



# PRODUCT INFORMATION

IA2640 / IA2633

2349EC

Please note that in Immunoassay Premium- Level 3, lot 2349EC, the value for T-Uptake is currently unavailable and will be updated in due course.

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

CCS INC767

## 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> 2349EC	<b>EXPIRY:</b> 2026-11-28	

### INTENDED USE

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

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

### SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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.

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 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
----	-----

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

27 Mar '24 me

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
17-OH-Progesterone	nmol/l	35.7	26.8	44.6	DIAsource ELISA
	ng/ml	11.8	8.87	14.7	
	nmol/l	30.6	23.0	38.3	SNIBE Maglumi Analysers
	ng/ml	10.1	7.61	12.6	
25-OH Vitamin D	nmol/l	131	98.3	164	Siemens Centaur XP/XPT/Classic
	nmol/l	84.1	63.1	105	Roche Vitamin D Total
	nmol/l	98.9	74.2	124	Abbott Architect (3L52)
	nmol/l	161	121	201	Vitros ECi
	nmol/l	100	75.0	125	BioMerieux Vidas
	nmol/l	125	93.8	156	Beckman Dxl 600/800
	nmol/l	97.9	73.4	122	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	107	80.3	134	Diasorin Liaison XL
	nmol/l	100	75.0	125	Abbott Alinity i
	nmol/l	140	105	175	Siemens Atellica IM
	nmol/l	90.4	67.8	113	Roche Vitamin D Total II e801
nmol/l	85.9	64.4	107	Roche Vitamin D Total III	
ACTH	pmol/l	23.2	17.4	29.0	Siemens Immulite 2000/2500
	pg/ml	105	79.1	131	
	pmol/l	6.81	5.11	8.51	Roche Cobas 4000/E411
	pg/ml	31.0	23.2	38.8	
	pmol/l	6.95	5.21	8.69	Roche Cobas e601/602
	pg/ml	31.6	23.7	39.5	
	pmol/l	23.5	17.6	29.4	Siemens Immulite 1000
	pg/ml	107	80.0	134	
Aldosterone	pmol/l	713	535	891	Diasorin Liaison XL
	pg/ml	257	193	321	
Alphafoetoprotein	KIU/l = IU/ml	195	156	234	Siemens Centaur XP/XPT/Classic
	ng/ml	236	189	283	
	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	179	143	215	Roche Cobas e601/602
	ng/ml	217	173	261	
	KIU/l = IU/ml	192	154	230	Roche Cobas 4000/E411
	ng/ml	232	186	278	
KIU/l = IU/ml	199	159	239	Siemens Atellica IM	
	ng/ml	241	192	290	
KIU/l = IU/ml	174	139	209	Abbott Alinity i	
	ng/ml	211	168	254	

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	KIU/l = IU/ml	188	150	226	Roche Cobas e402/e801
	ng/ml	227	182	272	
Amikacin	µmol/l	24.1	19.3	28.9	Gravimetric
	µg/ml	14.1	11.3	16.9	
Androstenedione	nmol/l	34.9	26.2	43.6	Siemens Immulite 2000
	ng/ml	10.0	7.52	12.5	
Beta-2-microglobulin	µg/ml = mg/l	5.50	4.40	6.60	Roche Cobas 6000/8000
C-Peptide	nmol/l	2.140	1.610	2.680	Roche Cobas e601/602
	ng/ml	6.46	4.86	8.06	
	nmol/l	2.220	1.670	2.780	Roche Cobas e402/e801
	ng/ml	6.70	5.04	8.36	
Carbamazepine	µmol/l	72.3	57.8	86.8	Abbott Architect (CMIA)
	µg/ml	17.1	13.7	20.5	Roche Cobas 6000/8000
	µmol/l	69.2	55.4	83.0	
	µg/ml	16.4	13.1	19.7	
	µmol/l	72.2	57.8	86.6	
	µg/ml	17.1	13.7	20.5	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	56.3	45.0	67.6	BioMerieux Vidas
	ng/ml = µg/l	54.5	43.6	65.4	Vitros ECI
	ng/ml = µg/l	54.4	43.5	65.3	Beckman Access
	ng/ml = µg/l	59.5	47.6	71.4	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	62.7	50.2	75.2	Abbott Architect
	ng/ml = µg/l	50.5	40.4	60.6	Beckman DxI800
	ng/ml = µg/l	47.3	37.8	56.8	Roche Cobas e601/602
	ng/ml = µg/l	48.2	38.6	57.8	Roche Cobas 4000/E411
	ng/ml = µg/l	57.8	46.2	69.4	Siemens Atellica IM
	ng/ml = µg/l	48.6	38.9	58.3	Roche Cobas e402/e801
	ng/ml = µg/l	64.5	51.6	77.4	Abbott Alinity i
Cortisol	nmol/l	1204	903	1505	Siemens Centaur XP/XPT/Classic
	µg/dl	43.3	32.5	54.1	
	nmol/l	820	615	1025	Siemens Immulite 2000/2500
	µg/dl	29.5	22.1	36.9	
	nmol/l	884	663	1105	Vitros ECI
	µg/dl	31.8	23.9	39.7	
	nmol/l	913	685	1141	Abbott Architect
	µg/dl	32.9	24.7	41.1	
	nmol/l	971	728	1214	Beckman DxI800
	µg/dl	35.0	26.2	43.8	
	nmol/l	1073	805	1341	Roche Cobas e601/602
	µg/dl	38.6	29.0	48.2	
	nmol/l	1091	818	1364	Roche Cobas 4000/E411
	µg/dl	39.3	29.4	49.2	
nmol/l	1046	785	1308	Roche Cobas 4000/e411 Gen II	
µg/dl	37.7	28.3	47.1		
nmol/l	997	748	1246	Roche Cobas e601/602 Gen II	
µg/dl	35.9	26.9	44.9		

