica IM
µU/ml = mIU/l	18.8	15.0	22.6	Abbott Alinity i	
µU/ml = mIU/l	20.6	16.5	24.7	Roche Cobas e402/e801	

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Tobramycin	µmol/l	10.3	8.24	12.4	Gravimetric
	µg/ml	4.82	3.86	5.80	
Total Beta hCG	mU/ml=IU/l	466	373	559	BioMerieux Vidas
	IU/ml	0.466	0.373	0.559	
	mU/ml=IU/l	454	363	545	Vitros ECi
	IU/ml	0.454	0.363	0.545	
	mU/ml=IU/l	218	174	262	Siemens Centaur XP/XPT/Classic
	IU/ml	0.218	0.174	0.262	
	mU/ml=IU/l	504	403	605	Siemens Immulite 2000
	IU/ml	0.504	0.403	0.605	
	mU/ml=IU/l	254	203	305	Abbott Architect
	IU/ml	0.254	0.203	0.305	
	mU/ml=IU/l	290	232	348	Roche hCG+Beta
	IU/ml	0.290	0.232	0.348	
	mU/ml=IU/l	249	199	299	Beckman Access Total BhCG (5th IS)
	IU/ml	0.249	0.199	0.299	
	mU/ml=IU/l	260	208	312	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.260	0.208	0.312	
	mU/ml=IU/l	224	179	269	Siemens Atellica IM
	IU/ml	0.224	0.179	0.269	
mU/ml=IU/l	250	200	300	Abbott Alinity i	
IU/ml	0.250	0.200	0.300		
mU/ml=IU/l	282	226	338	Roche hCG+Beta e801	
IU/ml	0.282	0.226	0.338		
Total T3	nmol/l	6.45	4.84	8.06	Siemens Centaur XP/XPT/Classic
	ng/ml	4.20	3.15	5.25	
	ng/dl	420	315	525	
	nmol/l	5.02	3.77	6.28	Abbott Architect
	ng/ml	3.27	2.45	4.09	
	ng/dl	327	245	409	
	nmol/l	6.75	5.06	8.44	Vitros ECi
	ng/ml	4.39	3.29	5.49	
	ng/dl	439	329	549	
	nmol/l	6.01	4.51	7.51	Roche Cobas 4000/E411
	ng/ml	3.91	2.94	4.88	
	ng/dl	391	294	488	
	nmol/l	6.09	4.57	7.61	Roche Cobas e601/602
	ng/ml	3.96	2.98	4.94	
	ng/dl	396	298	494	
	nmol/l	5.13	3.85	6.41	Abbott Alinity i
	ng/ml	3.34	2.51	4.17	
	ng/dl	334	251	417	
nmol/l	6.78	5.09	8.48	Siemens Atellica IM	
ng/ml	4.41	3.31	5.51		
ng/dl	441	331	551		
nmol/l	6.43	4.82	8.04	Roche Cobas e402/e801	
ng/ml	4.19	3.14	5.24		
ng/dl	419	314	524		

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Range					
Analyte	unit	Target	low	high	methods
Total T4	nmol/l	214	161	268	Vitros ECI
	µg/dl	16.7	12.6	20.8	
	ng/ml	167	126	208	
	nmol/l	214	161	268	Beckman Access
	µg/dl	16.7	12.6	20.8	
	ng/ml	167	126	208	
	nmol/l	225	169	281	Siemens Centaur XP/XPT/Classic
	µg/dl	17.6	13.2	22.0	
	ng/ml	176	132	220	
	nmol/l	191	143	239	Siemens Immulite 2000/2500
	µg/dl	14.9	11.2	18.6	
	ng/ml	149	112	186	
	nmol/l	198	149	248	Abbott Architect
	µg/dl	15.4	11.6	19.2	
	ng/ml	154	116	192	
	nmol/l	182	137	228	Roche Cobas 4000/E411
	µg/dl	14.2	10.7	17.7	
	ng/ml	142	107	177	
	nmol/l	190	143	238	Roche Cobas e601/602
	µg/dl	14.8	11.2	18.4	
	ng/ml	148	112	184	
nmol/l	191	143	239	Abbott Alinity i	
µg/dl	14.9	11.2	18.6		
ng/ml	149	112	186		
nmol/l	217	163	271	Siemens Atellica IM	
µg/dl	16.9	12.7	21.1		
ng/ml	169	127	211		
nmol/l	175	131	219	Roche Cobas e402/e801	
µg/dl	13.7	10.2	17.2		
ng/ml	137	102	172		
Valproic Acid	µmol/l	980	784	1176	Siemens Centaur XP/XPT/Classic
	µg/ml	141	113	169	
	µmol/l	925	740	1110	Abbott Architect (CMIA)
	µg/ml	133	107	159	
	µmol/l	908	726	1090	Roche Cobas 6000/8000
	µg/ml	131	105	157	
	µmol/l	889	711	1067	Abbott Alinity (PETINA)
µg/ml	128	103	153		
µmol/l	1116	893	1339	Gravimetric	
µg/ml	161	129	193		
Vancomycin	µmol/l	12.0	9.60	14.4	Abbott Architect (CMIA)
	µg/ml	17.8	14.3	21.3	
	µmol/l	10.4	8.32	12.5	Roche Cobas 6000/8000
	µg/ml	15.5	12.4	18.6	

