

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

CAT. NO.	IA3110	GTIN:	05055273207262	SIZE	12 x 5 ml
CAT. NO.	IA3112	GTIN:	05055273207286	SIZE	4 x 5 ml
LOT NO.	2107EC	EXPIRY:	2024-12-28		

INTENDED USE

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

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

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

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

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

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

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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 Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

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

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

EC	REP	Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland
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IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
17-OH-Progesterone	nmol/l	11.5	8.63	14.4	Immunotech RIA
	ng/ml	3.81	2.86	4.76	
	nmol/l	16.0	12.0	20.0	ELISA
	ng/ml	5.30	3.97	6.63	
	nmol/l	19.1	14.3	23.9	DRG ELISA
	ng/ml	6.32	4.73	7.91	
	nmol/l	15.6	11.7	19.5	DIAsource RIA
	ng/ml	5.16	3.87	6.45	
25-OH Vitamin D	nmol/l	17.6	13.2	22.0	DIAsource ELISA
	ng/ml	5.83	4.37	7.29	
	nmol/l	16.6	12.5	20.8	LC/MS
	ng/ml	5.49	4.14	6.84	
	nmol/l	69.6	52.2	87.0	Diasorin Liaison
	nmol/l	87.8	65.9	110	Siemens Centaur XP/XPT/Classic
	nmol/l	62.1	46.6	77.6	Roche Vitamin D Total
	nmol/l	62.1	46.6	77.6	Abbott Architect (3L52)
	nmol/l	80.3	60.2	100	Vitros ECI
	nmol/l	62.3	46.7	77.9	Tosoh Series
	nmol/l	75.5	56.6	94.4	BioMerieux Vidas
	nmol/l	52.6	39.5	65.8	Beckman Dxl 600/800
	nmol/l	66.0	49.5	82.5	Fujirebio Lumipulse G Series
	nmol/l	57.7	43.3	72.1	Beckman Access 25 OH Vitamin D Total
	nmol/l	57.2	42.9	71.5	LC/MS
	nmol/l	61.5	46.1	76.9	Abbott Architect (5P02)/Alinity (8P45)
	nmol/l	68.4	51.3	85.5	Diasorin Liaison XL
	nmol/l	65.4	49.1	81.8	Roche Vitamin D Total II
ACTH	nmol/l	64.3	48.2	80.4	Abbott Alinity i
	nmol/l	86.3	64.7	108	Siemens Atellica IM
	nmol/l	60.5	45.4	75.6	Roche Vitamin D Total II e801
	pmol/l	11.0	8.25	13.8	Siemens Immulite 2000/2500
	pg/ml	50.0	37.5	62.5	
	pmol/l	19.7	14.8	24.6	CIS IRMA
	pg/ml	89.5	67.3	112	
	pmol/l	10.6	7.95	13.3	Siemens Immulite 1000
Aldosterone	pg/ml	48.2	36.1	60.3	
	pmol/l	7.83	5.87	9.79	Roche Cobas e402/e801
	pg/ml	35.6	26.7	44.5	
	pmol/l	118	88.5	148	CIS RIA
	pg/ml	42.6	31.9	53.3	
	pmol/l	424	318	530	Immunotech RIA
	pg/ml	153	115	191	
	pmol/l	351	263	439	IDS iSYS
	pg/ml	127	94.9	159	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Aldosterone	pmol/l	339	254	424	Diasorin Liaison
	pg/ml	122	91.6	152	
	pmol/l	353	265	441	Diasorin Liaison XL
	pg/ml	127	95.6	158	
Alphafoetoprotein	KIU/l = IU/ml	42.6	34.1	51.1	Abbott AFP-EIA
	ng/ml	51.5	41.3	61.7	
	KIU/l = IU/ml	42.8	34.2	51.4	Abbott Architect
	ng/ml	51.8	41.4	62.2	
	KIU/l = IU/ml	44.3	35.4	53.2	BioMerieux Vidas
	ng/ml	53.6	42.8	64.4	
	KIU/l = IU/ml	48.5	38.8	58.2	Siemens Centaur XP/XPT/Classic
	ng/ml	58.7	46.9	70.5	
	KIU/l = IU/ml	44.0	35.2	52.8	Siemens Immulite 2000/2500
	ng/ml	53.2	42.6	63.8	
	KIU/l = IU/ml	46.3	37.0	55.6	Siemens Immulite 1000
	ng/ml	56.0	44.8	67.2	
	KIU/l = IU/ml	40.6	32.5	48.7	Beckman DxI800
	ng/ml	49.1	39.3	58.9	
	KIU/l = IU/ml	46.3	37.0	55.6	Roche Elecsys
	ng/ml	56.0	44.8	67.2	
	KIU/l = IU/ml	42.8	34.2	51.4	Diasorin Liaison
	ng/ml	51.8	41.4	62.2	
	KIU/l = IU/ml	42.8	34.2	51.4	Beckman Access
	ng/ml	51.8	41.4	62.2	
	KIU/l = IU/ml	42.0	33.6	50.4	Tosoh Series
	ng/ml	50.8	40.7	60.9	
	KIU/l = IU/ml	43.8	35.0	52.6	Vitros ECi
	ng/ml	45.6	36.5	54.7	
	KIU/l = IU/ml	47.6	38.1	57.1	Roche Cobas e601/602
	ng/ml	57.6	46.1	69.1	
	KIU/l = IU/ml	66.0	52.8	79.2	CIS IRMA
	ng/ml	79.9	63.9	95.9	
	KIU/l = IU/ml	48.6	38.9	58.3	Roche Cobas 4000/E411
	ng/ml	58.8	47.1	70.5	
	KIU/l = IU/ml	45.4	36.3	54.5	Fujirebio Lumipulse G Series
	ng/ml	54.9	43.9	65.9	
	KIU/l = IU/ml	46.1	36.9	55.3	Siemens Dimension
	ng/ml	55.8	44.6	67.0	
	KIU/l = IU/ml	49.6	39.7	59.5	Siemens Centaur CP
	ng/ml	60.0	48.0	72.0	
	KIU/l = IU/ml	48.9	39.1	58.7	Sysmex HISCL Series
	ng/ml	59.2	47.3	71.1	
	KIU/l = IU/ml	49.3	39.4	59.2	Diasorin Liaison XL
	ng/ml	59.7	47.7	71.7	
	KIU/l = IU/ml	48.2	38.6	57.8	Siemens Atellica IM
	ng/ml	58.3	46.7	69.9	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	42.7	34.2	51.2	Abbott Alinity i
	ng/ml	51.7	41.4	62.0	
	KIU/l = IU/ml	45.7	36.6	54.8	Roche Cobas e402/e801
	ng/ml	55.3	44.3	66.3	
	KIU/l = IU/ml	38.7	31.0	46.4	Tosoh AIA-CL Series
	ng/ml	46.8	37.5	56.1	
Amikacin	µmol/l	15.8	12.6	19.0	EMIT
	µg/ml	9.25	7.38	11.1	
	µmol/l	14.4	11.5	17.3	Roche Cobas 6000/8000
	µg/ml	8.43	6.73	10.1	
	µmol/l	14.8	11.8	17.8	Abbott Architect
	µg/ml	8.67	6.91	10.4	
	µmol/l	14.8	11.8	17.8	Thermo Scientific QMS Amikacin
	µg/ml	8.67	6.91	10.4	
Androstenedione	µmol/l	15.3	12.2	18.4	Abbott Alinity
	µg/ml	8.96	7.14	10.8	
	µmol/l	15.2	12.2	18.2	Gravimetric
	µg/ml	8.90	7.14	10.7	
	nmol/l	7.46	5.60	9.33	Beckman Coulter RIA
	ng/ml	2.14	1.61	2.67	
	nmol/l	17.5	13.1	21.9	Siemens Immulite 2000
	ng/ml	5.02	3.76	6.28	
Beta-2-microglobulin	nmol/l	7.56	5.67	9.45	LC/MS
	ng/ml	2.17	1.63	2.71	
	nmol/l	9.71	7.28	12.1	Diasorin Liaison XL
	ng/ml	2.79	2.09	3.49	
	µg/ml = mg/l	3.08	2.46	3.70	Abbott Architect
	µg/ml = mg/l	3.35	2.68	4.02	BioMerieux Vidas
	µg/ml = mg/l	3.01	2.41	3.61	Behring Nephelometer
	µg/ml = mg/l	2.92	2.34	3.50	Siemens Immulite 2000/2500
C-Peptide	µg/ml = mg/l	3.16	2.53	3.79	Tosoh Series
	µg/ml = mg/l	3.08	2.46	3.70	Roche Cobas 6000/8000
	µg/ml = mg/l	2.70	2.16	3.24	Diasorin Liaison XL
	µg/ml = mg/l	3.00	2.40	3.60	Siemens Atellica CH
	µg/ml = mg/l	3.11	2.49	3.73	Abbott Alinity
	nmol/l	1.960	1.470	2.450	Siemens Immulite 2000/2500
	ng/ml	5.92	4.44	7.40	
	nmol/l	2.060	1.550	2.580	Roche Elecsys
	ng/ml	6.22	4.68	7.76	
	nmol/l	2.040	1.530	2.550	Roche Cobas e601/602
	ng/ml	6.16	4.62	7.70	
	nmol/l	1.890	1.420	2.360	Siemens Immulite 1000
	ng/ml	5.71	4.29	7.13	
	nmol/l	2.020	1.520	2.530	Diasorin Liaison
	ng/ml	6.10	4.59	7.61	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	2.100	1.580	2.630	Roche Cobas 4000/E411
	ng/ml	6.34	4.77	7.91	
	nmol/l	1.880	1.410	2.350	Abbott Architect
	ng/ml	5.68	4.26	7.10	
	nmol/l	1.360	1.020	1.700	Siemens Centaur XP/XPT/Classic
	ng/ml	4.11	3.08	5.14	
	nmol/l	1.780	1.340	2.230	Tosoh Series
	ng/ml	5.37	4.05	6.69	
	nmol/l	2.140	1.610	2.680	Diasorin Liaison XL
	ng/ml	6.46	4.86	8.06	
	nmol/l	2.030	1.520	2.540	Roche Cobas e402/e801
	ng/ml	6.13	4.59	7.67	
	nmol/l	1.290	0.968	1.610	Siemens Atellica IM
	ng/ml	3.89	2.92	4.86	
	nmol/l	1.930	1.450	2.410	Vitros ECI
	ng/ml	5.83	4.38	7.28	
CA 15-3	nmol/l	1.260	0.945	1.580	Beckman Access
	ng/ml	3.80	2.85	4.75	
	nmol/l	1.840	1.380	2.300	Abbott Alinity i
	ng/ml	5.55	4.17	6.93	
	U/ml	56.6	45.3	67.9	Abbott Architect
	U/ml	38.4	30.7	46.1	BioMerieux Vidas
	U/ml	41.9	33.5	50.3	Siemens Centaur XP/XPT/Classic
	U/ml	46.4	37.1	55.7	Siemens Immulite 2000/2500
	U/ml	53.8	43.0	64.6	Siemens Immulite 1000
	U/ml	19.2	15.4	23.0	Beckman Dxl800
	U/ml	41.8	33.4	50.2	Roche Elecsys
	U/ml	40.8	32.6	49.0	Diasorin Liaison
	U/ml	19.2	15.4	23.0	Beckman Access
	U/ml	49.7	39.8	59.6	Tosoh Series
	U/ml	35.9	28.7	43.1	Vitros ECI
	U/ml	41.2	33.0	49.4	Roche Cobas e601/602
CA 19-9	U/ml	41.3	33.0	49.6	Roche Cobas 4000/E411
	U/ml	43.3	34.6	52.0	Diasorin Liaison XL
	U/ml	44.2	35.4	53.0	Siemens Atellica IM
	U/ml	38.9	31.1	46.7	Roche Cobas e402/e801
	U/ml	54.2	43.4	65.0	Abbott Alinity i
	U/ml	114	91.2	137	BioMerieux Vidas
	U/ml	158	126	190	Siemens Centaur XP/XPT/Classic
	U/ml	152	122	182	Siemens Immulite 2000/2500
	U/ml	152	122	182	Beckman Dxl800
	U/ml	73.0	58.4	87.6	Roche Elecsys
	U/ml	170	136	204	Beckman Access
	U/ml	59.9	47.9	71.9	Tosoh Series
	U/ml	151	121	181	Vitros ECI
	U/ml	222	178	266	Abbott Architect XR/XR2/XRL