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Cortisol	nmol/l	1266	950	1583	Siemens Atellica IM
	µg/dl	45.6	34.2	57.0	
	nmol/l	974	731	1218	Roche Cobas e402/e801
	µg/dl	35.1	26.3	43.9	
	nmol/l	1019	764	1274	Roche Cobas e801 Gen II
	µg/dl	36.7	27.5	45.9	
DHEA-S	nmol/l	921	691	1151	Abbott Alinity i
	µg/dl	33.2	24.9	41.5	
	µmol/l	17.2	13.8	20.6	Siemens Immulite 2000/2500
	µmol/l	18.9	15.1	22.7	Abbott Architect
	µmol/l	14.7	11.8	17.6	Beckman DxI800
	µmol/l	24.8	19.8	29.8	Roche Cobas 4000/E411
Digoxin	µmol/l	23.5	18.8	28.2	Roche Cobas e601/602
	µmol/l	23.7	19.0	28.4	Roche Cobas e402/e801
	µmol/l	18.4	14.7	22.1	Abbott Alinity i
	nmol/l	4.04	3.23	4.85	Abbott Architect (CMIA)
	ng/ml	3.16	2.52	3.80	
	nmol/l	4.68	3.74	5.62	Roche Cobas e402/e801
Ethosuximide	ng/ml	3.66	2.92	4.40	
	nmol/l	5.12	4.10	6.14	Gravimetric
	ng/ml	4.00	3.20	4.80	
	µmol/l	493	394	592	Gravimetric
	µg/ml	69.9	55.9	83.9	
	Ferritin	ng/ml = µg/l	301	241	361
ng/ml = µg/l		194	155	233	Beckman Access
ng/ml = µg/l		171	137	205	Vitros ECI
ng/ml = µg/l		229	183	275	Siemens Centaur XP/XPT/Classic
ng/ml = µg/l		320	256	384	Abbott Architect
ng/ml = µg/l		283	226	340	Roche Modular E170 / Roche Cobas e601/602
ng/ml = µg/l		192	154	230	Beckman DxI800
ng/ml = µg/l		332	266	398	Abbott Alinity i
ng/ml = µg/l		218	174	262	Siemens Atellica IM
ng/ml = µg/l		277	222	332	Roche Cobas e402/e801
Folate	nmol/l	12.6	9.58	15.6	Siemens Immulite 2000
	ng/ml	5.56	4.22	6.90	
	nmol/l	10.9	8.28	13.5	Vitros ECI
	ng/ml	4.81	3.65	5.97	
	nmol/l	17.3	13.1	21.5	Abbott Architect
	ng/ml	7.63	5.78	9.48	
	nmol/l	37.8	28.7	46.9	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	16.7	12.7	20.7	
	nmol/l	19.9	15.1	24.7	Beckman DxI 600 / 800 - A98032
	ng/ml	8.78	6.66	10.9	
Folate	nmol/l	20.3	15.4	25.2	Roche Folate III - 07559992
	ng/ml	8.95	6.79	11.1	
	nmol/l	32.3	24.5	40.1	Siemens Atellica IM
	ng/ml	14.2	10.8	17.6	

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Folate	nmol/l	18.3	13.9	22.7	Abbott Alinity i
	ng/ml	8.07	6.13	10.0	
	nmol/l	20.3	15.4	25.2	Roche Folate 07027290 e801
	ng/ml	8.95	6.79	11.1	
Free T3	pmol/l	20.1	15.1	25.1	Beckman Access
	ng/dl	1.31	0.982	1.64	
	pg/ml	13.1	9.83	16.4	
	pmol/l	23.1	17.3	28.9	Siemens Centaur XP/XPT/Classic
	ng/dl	1.50	1.12	1.88	
	pg/ml	15.0	11.3	18.7	
	pmol/l	27.1	20.3	33.9	Abbott Architect, 2 point calibration
	ng/dl	1.76	1.32	2.20	
	pg/ml	17.6	13.2	22.0	
	pmol/l	17.5	13.1	21.9	Beckman Dxl800
	ng/dl	1.14	0.852	1.43	
	pg/ml	11.4	8.53	14.3	
	pmol/l	28.9	21.7	36.1	Roche Cobas 4000/E411
	ng/dl	1.88	1.41	2.35	
	pg/ml	18.8	14.1	23.5	
	pmol/l	29.1	21.8	36.4	Roche Cobas e601/602
	ng/dl	1.89	1.42	2.36	
	pg/ml	18.9	14.2	23.6	
	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	26.3	19.7	32.9	Abbott Architect, 6 point calibration	
ng/dl	1.71	1.28	2.14		
pg/ml	17.1	12.8	21.4		
pmol/l	29.0	21.8	36.3	Roche Cobas e402/e801	
ng/dl	1.89	1.42	2.36		
pg/ml	18.9	14.2	23.6		
pmol/l	27.7	20.8	34.6	Abbott Alinity, 6 point cal	
ng/dl	1.80	1.35	2.25		
pg/ml	18.0	13.5	22.5		
Free T4	pmol/l	45.3	34.0	56.6	Beckman Access
	ng/dl	3.53	2.65	4.41	
	pg/ml	35.3	26.5	44.1	
	pmol/l	89.9	67.4	112	Vitros ECI
	ng/dl	7.01	5.26	8.76	
	pg/ml	70.1	52.6	87.6	
	pmol/l	36.3	27.2	45.4	Siemens Centaur XP/XPT/Classic
	ng/dl	2.83	2.12	3.54	
	pg/ml	28.3	21.2	35.4	
	pmol/l	56.4	42.3	70.5	Siemens Immulite 2000/2500
	ng/dl	4.40	3.30	5.50	
	pg/ml	44.0	33.0	55.0	