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2277EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Range					
Analyte	unit	Target	low	high	methods
Vancomycin	µmol/l	10.8	8.64	13.0	Gravimetric
	µg/ml	16.0	12.8	19.3	
Vitamin B12	pmol/l	540	432	648	Beckman Access
	pg/ml	732	585	879	
	pmol/l	728	582	874	Siemens Centaur XP/XPT/Classic
	pg/ml	986	789	1183	
	pmol/l	698	558	838	Siemens Immulite 2000
	pg/ml	946	756	1136	
	pmol/l	625	500	750	Abbott Architect
	pg/ml	847	678	1016	
	pmol/l	598	478	718	Vitros ECI
	pg/ml	810	648	972	
	pmol/l	579	463	695	Beckman DxI800
	pg/ml	785	627	943	
	pmol/l	702	562	842	Roche Cobas 4000/e411 Gen II
	pg/ml	951	762	1140	
	pmol/l	708	566	850	Roche Cobas e601/602 Gen II
	pg/ml	959	767	1151	
pmol/l	705	564	846	Siemens Atellica IM	
pg/ml	955	764	1146		
pmol/l	644	515	773	Abbott Alinity i	
pg/ml	873	698	1048		
pmol/l	690	552	828	Roche Cobas e801 Gen II	
pg/ml	935	748	1122		

**ADDITIONAL VALUES FOR  
IMMUNOASSAY PREMIUM - LEVEL 3  
(IA PREMIUM 3)  
Cat No. IA2640 / IA2633  
Lot No. 2277EC  
GTIN: 05055273203868 / 05055273203837**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Insulin	mU/l	24.7	18.5 – 30.9	Beckman Access/LXi725
	µU/ml	24.7	18.5 – 30.9	

**EC REP**

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

09 Oct '24 me

**ADDITIONAL VALUES FOR  
IMMUNOASSAY PREMIUM - LEVEL 3  
(IA PREMIUM 3)  
Cat No. IA2640 / IA2633  
Lot No. 2277EC  
GTIN: 05055273203868 / 05055273203837**

COMPONENT	UNITS	TARGET	RANGE	METHOD
25-OH Vitamin D	nmol/l	126	94.5 - 158	Siemens Dimension EXL/200

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

09 Oct '24 me



## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

<b>CAT. NO.</b> IA2640	<b>GTIN:</b> 05055273203868	<b>SIZE:</b> 12 x 5 ml
<b>CAT. NO.</b> IA2633	<b>GTIN:</b> 05055273203837	<b>SIZE:</b> 4 x 5 ml
<b>LOT NO.</b> 2277EC	<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.

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 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 - Level 3: 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](mailto:Technical.Services@randox.com).

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

07 Nov '24 me

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2271EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Cortisol	µg/dL	34.1	24.9	43.3	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		34.1	24.9	43.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
C-Peptide	ng/mL	6.57	4.79	8.34	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		6.57	4.79	8.34	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
DHEA-S	µg/dL	707	516	898	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		707	516	898	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Insulin	µIU/mL	30.5	20.7	40.2	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		33.4	22.7	44.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Alphafoetoprotein	ng/ml	234	171	297	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		234	171	297	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Carcinoembryonic Antigen (CEA)	ng/ml	39.7	29.0	50.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		39.7	29.0	50.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Ferritin	ng/mL	357	260	453	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		357	260	453	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Free	ng/mL	24.5	17.9	31.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		24.5	17.9	31.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Total	ng/mL	25.1	18.3	31.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		25.1	18.3	31.8	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Oestradiol	pg/mL	591	431	750	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501
		591	431	750	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501
		624	424	823	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001
		624	424	823	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001
FSH	mIU/mL	83.2	60.8	106	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101
		83.2	60.8	106	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101
		69.1	41.5	96.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401
		69.1	41.5	96.7	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401
Total Beta hCG	mIU/mL	225	153	297	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i
		214	145	282	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i
		544	327	762	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i
		544	327	762	Wiener Lab CLIA Series & Mindray hCG2 CL 900i
Luteinising Hormone (LH)	mIU/mL	59.8	43.6	75.9	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		59.8	43.6	75.9	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Prolactin	ng/mL	62.1	42.3	82.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		62.1	42.3	82.0	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Progesterone	ng/mL	>40.00			Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		>40.00			Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
		31.6	21.5	41.7	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i
		31.6	21.5	41.7	Wiener Lab CLIA Series & Mindray PROG II CL 900i

## IMMUNOASSAY PREMIUM - LEVEL 3 (IA PREMIUM 3)

Cat. No. IA2640 / IA2633 Lot. No. 2271EC Size 12 x 5ml / 4 x 5ml Expiry 2026-05-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	ng/mL	11.8	8.58	14.9	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		11.8	8.58	14.9	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		10.8	7.90	13.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		10.8	7.90	13.7	Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		7.52	5.11	9.93	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		7.52	5.11	9.93	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Folate	ng/mL	>20.00			Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		>20.00			Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Vitamin B12	pg/mL	989	673	1306	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		989	673	1306	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Free T3	pg/mL	13.4	9.12	17.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X
		13.4	9.12	17.7	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X
		13.4	9.12	17.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00
		13.4	9.12	17.7	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00
Free T4	ng/dL	4.50	3.06	5.94	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		4.50	3.06	5.94	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		>6.00			Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		>6.00			Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T3	ng/mL	3.08	2.09	4.07	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		3.08	2.09	4.07	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		3.08	2.09	4.07	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		3.08	2.09	4.07	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Total T4	µg/dL	16.7	11.3	22.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		16.7	11.3	22.0	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		14.8	10.8	18.8	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		14.8	10.8	18.8	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00
Thyroid Stimulating Hormone	µIU/mL	27.7	20.2	35.2	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		27.7	20.2	35.2	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		22.3	16.2	28.3	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		22.3	16.2	28.3	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00