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
CA 19-9	U/ml	73.6	58.9	88.3	Roche Cobas e601/602
	U/ml	75.7	60.6	90.8	Roche Cobas 4000/E411
	U/ml	154	123	185	Fujirebio Lumipulse G Series
	U/ml	97.9	78.3	117	Izotop RIA
	U/ml	129	103	155	Siemens Centaur CP
	U/ml	128	102	154	Diasorin Liaison XL
	U/ml	156	125	187	Siemens Atellica IM
	U/ml	74.8	59.8	89.8	Roche Cobas e402/e801
	U/ml	225	180	270	Abbott Alinity XR/XR2/XRL
CA125	U/ml	110	88.0	132	Abbott Architect
	U/ml	81.8	65.4	98.2	BioMerieux Vidas
	U/ml	92.9	74.3	111	Siemens Centaur XP/XPT/Classic OV Kit
	U/ml	96.1	76.9	115	Siemens Centaur XP/XPT/Classic CA125 II kit
	U/ml	80.0	64.0	96.0	Siemens Immulite 2000/2500
	U/ml	95.7	76.6	115	Siemens Immulite 1000
	U/ml	69.6	55.7	83.5	Beckman Dxl800
	U/ml	80.3	64.2	96.4	Roche Elecsys
	U/ml	71.1	56.9	85.3	Beckman Access
	U/ml	145	116	174	Tosoh Series
	U/ml	81.2	65.0	97.4	Vitros ECi
	U/ml	80.9	64.7	97.1	Roche Cobas 4000/E411
	U/ml	81.6	65.3	97.9	Roche Cobas e601/602
	U/ml	66.6	53.3	79.9	Fujirebio Lumipulse G Series
	U/ml	93.2	74.6	112	Siemens Centaur CP CA125 II kit
	U/ml	102	81.6	122	Diasorin Liaison XL
	U/ml	107	85.6	128	Siemens Atellica IM
	U/ml	78.2	62.6	93.8	Roche Cobas e402/e801
	U/ml	113	90.4	136	Abbott Alinity i
Carbamazepine	µmol/l	38.7	31.0	46.4	Abbott Architect (CMIA)
	µg/ml	9.15	7.33	11.0	
	µmol/l	42.8	34.2	51.4	Siemens Centaur XP/XPT/Classic
	µg/ml	10.1	8.08	12.1	
	µmol/l	34.5	27.6	41.4	Siemens Dimension
	µg/ml	8.16	6.52	9.80	
	µmol/l	32.5	26.0	39.0	Siemens Immulite 2000/2500
	µg/ml	7.68	6.15	9.21	
	µmol/l	38.0	30.4	45.6	Roche Integra
	µg/ml	8.98	7.19	10.8	
	µmol/l	38.3	30.6	46.0	Vitros
	µg/ml	9.05	7.23	10.9	
	µmol/l	38.7	31.0	46.4	Roche Cobas 6000/8000
	µg/ml	9.15	7.33	11.0	
	µmol/l	39.3	31.4	47.2	Beckman DxC
	µg/ml	9.29	7.42	11.2	
	µmol/l	39.7	31.8	47.6	Beckman AU400/600/640/2700/5400
	µg/ml	9.39	7.52	11.3	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Carbamazepine	µmol/l	31.9	25.5	38.3	Abbott Architect (PETINA)
	µg/ml	7.54	6.03	9.05	
	µmol/l	40.3	32.2	48.4	EMIT
	µg/ml	9.53	7.61	11.5	
	µmol/l	36.3	29.0	43.6	Siemens Atellica CH
	µg/ml	8.58	6.86	10.3	
	µmol/l	30.1	24.1	36.1	Abbott Alinity (PETINA)
	µg/ml	7.12	5.70	8.54	
	µmol/l	38.5	30.8	46.2	Gravimetric
	µg/ml	9.10	7.28	10.9	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	33.6	26.9	40.3	Abbott Architect
	ng/ml = µg/l	24.9	19.9	29.9	BioMerieux Vidas
	ng/ml = µg/l	26.5	21.2	31.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	26.2	21.0	31.4	CIS RIA Coated tube
	ng/ml = µg/l	36.4	29.1	43.7	Siemens Immulite 2000/2500
	ng/ml = µg/l	37.9	30.3	45.5	Siemens Immulite 1000
	ng/ml = µg/l	24.4	19.5	29.3	Beckman Dxl800
	ng/ml = µg/l	24.7	19.8	29.6	Roche Elecsys
	ng/ml = µg/l	22.5	18.0	27.0	Diasorin Liaison
	ng/ml = µg/l	25.8	20.6	31.0	Beckman Access
	ng/ml = µg/l	38.6	30.9	46.3	Tosoh Series
	ng/ml = µg/l	29.0	23.2	34.8	Vitros ECi
	ng/ml = µg/l	24.4	19.5	29.3	Roche Cobas e601/602
	ng/ml = µg/l	24.8	19.8	29.8	Roche Cobas 4000/E411
	ng/ml = µg/l	34.0	27.2	40.8	Fujirebio Lumipulse G Series
	ng/ml = µg/l	32.5	26.0	39.0	Boditech Med Inc i-CHROMA
	ng/ml = µg/l	26.6	21.3	31.9	Siemens Centaur CP
	ng/ml = µg/l	24.9	19.9	29.9	Diasorin Liaison XL
	ng/ml = µg/l	26.0	20.8	31.2	Siemens Atellica IM
	ng/ml = µg/l	24.4	19.5	29.3	Roche Cobas e402/e801
	ng/ml = µg/l	32.9	26.3	39.5	Abbott Alinity i
Cortisol	nmol/l	559	419	699	Abbott Architect
	µg/dl	20.1	15.1	25.1	
	nmol/l	579	434	724	BioMerieux Vidas
	µg/dl	20.8	15.6	26.0	
	nmol/l	734	551	918	Siemens Centaur XP/XPT/Classic
	µg/dl	26.4	19.8	33.0	
	nmol/l	514	386	643	CIS RIA
	µg/dl	18.5	13.9	23.1	
	nmol/l	583	437	729	Siemens Immulite 2000/2500
	µg/dl	21.0	15.7	26.3	
	nmol/l	669	502	836	Siemens Immulite 1000
	µg/dl	24.1	18.1	30.1	
	nmol/l	626	470	783	Beckman Dxl800
	µg/dl	22.5	16.9	28.1	
	nmol/l	618	464	773	Roche Elecsys
	µg/dl	22.2	16.7	27.7	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Cortisol	nmol/l	678	509	848	Beckman Access
	µg/dl	24.4	18.3	30.5	
	nmol/l	677	508	846	Tosoh Series
	µg/dl	24.4	18.3	30.5	
	nmol/l	586	440	733	Vitros ECI
	µg/dl	21.1	15.8	26.4	
	nmol/l	631	473	789	Roche Cobas e601/602
	µg/dl	22.7	17.0	28.4	
	nmol/l	663	497	829	Roche Cobas 4000/E411
	µg/dl	23.9	17.9	29.9	
	nmol/l	787	590	984	Siemens Centaur CP
	µg/dl	28.3	21.2	35.4	
	nmol/l	636	477	795	Roche Cobas 4000/e411 Gen II
	µg/dl	22.9	17.2	28.6	
	nmol/l	627	470	784	Roche Cobas e601/602 Gen II
	µg/dl	22.6	16.9	28.3	
	nmol/l	646	485	808	Roche Elecsys Gen II
	µg/dl	23.3	17.5	29.1	
	nmol/l	594	446	743	Diasorin Liaison XL
	µg/dl	21.4	16.1	26.7	
DHEA-S	nmol/l	760	570	950	Siemens Atellica IM
	µg/dl	27.4	20.5	34.3	
	nmol/l	627	470	784	Roche Cobas e402/e801
	µg/dl	22.6	16.9	28.3	
	nmol/l	690	518	863	Tosoh AIA-CL Series
	µg/dl	24.8	18.6	31.0	
	nmol/l	556	417	695	Abbott Alinity i
	µg/dl	20.0	15.0	25.0	
	µmol/l	13.5	10.8	16.2	Abbott Architect
	µmol/l	11.9	9.52	14.3	Siemens Immulite 2000/2500
	µmol/l	10.6	8.48	12.7	Siemens Immulite 1000
	µmol/l	11.5	9.20	13.8	Beckman Dxl800
	µmol/l	18.8	15.0	22.6	Roche Elecsys
	µmol/l	12.3	9.84	14.8	Beckman Access
Digoxin	µmol/l	10.9	8.72	13.1	Siemens Centaur XP/XPT/Classic
	µmol/l	16.9	13.5	20.3	Roche Cobas 4000/E411
	µmol/l	16.7	13.4	20.0	Roche Cobas e601/602
	µmol/l	10.0	8.00	12.0	Diasorin Liaison XL
	µmol/l	11.2	8.96	13.4	Siemens Atellica IM
	µmol/l	15.9	12.7	19.1	Roche Cobas e402/e801
	µmol/l	13.7	11.0	16.4	Abbott Alinity i
	nmol/l	2.38	1.90	2.86	Abbott Architect (CMIA)
	ng/ml	1.86	1.48	2.24	
	nmol/l	2.60	2.08	3.12	BioMerieux Vidas
	ng/ml	2.03	1.62	2.44	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Digoxin	nmol/l	3.13	2.50	3.76	Siemens Centaur XP/XPT/Classic
	ng/ml	2.44	1.95	2.93	
	nmol/l	2.78	2.22	3.34	Siemens Dimension
	ng/ml	2.17	1.73	2.61	
	nmol/l	2.91	2.33	3.49	Siemens Immulite 2000/2500
	ng/ml	2.27	1.82	2.72	
	nmol/l	2.81	2.25	3.37	Beckman Dxl800
	ng/ml	2.19	1.76	2.62	
	nmol/l	2.57	2.06	3.08	Roche Integra
	ng/ml	2.01	1.61	2.41	
	nmol/l	2.81	2.25	3.37	Roche Cobas e601/602
	ng/ml	2.19	1.76	2.62	
	nmol/l	2.87	2.30	3.44	Beckman AU400/600/640/2700/5400
	ng/ml	2.24	1.80	2.68	
	nmol/l	2.84	2.27	3.41	Roche Cobas 4000/E411
	ng/ml	2.22	1.77	2.67	
	nmol/l	2.53	2.02	3.04	Abbott Architect (PETINA)
	ng/ml	1.98	1.58	2.38	
	nmol/l	2.75	2.20	3.30	Roche Cobas e402/e801
	ng/ml	2.15	1.72	2.58	
	nmol/l	3.15	2.52	3.78	Siemens Atellica IM
	ng/ml	2.46	1.97	2.95	
	nmol/l	2.84	2.27	3.41	Siemens Atellica CH
	ng/ml	2.22	1.77	2.67	
	nmol/l	2.54	2.03	3.05	Abbott Alinity (CMIA)
	ng/ml	1.98	1.59	2.37	
	nmol/l	2.69	2.15	3.23	Abbott Alinity (PETINA)
	ng/ml	2.10	1.68	2.52	
	nmol/l	3.07	2.46	3.68	Gravimetric
	ng/ml	2.40	1.92	2.87	
	nmol/l	2.75	2.20	3.30	Roche Cobas C303/501/502/503/701
	ng/ml	2.15	1.72	2.58	
Ethosuximide	μmol/l	360	288	432	Gravimetric
	μg/ml	51.0	40.8	61.3	
Ferritin	ng/ml = μg/l	93.2	74.6	112	Abbott Architect
	ng/ml = μg/l	67.0	53.6	80.4	BioMerieux Vidas
	ng/ml = μg/l	64.7	51.8	77.6	Siemens Centaur XP/XPT/Classic
	ng/ml = μg/l	87.2	69.8	105	Siemens Dimension
	ng/ml = μg/l	75.7	60.6	90.8	Siemens Immulite 2000/2500
	ng/ml = μg/l	66.0	52.8	79.2	Siemens Immulite 1000
	ng/ml = μg/l	58.9	47.1	70.7	Beckman Dxl800
	ng/ml = μg/l	91.9	73.5	110	Roche Elecsys/Cobas e411
	ng/ml = μg/l	74.6	59.7	89.5	Diasorin Liaison
	ng/ml = μg/l	91.0	72.8	109	Roche Modular E170 / Roche Cobas e601/602
	ng/ml = μg/l	60.1	48.1	72.1	Beckman Access
	ng/ml = μg/l	59.4	47.5	71.3	Tosoh Series