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Free T4	pmol/l	37.1	27.8	46.4	Abbott Architect
	ng/dl	2.89	2.17	3.61	
	pg/ml	28.9	21.7	36.1	
	pmol/l	48.7	36.5	60.9	Beckman Dxl800
	ng/dl	3.80	2.85	4.75	
	pg/ml	38.0	28.5	47.5	
	pmol/l	53.6	40.2	67.0	Roche Cobas e601/602
	ng/dl	4.18	3.14	5.22	
	pg/ml	41.8	31.4	52.2	
	pmol/l	53.3	40.0	66.6	Roche Cobas 4000/E411
	ng/dl	4.16	3.12	5.20	
	pg/ml	41.6	31.2	52.0	
	pmol/l	38.1	28.6	47.6	Siemens Atellica IM
	ng/dl	2.97	2.23	3.71	
	pg/ml	29.7	22.3	37.1	
pmol/l	36.7	27.5	45.9	Abbott Alinity i	
ng/dl	2.86	2.15	3.57		
pg/ml	28.6	21.5	35.7		
pmol/l	55.7	41.8	69.6	Roche Cobas e402/e801	
ng/dl	4.34	3.26	5.42		
pg/ml	43.4	32.6	54.2		
FSH	mU/ml	74.0	59.2	88.8	BioMerieux Vidas
	mU/ml	49.1	39.3	58.9	Vitros ECi
	mU/ml	84.3	67.4	101	Siemens Centaur XP/XPT/Classic
	mU/ml	62.6	50.1	75.1	Siemens Immulite 2000/2500
	mU/ml	56.3	45.0	67.6	Abbott Architect
	mU/ml	67.5	54.0	81.0	Beckman Dxl800
	mU/ml	59.9	47.9	71.9	Roche Cobas 4000/E411
	mU/ml	59.2	47.4	71.0	Roche Cobas e601/602
	mU/ml	82.8	66.2	99.0	Siemens Atellica IM
	mU/ml	55.5	44.4	66.6	Abbott Alinity i
	mU/ml	58.0	46.4	69.6	Roche Cobas e402/e801
Gentamicin	µmol/l	11.7	9.36	14.0	Gravimetric
	µg/ml	5.59	4.47	6.71	
Growth Hormone (GH)	µU/ml	66.0	52.8	79.2	Siemens Immulite 2000/2500
	ng/ml	22.0	17.6	26.4	
	µU/ml	60.1	48.1	72.1	Roche Cobas e601/602
	ng/ml	20.0	16.0	24.0	
	µU/ml	54.7	43.8	65.6	Diasorin Liaison XL
	ng/ml	18.2	14.6	21.8	
Immunoglobulin E	KIU/l = IU/ml	452	362	542	BioMerieux Vidas
	KIU/l = IU/ml	533	426	640	Siemens Centaur XP/XPT/Classic
	KIU/l = IU/ml	461	369	553	Abbott Architect



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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin E	KIU/l = IU/ml	525	420	630	Roche Cobas 4000/E411
	KIU/l = IU/ml	504	403	605	Roche Cobas e601/602
	KIU/l = IU/ml	523	418	628	Roche Cobas e402/e801
Insulin	mU/l	6.56	4.92	8.20	Siemens Immulite 2000
	µU/ml	6.56	4.92	8.20	
	mU/l	23.8	17.9	29.8	Abbott Architect
	µU/ml	23.8	17.9	29.7	
	mU/l	30.0	22.5	37.5	Roche Cobas 4000/E411
	µU/ml	30.0	22.5	37.5	
	mU/l	29.9	22.4	37.4	Roche Cobas 6000/8000
	µU/ml	29.9	22.4	37.4	
	mU/l	25.4	19.1	31.8	Beckman Dxl 600/800
	µU/ml	25.4	19.1	31.7	
Luteinising Hormone (LH)	mU/ml	55.6	44.5	66.7	BioMerieux Vidas
	mU/ml	65.6	52.5	78.7	Vitros ECI
	mU/ml	52.5	42.0	63.0	Siemens Centaur XP/XPT/Classic
	mU/ml	72.5	58.0	87.0	Siemens Immulite 2000
	mU/ml	43.3	34.6	52.0	Abbott Architect
	mU/ml	42.6	34.1	51.1	Beckman Dxl800
	mU/ml	58.0	46.4	69.6	Roche Cobas 4000/E411
	mU/ml	57.4	45.9	68.9	Roche Cobas e601/602
	mU/ml	54.1	43.3	64.9	Siemens Atellica IM
	mU/ml	42.9	34.3	51.5	Abbott Alinity i
Oestradiol	mU/ml	60.1	48.1	72.1	Roche Cobas e402/e801
	pmol/l	4100	3280	4920	BioMerieux Vidas
	pg/ml	1115	892	1338	
	pmol/l	1771	1417	2125	Abbott Architect
	pg/ml	482	385	579	
	pmol/l	2263	1810	2716	Roche Cobas e601/602 (Estradiol III)
	pg/ml	616	492	740	
	pmol/l	2284	1827	2741	Roche Elecsys (Estradiol III)
	pg/ml	621	497	745	
	pmol/l	2253	1802	2704	Roche Cobas 4000/E411 (Estradiol III)
	pg/ml	613	490	736	
	pmol/l	2272	1818	2726	Beckman Dxl600/800 Sensitive B84493
	pg/ml	618	494	742	
	pmol/l	4097	3278	4916	Siemens Atellica IM
pg/ml	1114	892	1336		
pmol/l	1714	1371	2057	Abbott Alinity i	
pg/ml	466	373	559		
pmol/l	2273	1818	2728	Roche Cobas e801 (Estradiol III)	
pg/ml	618	494	742		
Paracetamol	mmol/l	0.460	0.368	0.552	Roche Cobas c501/502/503/701/702
	mg/l	69.6	55.7	83.5	

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Paracetamol	mmol/l	0.529	0.420	0.630	Gravimetric
	mg/l	80.0	63.5	95.3	
Phenobarbital	µmol/l	117	93.6	140	Siemens Immulite 2000/2500
	µg/ml	27.1	21.7	32.5	Beckman AU400/600/640/2700/5400
	µmol/l	113	90.4	136	
	µg/ml	26.2	21.0	31.4	Roche Cobas C303/501/502/503/701
	µmol/l	123	98.4	148	
	µg/ml	28.5	22.8	34.2	
Phenytoin	µmol/l	88.0	70.4	106	Abbott Architect
	µg/ml	22.2	17.8	26.6	Roche Cobas 6000/8000
	µmol/l	89.3	71.4	107	
	µg/ml	22.5	18.0	27.0	
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	128	102	154	BioMerieux Vidas
	ng/ml	40.1	31.9	48.3	Siemens Centaur XP/XPT/Classic
	nmol/l	78.5	62.8	94.2	
	ng/ml	24.6	19.7	29.5	Siemens Immulite 2000/2500
	nmol/l	78.2	62.6	93.8	
	ng/ml	24.5	19.6	29.4	Abbott Architect
	nmol/l	105	84.0	126	
	ng/ml	32.9	26.3	39.5	Beckman Dxl Prog DE Cal A80773
	nmol/l	78.9	63.1	94.7	
	ng/ml	24.7	19.8	29.6	Roche Cobas e601/602 (Prog. III)
	nmol/l	102	81.6	122	
	ng/ml	31.9	25.5	38.3	Roche Cobas 4000/e411 (Prog. III)
	nmol/l	105	84.0	126	
	ng/ml	32.9	26.3	39.5	Abbott Alinity i
nmol/l	96.9	77.5	116		
ng/ml	30.3	24.3	36.3	Siemens Atellica IM	
nmol/l	80.6	64.5	96.7		
ng/ml	25.2	20.2	30.2	Roche Cobas e801 (Prog. III)	
nmol/l	106	84.8	127		
ng/ml	33.2	26.5	39.9		
Prolactin	µU/ml	1027	822	1232	BioMerieux Vidas
	µU/ml	856	685	1027	Vitros ECI
	µU/ml	791	633	949	Siemens Centaur XP/XPT/Classic
	µU/ml	900	720	1080	Abbott Architect
	µU/ml	832	666	998	Beckman Dxl800
	µU/ml	1256	1005	1507	Roche Cobas 4000/E411
	µU/ml	1169	935	1403	Roche Cobas e601/602
	µU/ml	753	602	904	Siemens Atellica IM