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	54.2	43.4	65.0	Vitros ECI
	ng/ml = µg/l	88.5	70.8	106	Roche Cobas 4000/c311
	ng/ml = µg/l	72.8	58.2	87.4	Beckman AU400/600/640/2700/5400
	ng/ml = µg/l	91.1	72.9	109	Roche Cobas c501/502/503/701/702
	ng/ml = µg/l	66.2	53.0	79.4	Siemens Centaur CP
	ng/ml = µg/l	87.6	70.1	105	Diasorin Liaison XL
	ng/ml = µg/l	95.1	76.1	114	Abbott Alinity i
	ng/ml = µg/l	60.5	48.4	72.6	Siemens Atellica IM
	ng/ml = µg/l	91.2	73.0	109	Roche Cobas e402/e801
Folate	nmol/l	9.89	7.52	12.3	Abbott Architect
	ng/ml	4.36	3.32	5.40	
	nmol/l	22.5	17.1	27.9	Siemens Centaur XP/XPT/Classic (enhanced kit)
	ng/ml	9.92	7.54	12.3	
	nmol/l	8.44	6.41	10.5	Siemens Immulite 2000
	ng/ml	3.72	2.83	4.61	
	nmol/l	11.5	8.74	14.3	Beckman Dxl 600 / 800 - A14208
	ng/ml	5.07	3.85	6.29	
	nmol/l	11.8	8.97	14.6	Beckman Access
	ng/ml	5.20	3.96	6.44	
	nmol/l	7.68	5.84	9.52	Vitros ECI
	ng/ml	3.39	2.58	4.20	
	nmol/l	6.76	5.14	8.38	Siemens Dimension
	ng/ml	2.98	2.27	3.69	
	nmol/l	11.9	9.04	14.8	Beckman Dxl 600 / 800 - A98032
	ng/ml	5.25	3.99	6.51	
	nmol/l	26.5	20.1	32.9	Siemens Centaur CP (enhanced kit)
	ng/ml	11.7	8.86	14.5	
	nmol/l	10.8	8.21	13.4	Roche Folate III - 04476433
	ng/ml	4.76	3.62	5.90	
	nmol/l	10.8	8.21	13.4	Roche Elecsys Folate
	ng/ml	4.76	3.62	5.90	
	nmol/l	11.1	8.44	13.8	Roche Folate III - 07559992
	ng/ml	4.90	3.72	6.08	
	nmol/l	19.9	15.1	24.7	Siemens Atellica IM
	ng/ml	8.78	6.66	10.9	
	nmol/l	10.7	8.13	13.3	Abbott Alinity i
	ng/ml	4.72	3.59	5.85	
	nmol/l	11.6	8.82	14.4	Roche Folate 07027290 e801
	ng/ml	5.12	3.89	6.35	
Free T3	pmol/l	10.6	7.95	13.3	Abbott Architect, 2 point calibration
	ng/dl	0.689	0.517	0.861	
	pg/ml	6.90	5.18	8.62	
	pmol/l	11.6	8.70	14.5	BioMerieux Vidas
	ng/dl	0.754	0.566	0.942	
	pg/ml	7.55	5.66	9.44	
	pmol/l	11.8	8.85	14.8	Siemens Centaur XP/XPT/Classic
	ng/dl	0.767	0.575	0.959	
	pg/ml	7.68	5.76	9.60	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Free T3	pmol/l	8.47	6.35	10.6	Siemens Immulite 2000/2500
	ng/dl	0.551	0.413	0.689	
	pg/ml	5.51	4.13	6.89	
	pmol/l	9.21	6.91	11.5	Siemens Immulite 1000
	ng/dl	0.599	0.449	0.749	
	pg/ml	6.00	4.50	7.50	
	pmol/l	8.46	6.35	10.6	Beckman Dxl800
	ng/dl	0.550	0.413	0.687	
	pg/ml	5.51	4.13	6.89	
	pmol/l	13.7	10.3	17.1	Roche Elecsys
	ng/dl	0.891	0.670	1.11	
	pg/ml	8.92	6.71	11.1	
	pmol/l	14.6	11.0	18.3	Diasorin Liaison
	ng/dl	0.949	0.715	1.18	
	pg/ml	9.50	7.16	11.8	
	pmol/l	9.44	7.08	11.8	Beckman Access
	ng/dl	0.614	0.460	0.768	
	pg/ml	6.15	4.61	7.69	
	pmol/l	15.6	11.7	19.5	Tosoh Series
	ng/dl	1.01	0.761	1.26	
	pg/ml	10.2	7.62	12.8	
	pmol/l	28.4	21.3	35.5	Vitros ECI
	ng/dl	1.85	1.38	2.32	
	pg/ml	18.5	13.9	23.1	
	pmol/l	13.5	10.1	16.9	Roche Cobas 4000/E411
	ng/dl	0.878	0.657	1.10	
	pg/ml	8.79	6.58	11.0	
	pmol/l	13.6	10.2	17.0	Roche Cobas e601/602
	ng/dl	0.884	0.663	1.11	
	pg/ml	8.85	6.64	11.1	
	pmol/l	13.9	10.4	17.4	Fujirebio Lumipulse G Series
	ng/dl	0.904	0.676	1.13	
	pg/ml	9.05	6.77	11.3	
	pmol/l	12.0	9.00	15.0	Siemens Centaur CP
	ng/dl	0.780	0.585	0.975	
	pg/ml	7.81	5.86	9.76	
	pmol/l	14.0	10.5	17.5	Sysmex HISCL Series
	ng/dl	0.910	0.683	1.14	
	pg/ml	9.11	6.84	11.4	
	pmol/l	15.5	11.6	19.4	Diasorin Liaison XL
	ng/dl	1.01	0.754	1.27	
	pg/ml	10.1	7.55	12.7	
	pmol/l	12.5	9.38	15.6	Siemens Atellica IM
	ng/dl	0.813	0.610	1.02	
	pg/ml	8.14	6.11	10.2	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Free T3	pmol/l	11.1	8.33	13.9	Abbott Alinity, 2 point cal
	ng/dl	0.722	0.541	0.903	
	pg/ml	7.23	5.42	9.04	
	pmol/l	10.7	8.03	13.4	Abbott Architect, 6 point calibration
	ng/dl	0.696	0.522	0.870	
	pg/ml	6.97	5.23	8.71	
	pmol/l	13.6	10.2	17.0	Roche Cobas e402/e801
	ng/dl	0.884	0.663	1.11	
	pg/ml	8.85	6.64	11.1	
	pmol/l	12.5	9.38	15.6	Tosoh AIA-CL Series
	ng/dl	0.813	0.610	1.02	
	pg/ml	8.14	6.11	10.2	
Free T4	pmol/l	11.1	8.33	13.9	Abbott Alinity, 6 point cal
	ng/dl	0.722	0.541	0.903	
	pg/ml	7.23	5.42	9.04	
	pmol/l	21.6	16.2	27.0	Abbott Architect
	ng/dl	1.68	1.26	2.10	
	pg/ml	16.8	12.6	21.0	
	pmol/l	22.6	17.0	28.3	Siemens Centaur XP/XPT/Classic
	ng/dl	1.76	1.33	2.19	
	pg/ml	17.6	13.3	21.9	
	pmol/l	30.1	22.6	37.6	CIS RIA Coated tube
	ng/dl	2.35	1.76	2.94	
	pg/ml	23.5	17.6	29.4	
	pmol/l	32.2	24.2	40.3	Siemens Immulite 2000/2500
	ng/dl	2.51	1.89	3.13	
	pg/ml	25.1	18.9	31.3	
	pmol/l	33.1	24.8	41.4	Siemens Immulite 1000
	ng/dl	2.58	1.93	3.23	
	pg/ml	25.8	19.3	32.3	
	pmol/l	23.9	17.9	29.9	Beckman Dxl800
	ng/dl	1.86	1.40	2.32	
	pg/ml	18.6	14.0	23.2	
	pmol/l	28.8	21.6	36.0	Roche Elecsys
	ng/dl	2.25	1.68	2.82	
	pg/ml	22.5	16.8	28.2	
	pmol/l	33.0	24.8	41.3	Diasorin Liaison
	ng/dl	2.57	1.93	3.21	
	pg/ml	25.7	19.3	32.1	
	pmol/l	24.8	18.6	31.0	Beckman Access
	ng/dl	1.93	1.45	2.41	
	pg/ml	19.3	14.5	24.1	
	pmol/l	30.5	22.9	38.1	Tosoh Series
	ng/dl	2.38	1.79	2.97	
	pg/ml	23.8	17.9	29.7	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Free T4	pmol/l	63.5	47.6	79.4	Vitros ECI
	ng/dl	4.95	3.71	6.19	
	pg/ml	49.5	37.1	61.9	
	pmol/l	29.3	22.0	36.6	BioMerieux Vidas
	ng/dl	2.29	1.72	2.86	
	pg/ml	22.9	17.2	28.6	
	pmol/l	29.1	21.8	36.4	Roche Cobas e601/602
	ng/dl	2.27	1.70	2.84	
	pg/ml	22.7	17.0	28.4	
	pmol/l	21.5	16.1	26.9	Immunotech IRMA
	ng/dl	1.68	1.26	2.10	
	pg/ml	16.8	12.6	21.0	
	pmol/l	29.0	21.8	36.3	Roche Cobas 4000/E411
	ng/dl	2.26	1.70	2.82	
	pg/ml	22.6	17.0	28.2	
	pmol/l	30.1	22.6	37.6	Biomerieux Vidas FT4N Kit
	ng/dl	2.35	1.76	2.94	
	pg/ml	23.5	17.6	29.4	
	pmol/l	23.1	17.3	28.9	Fujirebio Lumipulse G Series
	ng/dl	1.80	1.35	2.25	
	pg/ml	18.0	13.5	22.5	
	pmol/l	24.4	18.3	30.5	Siemens Dimension Exl LOCI
	ng/dl	1.90	1.43	2.37	
	pg/ml	19.0	14.3	23.7	
	pmol/l	23.0	17.3	28.8	Siemens Centaur CP
	ng/dl	1.79	1.35	2.23	
	pg/ml	17.9	13.5	22.3	
	pmol/l	30.6	23.0	38.3	Sysmex HISCL Series
	ng/dl	2.39	1.79	2.99	
	pg/ml	23.9	17.9	29.9	
	pmol/l	35.2	26.4	44.0	Diasorin Liaison XL
	ng/dl	2.75	2.06	3.44	
	pg/ml	27.5	20.6	34.4	
	pmol/l	23.1	17.3	28.9	Siemens Atellica IM
	ng/dl	1.80	1.35	2.25	
	pg/ml	18.0	13.5	22.5	
	pmol/l	20.8	15.6	26.0	Abbott Alinity i
	ng/dl	1.62	1.22	2.02	
	pg/ml	16.2	12.2	20.2	
	pmol/l	29.2	21.9	36.5	Roche Cobas e402/e801
	ng/dl	2.28	1.71	2.85	
	pg/ml	22.8	17.1	28.5	
	pmol/l	29.2	21.9	36.5	Tosoh AIA-CL Series
	ng/dl	2.28	1.71	2.85	
	pg/ml	22.8	17.1	28.5	
FSH	mU/ml	24.1	19.3	28.9	Abbott Architect

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
FSH	mU/ml	28.8	23.0	34.6	BioMerieux Vidas
	mU/ml	30.3	24.2	36.4	Siemens Centaur XP/XPT/Classic
	mU/ml	25.7	20.6	30.8	Siemens Immulite 2000/2500
	mU/ml	26.7	21.4	32.0	Siemens Immulite 1000
	mU/ml	28.6	22.9	34.3	Beckman Dxl800
	mU/ml	26.3	21.0	31.6	Roche/BM Elecsys
	mU/ml	27.9	22.3	33.5	Beckman Access
	mU/ml	29.2	23.4	35.0	Tosoh Series
	mU/ml	20.0	16.0	24.0	Vitros ECI
	mU/ml	27.2	21.8	32.6	Roche Cobas 4000/E411
	mU/ml	25.0	20.0	30.0	Roche Cobas e601/602
	mU/ml	23.2	18.6	27.8	Fujirebio Lumipulse G Series
	mU/ml	29.1	23.3	34.9	Siemens Centaur CP
	mU/ml	37.0	29.6	44.4	Diasorin Liaison XL
	mU/ml	30.0	24.0	36.0	Siemens Atellica IM
	mU/ml	24.7	19.8	29.6	Abbott Alinity i
	mU/ml	25.4	20.3	30.5	Roche Cobas e402/e801
Gentamicin	µmol/l	7.85	6.28	9.42	Roche Integra
	µg/ml	3.75	3.00	4.50	
	µmol/l	8.70	6.96	10.4	Siemens Centaur XP/XPT/Classic
	µg/ml	4.16	3.33	4.99	
	µmol/l	8.54	6.83	10.2	Abbott Architect (CMIA)
	µg/ml	4.08	3.26	4.90	
	µmol/l	8.67	6.94	10.4	Siemens Dimension Vista
	µg/ml	4.14	3.32	4.96	
	µmol/l	6.20	4.96	7.44	Roche Cobas 6000/8000 Online KIMS
	µg/ml	2.96	2.37	3.55	
	µmol/l	8.15	6.52	9.78	Roche Cobas 6000/8000 CEDIA
	µg/ml	3.90	3.12	4.68	
	µmol/l	8.26	6.61	9.91	Abbott Architect (PETINA)
	µg/ml	3.95	3.16	4.74	
	µmol/l	9.85	7.88	11.8	EMIT
	µg/ml	4.71	3.77	5.65	
	µmol/l	8.09	6.47	9.71	Siemens Atellica CH
	µg/ml	3.87	3.09	4.65	
	µmol/l	8.83	7.06	10.6	Abbott Alinity (PETINA)
	µg/ml	4.22	3.37	5.07	
Growth Hormone (GH)	µU/ml	18.3	14.6	22.0	Siemens Immulite 2000/2500
	ng/ml	6.09	4.86	7.32	
	µU/ml	16.5	13.2	19.8	Siemens Immulite 1000
	ng/ml	5.49	4.40	6.58	
	µU/ml	13.5	10.8	16.2	Beckman Dxl800
	ng/ml	4.50	3.60	5.40	
	µU/ml	14.6	11.7	17.5	Beckman Access
	ng/ml	4.86	3.90	5.82	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Growth Hormone (GH)	µU/ml	18.0	14.4	21.6	Tosoh Series
	ng/ml	5.99	4.80	7.18	
	µU/ml	14.5	11.6	17.4	Diasorin Liaison
	ng/ml	4.83	3.86	5.80	
	µU/ml	16.2	13.0	19.4	Roche Cobas 4000/E411
	ng/ml	5.39	4.33	6.45	
	µU/ml	16.4	13.1	19.7	Roche Cobas e601/602
	ng/ml	5.46	4.36	6.56	
	µU/ml	14.2	11.4	17.0	Diasorin Liaison XL
	ng/ml	4.73	3.80	5.66	
	µU/ml	16.4	13.1	19.7	Roche Cobas e402/e801
	ng/ml	5.46	4.36	6.56	
Immunoglobulin E	µU/ml	15.7	12.6	18.8	Tosoh AIA-CL Series
	ng/ml	5.23	4.20	6.26	
	KIU/I = IU/ml	107	85.6	128	Abbott Architect
	KIU/I = IU/ml	119	95.2	143	BioMerieux Vidas
	KIU/I = IU/ml	128	102	154	Siemens Centaur XP/XPT/Classic
	KIU/I = IU/ml	131	105	157	Siemens Immulite 2000/2500
	KIU/I = IU/ml	130	104	156	Siemens Immulite 1000
	KIU/I = IU/ml	140	112	168	Roche Elecsys
	KIU/I = IU/ml	122	97.6	146	Pharmacia Unicap
	KIU/I = IU/ml	116	92.8	139	Tosoh Series
	KIU/I = IU/ml	142	114	170	Roche Cobas 4000/E411
	KIU/I = IU/ml	138	110	166	Roche Cobas e601/602
	KIU/I = IU/ml	123	98.4	148	Siemens Centaur CP
	KIU/I = IU/ml	155	124	186	Agappe Mispa i2
	KIU/I = IU/ml	131	105	157	Siemens Atellica IM
	KIU/I = IU/ml	141	113	169	Roche Cobas e402/e801
Insulin	KIU/I = IU/ml	108	86.4	130	Abbott Alinity
	mU/I	12.2	9.15	15.3	Siemens Centaur XP/XPT/Classic
	µU/ml	12.2	9.15	15.3	
	mU/I	5.11	3.83	6.39	Siemens Immulite 1000
	µU/ml	5.11	3.83	6.39	
	mU/I	5.12	3.84	6.40	Siemens Immulite 2000
	µU/ml	5.12	3.84	6.40	
	mU/I	14.0	10.5	17.5	Roche Elecsys
	µU/ml	14.0	10.5	17.5	
	mU/I	10.7	8.03	13.4	Beckman Access
	µU/ml	10.7	8.03	13.4	
	mU/I	11.1	8.33	13.9	Abbott Architect
	µU/ml	11.1	8.33	13.9	
	mU/I	16.5	12.4	20.6	Tosoh Series
	µU/ml	16.5	12.4	20.6	
	mU/I	14.1	10.6	17.6	Roche Cobas 4000/E411
	µU/ml	14.1	10.6	17.6	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Insulin	mU/l	10.2	7.65	12.8	Beckman Dxl 600/800
	µU/ml	10.2	7.65	12.8	
	mU/l	15.0	11.3	18.8	Diasorin Liaison
	µU/ml	15.0	11.3	18.7	
	mU/l	13.9	10.4	17.4	Roche Cobas 6000/8000
	µU/ml	13.9	10.4	17.4	
	mU/l	12.7	9.53	15.9	Fujirebio Lumipulse G Series
	µU/ml	12.7	9.53	15.9	
	mU/l	15.8	11.9	19.8	Diasorin Liaison XL
	µU/ml	15.8	11.9	19.7	
	mU/l	12.3	9.23	15.4	Siemens Atellica IM
	µU/ml	12.3	9.23	15.4	
	mU/l	9.99	7.49	12.5	Abbott Alinity i
	µU/ml	9.99	7.49	12.5	
	mU/l	17.4	13.1	21.8	Tosoh AIA-CL Series