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Prolactin	μU/ml	955	764	1146	Abbott Alinity i
	μU/ml	1146	917	1375	Roche Cobas e801 PRL II
PSA Free	ng/ml = μg/l	21.6	16.2	27.0	Abbott Architect
	ng/ml = μg/l	14.0	10.5	17.5	Beckman DXI standardised to Hybritech
	ng/ml = μg/l	16.8	12.6	21.0	Roche Cobas 4000/E411
	ng/ml = μg/l	16.3	12.2	20.4	Roche Cobas e601/602
	ng/ml = μg/l	21.6	16.2	27.0	Abbott Alinity i
PSA Total	ng/ml = μg/l	15.8	11.9	19.8	Roche Cobas e402/e801
	ng/ml = μg/l	26.1	19.6	32.6	Beckman Access standardised to Hybritech
	ng/ml = μg/l	19.7	14.8	24.6	Siemens Centaur XP/XPT/Classic
	ng/ml = μg/l	15.7	11.8	19.6	Abbott Architect
	ng/ml = μg/l	25.5	19.1	31.9	Beckman Dxl standardisd to Hybritech
	ng/ml = μg/l	19.3	14.5	24.1	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = μg/l	21.7	16.3	27.1	Roche Cobas 4000/E411
	ng/ml = μg/l	21.4	16.1	26.8	Roche Cobas e601/602
	ng/ml = μg/l	17.4	13.1	21.8	SNIBE Maglumi Analysers
	ng/ml = μg/l	21.2	15.9	26.5	Ortho Vitros 3600/5600/ECi PSA II
Salicylic Acid	mmol/l	21.8	16.4	27.3	Siemens Atellica IM
	mg/dl	16.4	12.3	20.5	Abbott Alinity i
SHBG	mmol/l	20.3	15.2	25.4	Roche Cobas e402/e801
	nmol/l	33.7	27.0	40.4	Siemens Immulite 2000/2500
	nmol/l	35.7	28.6	42.8	Abbott Architect
	nmol/l	31.8	25.4	38.2	Roche Cobas e801 - 413429
	nmol/l	32.7	26.2	39.2	Roche analysers - 413417/15
T Uptake	%U	34.8	27.8	41.8	Abbott Alinity i
Testosterone		TBD	TBD	TBD	Siemens Immulite 2000
	nmol/l	30.4	24.3	36.5	Siemens Immulite 2000/2500
	ng/ml	8.76	7.00	10.5	
	ng/dl	876	700	1052	
	nmol/l	26.4	21.1	31.7	Abbott Architect
	ng/ml	7.60	6.08	9.12	
	ng/dl	760	608	912	
	nmol/l	22.8	18.2	27.4	Beckman Dxl800
	ng/ml	6.57	5.24	7.90	
	ng/dl	657	524	790	
	nmol/l	25.4	20.3	30.5	Roche Cobas 4000/e411 Test II
	ng/ml	7.32	5.85	8.79	
	ng/dl	732	585	879	
nmol/l	26.3	21.0	31.6	Roche Cobas e601/602 Test II	
ng/ml	7.57	6.05	9.09		
ng/dl	757	605	909		
nmol/l	25.5	20.4	30.6	Abbott Architect 2nd Generation	
ng/ml	7.34	5.88	8.80		
ng/dl	734	588	880		

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods	
			low	high		
Testosterone	nmol/l	23.8	19.0	28.6	Siemens Centaur TST II	
	ng/ml	6.85	5.47	8.23		
	ng/dl	685	547	823		
	nmol/l	23.3	18.6	28.0	Siemens Atellica IM	
		ng/ml	6.71	5.36		8.06
		ng/dl	671	536		806
	nmol/l	25.5	20.4	30.6	Roche Cobas e801 Test II	
		ng/ml	7.34	5.88		8.80
		ng/dl	734	588		880
	nmol/l	26.2	21.0	31.4	Abbott Alinity i	
		ng/ml	7.55	6.05		9.05
		ng/dl	755	605		905
Theophylline	µmol/l	166	133	199	Gravimetric	
	µg/ml	29.9	24.0	35.9		
Thyroglobulin	ng/ml	32.8	24.6	41.0	Siemens Immulite 2000	
	ng/ml	60.3	45.2	75.4	Beckman Dxl800	
	ng/ml	72.8	54.6	91.0	Roche Cobas e601/602	
	ng/ml	78.8	59.1	98.5	Abbott Architect 2000i	
	ng/ml	75.0	56.3	93.8	Roche Cobas e601/602 Tg II	
	ng/ml	71.7	53.8	89.6	Roche Cobas e801 Tg II	
Thyroid Stimulating Hormone	µU/ml = mIU/l	17.6	14.1	21.1	Beckman Access hyperTSH 3rd Generation	
	µU/ml = mIU/l	19.9	15.9	23.9	Vitros ECi	
	µU/ml = mIU/l	19.4	15.5	23.3	Siemens Centaur XP/XPT/Classic	
	µU/ml = mIU/l	17.3	13.8	20.8	Siemens Immulite 2000/2500	
	µU/ml = mIU/l	14.6	11.7	17.5	Abbott Architect	
	µU/ml = mIU/l	17.5	14.0	21.0	Roche Cobas 4000/E411	
	µU/ml = mIU/l	17.3	13.8	20.8	Roche Cobas e601/602	
	µU/ml = mIU/l	19.7	15.8	23.6	Siemens Centaur XP/XPT/Classic TSH3-Ultra	
	µU/ml = mIU/l	16.1	12.9	19.3	Beckman Dxl 600/800 Access (3rd IS)	
	µU/ml = mIU/l	19.4	15.5	23.3	Siemens Atellica IM	
	µU/ml = mIU/l	14.6	11.7	17.5	Abbott Alinity i	
	µU/ml = mIU/l	16.5	13.2	19.8	Roche Cobas e402/e801	
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	673	538	808	BioMerieux Vidas	
	IU/ml	0.673	0.538	0.808		
	mU/ml=IU/l	628	502	754	Vitros ECi	
	IU/ml	0.628	0.502	0.754		
	mU/ml=IU/l	138	110	166	Siemens Centaur XP/XPT/Classic	
	IU/ml	0.138	0.110	0.166		
	mU/ml=IU/l	208	166	250	Abbott Architect	
	IU/ml	0.208	0.166	0.250		
	mU/ml=IU/l	323	258	388	Roche hCG+Beta	
	IU/ml	0.323	0.258	0.388		
	mU/ml=IU/l	189	151	227	Beckman Dxl Total BhCG (5th IS)	
	IU/ml	0.189	0.151	0.227		

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Range					
Analyte	unit	Target	low	high	methods
Total Beta hCG	mU/ml=IU/l	147	118	176	Siemens Atellica IM
	IU/ml	0.147	0.118	0.176	
	mU/ml=IU/l	208	166	250	Abbott Alinity i
	IU/ml	0.208	0.166	0.250	
	mU/ml=IU/l	315	252	378	
	IU/ml	0.315	0.252	0.378	Roche hCG+Beta e801
Total T3	nmol/l	7.09	5.32	8.86	Siemens Centaur XP/XPT/Classic
	ng/ml	4.62	3.46	5.78	
	ng/dl	462	346	578	
	nmol/l	5.31	3.98	6.64	Abbott Architect
	ng/ml	3.46	2.59	4.33	
	ng/dl	346	259	433	
	nmol/l	7.40	5.55	9.25	Vitros ECi
	ng/ml	4.82	3.61	6.03	
	ng/dl	482	361	603	
	nmol/l	6.40	4.80	8.00	Roche Cobas 4000/E411
	ng/ml	4.17	3.12	5.22	
	ng/dl	417	312	522	
	nmol/l	6.49	4.87	8.11	Roche Cobas e601/602
	ng/ml	4.22	3.17	5.27	
	ng/dl	422	317	527	
	nmol/l	5.28	3.96	6.60	Abbott Alinity i
	ng/ml	3.44	2.58	4.30	
	ng/dl	344	258	430	
	nmol/l	7.06	5.30	8.83	Siemens Atellica IM
	ng/ml	4.60	3.45	5.75	
	ng/dl	460	345	575	
nmol/l	6.73	5.05	8.41	Roche Cobas e402/e801	
ng/ml	4.38	3.29	5.47		
ng/dl	438	329	547		
Total T4	nmol/l	171	128	214	Vitros ECi
	µg/dl	13.3	9.98	16.6	
	ng/ml	133	100	166	
	nmol/l	176	132	220	Beckman Access
	µg/dl	13.7	10.3	17.1	
	ng/ml	137	103	171	
	nmol/l	185	139	231	Siemens Centaur XP/XPT/Classic
	µg/dl	14.4	10.8	18.0	
	ng/ml	144	108	180	
	nmol/l	161	121	201	Siemens Immulite 2000/2500
	µg/dl	12.6	9.44	15.8	
	ng/ml	126	94.4	158	
	nmol/l	169	127	211	Abbott Architect
	µg/dl	13.2	9.91	16.5	
	ng/ml	132	99.1	165	
nmol/l	152	114	190	Roche Cobas 4000/E411	
µg/dl	11.9	8.89	14.9		
ng/ml	119	88.9	149		

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Total T4	nmol/l	157	118	196	Roche Cobas e601/602
	µg/dl	12.2	9.20	15.2	
	ng/ml	122	92.0	152	
	nmol/l	169	127	211	Abbott Alinity i
	µg/dl	13.2	9.91	16.5	
	ng/ml	132	99.1	165	
	nmol/l	198	149	248	Siemens Atellica IM
	µg/dl	15.4	11.6	19.2	
	ng/ml	154	116	192	
	nmol/l	149	112	186	Roche Cobas e402/e801
	µg/dl	11.6	8.74	14.5	
	ng/ml	116	87.4	145	
Valproic Acid	µmol/l	982	786	1178	Abbott Architect (CMIA)
	µg/ml	142	113	171	
	µmol/l	1012	810	1214	Roche Cobas 6000/8000
	µg/ml	146	117	175	
	µmol/l	1116	893	1339	Gravimetric
	µg/ml	161	129	193	
Vancomycin	µmol/l	11.1	8.88	13.3	Abbott Architect (CMIA)
	µg/ml	16.5	13.2	19.8	
	µmol/l	9.52	7.62	11.4	Roche Cobas 6000/8000
	µg/ml	14.1	11.3	16.9	
	µmol/l	10.8	8.64	13.0	Gravimetric
	µg/ml	16.0	12.8	19.3	
Vitamin B12	pmol/l	506	405	607	Beckman Access
	pg/ml	686	549	823	
	pmol/l	655	524	786	Siemens Centaur XP/XPT/Classic
	pg/ml	888	710	1066	
	pmol/l	634	507	761	Siemens Immulite 2000
	pg/ml	859	687	1031	
	pmol/l	546	437	655	Abbott Architect
	pg/ml	740	592	888	
	pmol/l	583	466	700	Vitros ECI
	pg/ml	790	631	949	
	pmol/l	488	390	586	Beckman DxI800
	pg/ml	661	528	794	
	pmol/l	647	518	776	Roche Cobas 4000/e411 Gen II
	pg/ml	877	702	1052	
	pmol/l	619	495	743	Roche Cobas e601/602 Gen II
	pg/ml	839	671	1007	
	pmol/l	660	528	792	Siemens Atellica IM
	pg/ml	894	715	1073	
pmol/l	522	418	626	Abbott Alinity i	
pg/ml	707	566	848		