	µU/ml	17.4	13.1	21.7	
	mU/l	10.9	8.18	13.6	Vitros ECI
	µU/ml	10.9	8.18	13.6	
Luteinising Hormone (LH)	mU/ml	25.2	20.2	30.2	Abbott Architect
	mU/ml	28.7	23.0	34.4	BioMerieux Vidas
	mU/ml	31.7	25.4	38.0	Siemens Centaur XP/XPT/Classic
	mU/ml	43.6	34.9	52.3	Siemens Immulite 2000
	mU/ml	47.7	38.2	57.2	Siemens Immulite 1000
	mU/ml	26.2	21.0	31.4	Beckman Dxl800
	mU/ml	34.1	27.3	40.9	Roche Elecsys
	mU/ml	37.8	30.2	45.4	Diasorin Liaison
	mU/ml	27.1	21.7	32.5	Beckman Access
	mU/ml	28.5	22.8	34.2	Tosoh Series
	mU/ml	41.5	33.2	49.8	Vitros ECI
	mU/ml	34.8	27.8	41.8	Roche Cobas 4000/E411
	mU/ml	34.5	27.6	41.4	Roche Cobas e601/602
	mU/ml	28.5	22.8	34.2	Fujirebio Lumipulse G Series
	mU/ml	31.9	25.5	38.3	Siemens Centaur CP
	mU/ml	39.6	31.7	47.5	Diasorin Liaison XL
	mU/ml	32.2	25.8	38.6	Siemens Atellica IM
	mU/ml	24.7	19.8	29.6	Abbott Alinity i
	mU/ml	34.6	27.7	41.5	Roche Cobas e402/e801
Oestradiol	pmol/l	672	538	806	Abbott Architect
	pg/ml	183	146	220	
	pmol/l	1346	1077	1615	BioMerieux Vidas
	pg/ml	366	293	439	
	pmol/l	958	766	1150	Siemens Centaur XP/XPT/Classic
	pg/ml	261	208	314	
	pmol/l	984	787	1181	Siemens Immulite 2000/2500
	pg/ml	268	214	322	
	pmol/l	967	774	1160	Siemens Immulite 1000
	pg/ml	263	211	315	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Oestradiol	pmol/l	682	546	818	Beckman Dxl800
	pg/ml	186	149	223	
	pmol/l	704	563	845	Roche Elecsys (Estradiol II)
	pg/ml	191	153	229	
	pmol/l	808	646	970	Beckman Access
	pg/ml	220	176	264	
	pmol/l	800	640	960	Tosoh (E2)
	pg/ml	218	174	262	
	pmol/l	1095	876	1314	Vitros ECi
	pg/ml	298	238	358	
	pmol/l	602	482	722	Diasorin Liaison
	pg/ml	164	131	197	
	pmol/l	721	577	865	Roche Cobas e601/602 (Estradiol II)
	pg/ml	196	157	235	
	pmol/l	741	593	889	Roche Cobas 4000/E411 (Estradiol II)
	pg/ml	202	161	243	
	pmol/l	964	771	1157	Siemens Centaur XP/XPT/Classic Enhanced (eE2)
	pg/ml	262	210	314	
	pmol/l	989	791	1187	Siemens Centaur XP/XPT/Classic E26 III
	pg/ml	269	215	323	
	pmol/l	720	576	864	Tosoh (iE2-hsE2)
	pg/ml	196	157	235	
	pmol/l	987	790	1184	Siemens Centaur CP
	pg/ml	268	215	321	
	pmol/l	970	776	1164	Siemens Centaur CP Enhanced (eE2)
	pg/ml	264	211	317	
	pmol/l	735	588	882	Roche Cobas e601/602 (Estradiol III)
	pg/ml	200	160	240	
	pmol/l	731	585	877	Roche Elecsys (Estradiol III)
	pg/ml	199	159	239	
	pmol/l	728	582	874	Roche Cobas 4000/E411 (Estradiol III)
	pg/ml	198	158	238	
	pmol/l	551	441	661	Diasorin Liaison XL
	pg/ml	150	120	180	
	pmol/l	761	609	913	Beckman Access / Access 2 Sensitive B84493
	pg/ml	207	166	248	
	pmol/l	682	546	818	Beckman Dxl600/800 Sensitive B84493
	pg/ml	186	149	223	
	pmol/l	1005	804	1206	Siemens Atellica IM
	pg/ml	273	219	327	
	pmol/l	664	531	797	Abbott Alinity i
	pg/ml	181	144	218	
	pmol/l	727	582	872	Roche Cobas e801 (Estradiol III)
	pg/ml	198	158	238	
	pmol/l	823	658	988	Tosoh AIA-CL Series
	pg/ml	224	179	269	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Paracetamol	mmol/l	0.336	0.269	0.403	Abbott Architect
	mg/l	50.8	40.7	60.9	
	mmol/l	0.320	0.256	0.384	Roche Cobas c501/502/503/701/702
	mg/l	48.4	38.7	58.1	
	mmol/l	0.339	0.271	0.407	Beckman AU Instruments
	mg/l	51.3	41.0	61.6	
	mmol/l	0.334	0.267	0.401	Abbott Alinity
	mg/l	50.5	40.4	60.6	
Phenobarbital	mmol/l	0.348	0.280	0.420	Gravimetric
	mg/l	52.7	42.4	63.5	
	µmol/l	79.6	63.7	95.5	Abbott Architect (CMIA)
	µg/ml	18.5	14.8	22.2	
	µmol/l	71.2	57.0	85.4	Roche Cobas e601/602/801
	µg/ml	16.5	13.2	19.8	
	µmol/l	80.0	64.0	96.0	Siemens Immulite 2000/2500
	µg/ml	18.6	14.8	22.4	
	µmol/l	72.4	57.9	86.9	Beckman AU400/600/640/2700/5400
	µg/ml	16.8	13.4	20.2	
	µmol/l	108	86.4	130	Siemens Centaur XP/XPT/Classic
	µg/ml	25.1	20.0	30.2	
	µmol/l	78.6	62.9	94.3	Roche Integra
	µg/ml	18.2	14.6	21.8	
	µmol/l	73.6	58.9	88.3	Roche Cobas C303/501/502/503/701
	µg/ml	17.1	13.7	20.5	
Phenytoin	µmol/l	74.1	59.3	88.9	Abbott Architect (PETINA)
	µg/ml	17.2	13.8	20.6	
	µmol/l	81.9	65.5	98.3	Siemens Atellica CH
	µg/ml	19.0	15.2	22.8	
	µmol/l	67.5	54.0	81.0	Abbott Alinity (PETINA)
	µg/ml	15.7	12.5	18.9	
	µmol/l	77.6	62.1	93.1	Gravimetric
	µg/ml	18.0	14.4	21.6	