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

Cat. No. IA2640 / IA2633 Lot. No. 2349EC Size 12 x 5 ml / 4 x 4 ml Expiry 2026-11-28

### Range

Analyte	unit	Target	low	high	methods
Vitamin B12	pmol/l	592	474	710	Roche Cobas e801 Gen II
	pg/ml	802	642	962	

**ADDITIONAL VALUES FOR  
IMMUNOASSAY PREMIUM - LEVEL 3  
(IA PREMIUM 3)  
Cat No. IA2640 / IA2633  
Lot No. 2349EC  
GTIN: 05055273203868 / 05055273203837**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Insulin	mU/l	27.3	20.5 – 34.1	Beckman Access/LXi725
	µU/ml	27.3	20.5 – 34.1	

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

Rev. 09 Oct '24 me



Method		Immunoassay Premium - Level 3 (IA PREMIUM 3)					
Lot. No: 2349EC Cat. No: IA2640 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	nmol/l	152	114	190	19.0	38.0	Maccura i 1000 / i 800
Alpha-fetoprotein	ng/ml	243	194	292	24.5	49.0	Maccura i 1000 / i 800
	KIU/l = IU/ml	201	161	241	20.0	40.0	
C-Peptide	ng/ml	5.34	4.01	6.67	0.665	1.33	Maccura i 1000 / i 800
	nmol/l	1.77	1.33	2.21	0.220	0.440	
CEA	ng/ml = µg/l	49.5	39.6	59.4	4.95	9.90	Maccura i 1000 / i 800
Ferritin	ng/ml = µg/l	241	193	289	24.0	48.0	Maccura i 1000 / i 800
Folate	ng/ml	13.2	10.0	16.4	1.60	3.20	Maccura i 1000 / i 800
	nmol/l	29.9	22.7	37.1	3.60	7.20	
Free T3	ng/dl	1.51	1.13	1.89	0.190	0.380	Maccura i 1000 / i 800
	pg/ml	15.1	11.3	18.9	1.90	3.80	
	pmol/l	23.2	17.4	29.0	2.90	5.80	
Free T4	ng/dl	2.36	1.77	2.95	0.295	0.590	Maccura i 1000 / i 800
	pg/ml	23.6	17.7	29.5	2.95	5.90	
	pmol/l	30.2	22.7	37.7	3.75	7.50	
FSH	mU/ml	60.7	48.6	72.8	6.05	12.1	Maccura i 1000 / i 800
Growth Hormone (GH)	ng/ml	9.82	7.86	11.8	0.990	1.98	Maccura i 1000 / i 800
	µU/ml	29.5	23.6	35.4	2.95	5.90	
Insulin	mU/l	25.0	18.8	31.2	3.10	6.20	Maccura i 1000 / i 800
	µU/ml	25.0	18.8	31.2	3.10	6.20	
Luteinising Hormone (LH)	mU/ml	68.9	55.1	82.7	6.90	13.8	Maccura i 1000 / i 800
Oestradiol	pg/ml	607	486	728	60.5	121	Maccura i 1000 / i 800
	pmol/l	2230	1784	2676	223	446	
Progesterone	ng/ml	25.9	20.7	31.1	2.60	5.20	Maccura i 1000 / i 800
	nmol/l	82.8	66.2	99.4	8.30	16.6	
Prolactin	µIU/mL	1033	826	1240	104	207	Maccura i 1000 / i 800
PSA Free	ng/ml = µg/l	19.2	14.4	24.0	2.40	4.80	Maccura i 1000 / i 800
PSA Total	ng/ml = µg/l	16.1	12.1	20.1	2.00	4.00	Maccura i 1000 / i 800
Testosterone	ng/dl	790	632	948	79.0	158	Maccura i 1000 / i 800
	ng/ml	7.89	6.31	9.47	0.790	1.58	
	nmol/l	27.4	21.9	32.9	2.75	5.50	

Method		Immunoassay Premium - Level 3 (IA PREMIUM 3)					
Lot. No: 2349EC Cat. No: IA2640 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Thyroid Stimulating Hormone	µU/ml = mIU/l	20.2	16.2	24.2	2.00	4.00	Maccura i 1000 / i 800
Total Beta hCG	IU/ml	0.575	0.460	0.690	0.058	0.115	Maccura i 1000 / i 800
	mU/ml = IU/l	575	460	690	57.5	115	
Total T3	ng/dl	386	290	482	48.0	96.0	Maccura i 1000 / i 800
	ng/ml	3.87	2.90	4.84	0.485	0.970	
	nmol/l	5.95	4.46	7.44	0.745	1.49	
Total T4	ng/ml	119	89.3	149	15.0	30.0	Maccura i 1000 / i 800
	nmol/l	153	115	191	19.0	38.0	
	µg/dl	11.9	8.93	14.9	1.50	3.00	
Vitamin B12	pg/ml	786	629	943	78.5	157	Maccura i 1000 / i 800
	pmol/l	580	464	696	58.0	116	

## 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> 2349EC	<b>EXPIRY:</b> 2026-11-28	

### INTENDED USE

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

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

### SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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
----	-----

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. 2349EC		Size 12 x 5ml / 4 x 5ml		Expiry 2026-11-28	
Analyte	unit	Target	Range		methods		
			low	high			
Alphafoetoprotein	ng/ml	220	161	280	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		220	161	280	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
Carcinoembryonic Antigen (CEA)	ng/ml	39.6	28.9	50.2	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		39.6	28.9	50.2	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
Cortisol	µg/dL	35.0	23.8	46.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		35.0	23.8	46.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
C-Peptide	ng/mL	5.86	3.98	7.73	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		5.86	3.98	7.73	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
DHEA-S	µg/dL	698	475	922	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		698	475	922	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
Ferritin	ng/mL	275	201	349	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		273	199	346	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
FSH	mIU/mL	84.3	57.3	111	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101		
		84.3	57.3	111	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101		
		69.0	47.0	91.1	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401		
		69.0	47.0	91.1	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401		
Total Beta hCG	mIU/mL	175	119	231	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i		
		180	122	237	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i		
		801	545	1057	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i		
		827	563	1092	Wiener Lab CLIA Series & Mindray hCG2 CL 900i		
Insulin	µIU/mL	31.3	22.9	39.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		31.7	23.1	40.2	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
Luteinising Hormone (LH)	mIU/mL	64.4	47.0	81.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		66.4	48.5	84.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
Oestradiol	pg/mL	875	595	1156	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501		
		875	595	1156	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501		
		933	635	1232	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001		
		933	635	1232	Wiener Lab CLIA Series & Mindray CL Mindray CL 900i >= Lot 231001		
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		
		30.4	20.6	40.1	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i		
		30.4	20.6	40.1	Wiener Lab CLIA Series & Mindray PROG II CL 900i		
Prolactin	ng/mL	50.2	36.6	63.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		50.2	36.6	63.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
PSA Free	ng/mL	20.5	15.0	26.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		20.5	15.0	26.0	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		
PSA Total	ng/mL	21.6	15.8	27.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i		
		20.7	15.1	26.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i		

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

Cat. No. IA2640 / IA2633      Lot. No. 2349EC      Size 12 x 5ml / 4 x 5ml      Expiry 2026-11-28

Analyte	unit	Target	Range		methods
			low	high	
Free T3	pg/mL	14.5	10.6	18.4	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X
		14.7	10.7	18.7	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X
		13.8	10.1	17.5	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00
		13.8	10.1	17.5	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00
Total T3	ng/mL	3.32	2.42	4.21	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		3.32	2.42	4.21	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		3.17	2.32	4.03	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		3.17	2.32	4.03	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Free T4	ng/dL	3.66	2.67	4.65	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		3.66	2.67	4.65	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		4.83	3.53	6.13	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		4.83	3.53	6.13	Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T4	µg/dL	14.1	9.60	18.6	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		14.1	9.60	18.6	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		12.5	9.10	15.8	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		12.5	9.10	15.8	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00
Testosterone	ng/mL	11.1	7.55	14.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		11.1	7.55	14.7	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		10.4	7.08	13.7	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		10.4	7.08	13.7	Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		6.96	4.73	9.18	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		6.96	4.73	9.18	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Thyroid Stimulating Hormone	µIU/mL	21.4	15.7	27.2	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		21.2	15.5	26.9	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		17.5	12.8	22.2	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		17.5	12.8	22.2	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00
Vitamin B12	pg/mL	878	641	1115	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		874	638	1110	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i

Method		Immunoassay Premium - Level 3 (IA PREMIUM 3)					
Lot. No: 2349EC Cat. No: IA2640 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
1-25-(OH) <sub>2</sub> Vitamin D	pmol/l	367	257	477	55.0	110	DiaSorin Liaison XL
25-OH-Vitamin D	nmol/l	101	75.8	126	12.5	25.0	DiaSorin Liaison
	nmol/l	98.2	73.7	123	12.4	24.8	DiaSorin Liaison XL
Aldosterone	pg/ml	265	199	331	33.0	66.0	DiaSorin Liaison XL
	pmol/l	735	551	919	92.0	184	
Alpha-fetoprotein	ng/ml	240	192	288	24.0	48.0	DiaSorin Liaison
	KIU/l = IU/ml	198	158	238	20.0	40.0	
	ng/ml	242	194	290	24.0	48.0	DiaSorin Liaison XL
	KIU/l = IU/ml	200	160	240	20.0	40.0	
Androstenedione	ng/ml	6.20	4.65	7.75	0.775	1.55	DiaSorin Liaison XL
	nmol/l	21.6	16.2	27.0	2.70	5.40	
Beta-2-Microglobulin	µg/ml = mg/l	5.22	4.18	6.26	0.520	1.04	DiaSorin Liaison
	µg/ml = mg/l	5.00	4.00	6.00	0.500	1.00	DiaSorin Liaison XL
C-Peptide	ng/ml	7.10	5.33	8.87	0.885	1.77	DiaSorin Liaison
	nmol/l	2.35	1.76	2.94	0.295	0.590	
	ng/ml	7.25	5.44	9.06	0.905	1.81	DiaSorin Liaison XL
	nmol/l	2.40	1.80	3.00	0.300	0.600	
CEA	ng/ml = µg/l	55.6	44.5	66.7	5.55	11.1	DiaSorin Liaison XL
Cortisol	nmol/l	1403	1052	1754	176	351	DiaSorin Liaison XL
	µg/dl	50.5	37.9	63.1	6.30	12.6	
DHEA-S	µmol/l	15.3	12.2	18.4	1.55	3.10	DiaSorin Liaison XL
Ferritin	ng/ml = µg/l	298	238	358	30.0	60.0	DiaSorin Liaison XL
Folate	ng/ml	3.59	2.73	4.45	0.430	0.860	DiaSorin Liaison XL
	nmol/l	8.14	6.19	10.1	0.980	1.96	
Free T3	ng/dl	2.13	1.60	2.66	0.265	0.530	DiaSorin Liaison XL
	pg/ml	21.4	16.1	26.7	2.65	5.30	
	pmol/l	32.8	24.6	41.0	4.10	8.20	
Free T4	ng/dl	5.64	4.23	7.05	0.705	1.41	DiaSorin Liaison
	pg/ml	56.4	42.3	70.5	7.05	14.1	
	pmol/l	72.3	54.2	90.4	9.05	18.1	