	µmol/l	67.3	53.8	80.8	Abbott Architect
	µg/ml	17.0	13.6	20.4	
	µmol/l	77.7	62.2	93.2	Siemens Centaur XP/XPT/Classic
	µg/ml	19.6	15.7	23.5	
	µmol/l	74.7	59.8	89.6	Siemens Dimension
	µg/ml	18.9	15.1	22.7	
	µmol/l	65.7	52.6	78.8	Siemens Immulite 2000/2500
	µg/ml	16.6	13.3	19.9	
	µmol/l	66.9	53.5	80.3	Roche Integra
	µg/ml	16.9	13.5	20.3	
	µmol/l	66.6	53.3	79.9	Roche Cobas 6000/8000
	µg/ml	16.8	13.5	20.1	
	µmol/l	66.6	53.3	79.9	Beckman DxC
	µg/ml	16.8	13.5	20.1	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Phenytoin	µmol/l	70.4	56.3	84.5	Beckman AU Instruments
	µg/ml	17.8	14.2	21.4	
	µmol/l	63.0	50.4	75.6	EMIT
	µg/ml	15.9	12.7	19.1	
	µmol/l	73.8	59.0	88.6	Siemens Atellica CH
	µg/ml	18.6	14.9	22.3	
	µmol/l	69.4	55.5	83.3	Abbott Alinity
	µg/ml	17.5	14.0	21.0	
	µmol/l	71.3	57.0	85.6	Gravimetric
	µg/ml	18.0	14.4	21.6	
Primidone	µmol/l	22.5	18.0	27.0	Gravimetric
	µg/ml	4.91	3.93	5.89	
Progesterone	nmol/l	28.4	22.7	34.1	Abbott Architect
	ng/ml	8.89	7.11	10.7	
	nmol/l	40.8	32.6	49.0	BioMerieux Vidas
	ng/ml	12.8	10.2	15.4	
	nmol/l	24.3	19.4	29.2	Siemens Centaur XP/XPT/Classic
	ng/ml	7.61	6.07	9.15	
	nmol/l	25.9	20.7	31.1	Siemens Immulite 2000/2500
	ng/ml	8.11	6.48	9.74	
	nmol/l	30.0	24.0	36.0	Siemens Immulite 1000
	ng/ml	9.39	7.51	11.3	
	nmol/l	30.3	24.2	36.4	Beckman Dxl Prog Cal 33555
	ng/ml	9.48	7.57	11.4	
	nmol/l	31.6	25.3	37.9	Roche Elecsys (Prog. II)
	ng/ml	9.89	7.92	11.9	
	nmol/l	31.7	25.4	38.0	Beckman Access Prog Cal 33555
	ng/ml	9.92	7.95	11.9	
	nmol/l	36.8	29.4	44.2	Tosoh Series
	ng/ml	11.5	9.20	13.8	
	nmol/l	36.1	28.9	43.3	Vitros Eci
	ng/ml	11.3	9.05	13.6	
	nmol/l	32.1	25.7	38.5	Roche Cobas 4000/e411 (Prog. II)
	ng/ml	10.0	8.04	12.0	
	nmol/l	33.1	26.5	39.7	Roche Cobas e601/602 (Prog. II)
	ng/ml	10.4	8.29	12.5	
	nmol/l	29.2	23.4	35.0	Diasorin Liaison
	ng/ml	9.14	7.32	11.0	
	nmol/l	25.9	20.7	31.1	Beckman Dxl Prog DE Cal A80773
	ng/ml	8.11	6.48	9.74	
	nmol/l	29.6	23.7	35.5	Beckman Access Prog DE Cal A80773
	ng/ml	9.26	7.42	11.1	
	nmol/l	23.7	19.0	28.4	Siemens Centaur CP
	ng/ml	7.42	5.95	8.89	
	nmol/l	33.0	26.4	39.6	Roche Cobas e601/602 (Prog. III)
	ng/ml	10.3	8.26	12.3	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Progesterone	nmol/l	32.2	25.8	38.6	Roche Elecsys (Prog. III)
	ng/ml	10.1	8.08	12.1	
	nmol/l	32.6	26.1	39.1	Roche Cobas 4000/e411 (Prog. III)
	ng/ml	10.2	8.17	12.2	
	nmol/l	27.8	22.2	33.4	Diasorin Liaison XL
	ng/ml	8.70	6.95	10.5	
	nmol/l	27.2	21.8	32.6	Abbott Alinity i
	ng/ml	8.51	6.82	10.2	
	nmol/l	33.0	26.4	39.6	Roche Cobas e801 (Prog. III)
	ng/ml	10.3	8.26	12.3	
Prolactin	nmol/l	36.3	29.0	43.6	Tosoh AIA-CL Series
	ng/ml	11.4	9.08	13.7	
	nmol/l	24.9	19.9	29.9	Siemens Atellica IM
	ng/ml	7.79	6.23	9.36	
	µU/ml	675	540	810	Abbott Architect
	µU/ml	784	627	941	BioMerieux Vidas
	µU/ml	550	440	660	Siemens Centaur XP/XPT/Classic
	µU/ml	591	473	709	Siemens Immulite 2000/2500
	µU/ml	674	539	809	Siemens Immulite 1000
	µU/ml	559	447	671	Beckman Dxl800
	µU/ml	635	508	762	Roche Elecsys
	µU/ml	635	508	762	Diasorin Liaison
	µU/ml	589	471	707	Beckman Access
	µU/ml	643	514	772	Tosoh Series
	µU/ml	582	466	698	Vitros ECI
	µU/ml	620	496	744	Roche Elecsys/E170/Cobas 6000/8000 PRLII
	µU/ml	675	540	810	Immunotech IRMA
	µU/ml	646	517	775	Roche Cobas 4000/E411
	µU/ml	618	494	742	Roche Cobas e601/602
	µU/ml	745	596	894	Fujirebio Lumipulse G Series
PSA Free	µU/ml	543	434	652	Siemens Centaur CP
	µU/ml	713	570	856	Diasorin Liaison XL
	µU/ml	551	441	661	Siemens Atellica IM
	µU/ml	700	560	840	Abbott Alinity i
	µU/ml	614	491	737	Roche Cobas e801 PRL II
	ng/ml = µg/l	11.8	8.85	14.8	Abbott Architect
	ng/ml = µg/l	12.1	9.08	15.1	BioMerieux Vidas
	ng/ml = µg/l	9.69	7.27	12.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	10.6	7.95	13.3	Siemens Immulite 2000/2500
	ng/ml = µg/l	11.0	8.25	13.8	Siemens Immulite 1000
	ng/ml = µg/l	10.3	7.73	12.9	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	7.56	5.67	9.45	Roche Elecsys
	ng/ml = µg/l	9.23	6.92	11.5	Diasorin Liaison
	ng/ml = µg/l	10.3	7.73	12.9	Beckman Access standardised to Hybritech
	ng/ml = µg/l	7.58	5.69	9.48	Tosoh Series

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
PSA Free	ng/ml = µg/l	7.56	5.67	9.45	Roche Cobas 4000/E411
	ng/ml = µg/l	7.46	5.60	9.33	Roche Cobas e601/602
	ng/ml = µg/l	9.37	7.03	11.7	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	10.2	7.65	12.8	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	6.78	5.09	8.48	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	8.61	6.46	10.8	Fujirebio Lumipulse G Series
	ng/ml = µg/l	8.46	6.35	10.6	Diasorin Liaison XL
	ng/ml = µg/l	10.1	7.58	12.6	Siemens Atellica IM
	ng/ml = µg/l	11.4	8.55	14.3	Abbott Alinity i
	ng/ml = µg/l	7.24	5.43	9.05	Roche Cobas e402/e801
PSA Total	ng/ml = µg/l	7.52	5.64	9.40	Abbott Architect
	ng/ml = µg/l	10.8	8.10	13.5	BioMerieux Vidas
	ng/ml = µg/l	10.7	8.03	13.4	bioMerieux VIDAS TPSA
	ng/ml = µg/l	9.46	7.10	11.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	10.9	8.18	13.6	Siemens Immulite 2000/2500 1st generation
	ng/ml = µg/l	10.9	8.18	13.6	Siemens Immulite 2000/2500 3rd generation
	ng/ml = µg/l	11.7	8.78	14.6	Siemens Immulite 1000 1st generation
	ng/ml = µg/l	9.48	7.11	11.9	Beckman Dxl standardised to Hybritech
	ng/ml = µg/l	7.93	5.95	9.91	Beckman Dxl800 standardised to WHO IRP96/670
	ng/ml = µg/l	9.71	7.28	12.1	Roche Elecsys
	ng/ml = µg/l	9.06	6.80	11.3	Diasorin Liaison
	ng/ml = µg/l	9.77	7.33	12.2	Beckman Access standardised to Hybritech
	ng/ml = µg/l	9.51	7.13	11.9	Beckman Access standardised to WHO IRP96/670
	ng/ml = µg/l	7.69	5.77	9.61	Tosoh Series
	ng/ml = µg/l	9.89	7.42	12.4	Vitros ECI
	ng/ml = µg/l	11.1	8.33	13.9	CIS RIA Coated tube
	ng/ml = µg/l	9.92	7.44	12.4	Roche Cobas 4000/E411
	ng/ml = µg/l	9.68	7.26	12.1	Roche Cobas e601/602
	ng/ml = µg/l	18.2	13.7	22.8	Monobind Inc. ELISA / CLIA
	ng/ml = µg/l	7.46	5.60	9.33	Fujirebio Lumipulse G Series
	ng/ml = µg/l	9.82	7.37	12.3	Ortho Vitros 3600/5600/ECi PSA II
	ng/ml = µg/l	8.96	6.72	11.2	Siemens Centaur CP
	ng/ml = µg/l	9.59	7.19	12.0	Diasorin Liaison XL
	ng/ml = µg/l	10.1	7.58	12.6	Siemens Atellica IM
	ng/ml = µg/l	7.58	5.69	9.48	Abbott Alinity i
	ng/ml = µg/l	9.36	7.02	11.7	Roche Cobas e402/e801
Salicylic Acid	mmol/l	1.15	0.920	1.38	Abbott Architect
	mg/dl	15.9	12.7	19.1	
	mmol/l	1.16	0.928	1.39	Roche Cobas c501/502/503
	mg/dl	16.0	12.8	19.2	
	mmol/l	1.20	0.960	1.44	EMIT
	mg/dl	16.6	13.3	19.9	
	mmol/l	1.22	0.980	1.46	Gravimetric
SHBG	nmol/l	39.2	31.4	47.0	Siemens Immulite 1000
	nmol/l	39.4	31.5	47.3	Siemens Immulite 2000/2500