Method		Immunoassay Premium - Level 3 (IA PREMIUM 3)					
Lot. No: 2349EC Cat. No: IA2640 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Free T4	ng/dl	6.15	4.61	7.69	0.770	1.54	DiaSorin Liaison XL
	pg/ml	61.5	46.1	76.9	7.70	15.4	
	pmol/l	78.8	59.1	98.5	9.85	19.7	
FSH	mU/ml	70.4	56.3	84.5	7.05	14.1	DiaSorin Liaison
	mU/ml	96.2	77.0	115	9.40	18.8	DiaSorin Liaison XL
Growth Hormone (GH)	ng/ml	18.0	14.4	21.6	1.80	3.60	DiaSorin Liaison XL
	µU/ml	54.2	43.4	65.0	5.40	10.8	
Insulin	mU/l	32.4	24.3	40.5	4.05	8.10	DiaSorin Liaison
	µU/ml	32.4	24.3	40.5	4.05	8.10	
	mU/l	33.1	24.8	41.4	4.15	8.30	DiaSorin Liaison XL
	µU/ml	33.1	24.8	41.4	4.15	8.30	
Luteinising Hormone (LH)	mU/ml	65.6	52.5	78.7	6.55	13.1	DiaSorin Liaison
	mU/ml	72.2	57.8	86.6	7.20	14.4	DiaSorin Liaison XL
Oestradiol	pg/ml	502	402	602	50.0	100	DiaSorin Liaison XL
	pmol/l	1847	1478	2216	185	369	
Progesterone	ng/ml	28.4	22.7	34.1	2.85	5.70	DiaSorin Liaison XL
	nmol/l	90.6	72.5	109	9.20	18.4	
Prolactin	µU/mL	1043	834	1252	105	209	DiaSorin Liaison
	µU/mL	1084	867	1301	109	217	DiaSorin Liaison XL
PSA Free	ng/ml = µg/l	14.6	11.0	18.2	1.80	3.60	DiaSorin Liaison XL
PSA Total	ng/ml = µg/l	18.4	13.8	23.0	2.30	4.60	DiaSorin Liaison
	ng/ml = µg/l	18.9	14.2	23.6	2.35	4.70	DiaSorin Liaison XL
Testosterone	ng/dl	386	309	463	38.5	77.0	DiaSorin Liaison XL
	ng/ml	3.86	3.09	4.63	0.385	0.770	
	nmol/l	13.4	10.7	16.1	1.35	2.70	
Thyroglobulin	ng/ml	78.0	58.5	97.5	9.75	19.5	DiaSorin Liaison XL
Thyroid Stimulating Hormone	µU/ml = mIU/l	29.2	23.4	35.0	2.90	5.80	DiaSorin Liaison
	µU/ml = mIU/l	29.8	23.8	35.8	3.00	6.00	DiaSorin Liaison XL
Total Beta hCG	IU/ml	0.209	0.167	0.251	0.021	0.042	DiaSorin Liaison
	mU/ml = IU/l	209	167	251	21.0	42.0	

Method		Immunoassay Premium - Level 3 (IA PREMIUM 3)					
Lot. No: 2349EC Cat. No: IA2640 Expiry: 2026-11-28							
Size: 12 x 5ml / 4 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Total Beta hCG	IU/ml	0.203	0.162	0.244	0.021	0.041	DiaSorin Liaison XL
	mIU/ml = IU/l	203	162	244	20.5	41.0	
Total T3	ng/dl	347	260	434	43.5	87.0	DiaSorin Liaison XL
	ng/ml	3.48	2.61	4.35	0.435	0.870	
	nmol/l	5.35	4.01	6.69	0.670	1.34	
Total T4	ng/ml	120	90.0	150	15.0	30.0	DiaSorin Liaison
	nmol/l	154	116	192	19.0	38.0	
	µg/dl	12.0	9.00	15.0	1.50	3.00	
	ng/ml	122	91.5	153	15.5	31.0	DiaSorin Liaison XL
	nmol/l	156	117	195	19.5	39.0	
	µg/dl	12.2	9.15	15.3	1.55	3.10	
Vitamin B12	pg/ml	789	631	947	79.0	158	DiaSorin Liaison XL
	pmol/l	582	466	698	58.0	116	



**ADDITIONAL VALUES FOR  
IMMUNOASSAY PREMIUM - LEVEL 3  
(IA PREMIUM 3)**

**Cat No. IA2640 / IA2633**

**Lot No. 2349EC**

**GTIN: 05055273203868 / 05055273203837**

COMPONENT	UNITS	TARGET	RANGE	METHOD
25-OH Vitamin D II	ng/ml	51.8	36.3 - 67.3	SNIBE Maglumi Analysers II
Alpha-fetoprotein	IU/ml	193	135 - 251	SNIBE Maglumi Analysers
Androstenedione	ng/ml	5.77	4.04 - 7.50	SNIBE Maglumi Analysers
Beta-2-microglobulin	µg/ml	5.06	3.54 - 6.58	SNIBE Maglumi Analysers
C-Peptide	ng/ml	7.47	5.23 - 9.71	SNIBE Maglumi Analysers
Carcinoembryonic Antigen (CEA)	ng/ml	46.6	32.6 - 60.6	SNIBE Maglumi Analysers
Cortisol	ng/ml	437	306 - 568	SNIBE Maglumi Analysers
DHEA-S	ug/dl	673	471 - 875	SNIBE Maglumi Analysers
Digoxin	ng/ml	3.79	2.65 - 4.93	SNIBE Maglumi Analysers
Ferritin	ng/ml	307	215 - 399	SNIBE Maglumi Analysers
Free T3	pg/ml	26.3	18.4 - 34.2	SNIBE Maglumi Analysers
Free T4	pg/ml	48.6	34.0 - 63.2	SNIBE Maglumi Analysers
FSH	mU/ml	72.0	50.4 - 93.6	SNIBE Maglumi Analysers
Growth Hormone (GH)	ng/ml	26.3	18.4 - 34.2	SNIBE Maglumi Analysers
Immunoglobulin E	IU/ml	437	306 - 568	SNIBE Maglumi Analysers
Insulin	uIU/ml	24.6	17.2 - 32.0	SNIBE Maglumi Analysers
Oestradiol	pg/ml	1263	884 - 1642	SNIBE Maglumi Analysers
Luteinising Hormone (LH)	mU/ml	65.3	45.7 - 84.9	SNIBE Maglumi Analysers
Prolactin	µU/ml	1000	700 - 1300	SNIBE Maglumi Analysers
PSA Free	ng/ml	15.3	10.7 - 19.9	SNIBE Maglumi Analysers
PSA Total	ng/ml	18.4	12.9 - 23.9	SNIBE Maglumi Analysers
Progesterone	ng/ml	25.0	17.5 - 32.5	SNIBE Maglumi Analysers
SHBG	nmol/l	42.7	29.9 - 55.5	SNIBE Maglumi Analysers

COMPONENT	UNITS	TARGET	RANGE	METHOD
Thyroid Stimulating Hormone	μU/ml	11.8	8.26 - 15.3	SNIBE Maglumi Analysers
Total Beta hCG	mIU/ml	598	419 - 777	SNIBE Maglumi Analysers
Total T3	ng/ml	3.42	2.39 - 4.45	SNIBE Maglumi Analysers
Total T4	ng/ml	137	95.9 - 178	SNIBE Maglumi Analysers
Testosterone	ng/ml	5.86	4.10 - 7.62	SNIBE Maglumi Analysers

EC	REP
----	-----

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

14 Jan '25 me