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
SHBG	nmol/l	41.8	33.4	50.2	Abbott Architect
	nmol/l	43.6	34.9	52.3	Beckman Access
	nmol/l	40.2	32.2	48.2	Beckman Dxl800
	nmol/l	38.5	30.8	46.2	Siemens Atellica IM
	nmol/l	39.0	31.2	46.8	Roche analysers - 413417/15
	nmol/l	37.2	29.8	44.6	Roche Cobas e801 - 413429
	nmol/l	40.9	32.7	49.1	Abbott Alinity i
T Uptake	%U	33.6	27.6	39.6	Siemens Immulite 2000
Testosterone	nmol/l	12.3	9.84	14.8	Abbott Architect
	ng/ml	3.54	2.83	4.25	
	ng/dl	354	283	425	
	nmol/l	11.0	8.80	13.2	BioMerieux Vidas
	ng/ml	3.17	2.53	3.81	
	ng/dl	317	253	381	
	nmol/l	12.8	10.2	15.4	Siemens Centaur XP/XPT/Classic
	ng/ml	3.69	2.94	4.44	
	ng/dl	369	294	444	
	nmol/l	11.7	9.36	14.0	CIS RIA Coated tube
	ng/ml	3.37	2.70	4.04	
	ng/dl	337	270	404	
	nmol/l	14.1	11.3	16.9	Siemens Immulite 2000/2500
	ng/ml	4.06	3.25	4.87	
	ng/dl	406	325	487	
	nmol/l	11.0	8.80	13.2	Beckman Dxl800
	ng/ml	3.17	2.53	3.81	
	ng/dl	317	253	381	
	nmol/l	12.0	9.60	14.4	Beckman Access
	ng/ml	3.46	2.76	4.16	
	ng/dl	346	276	416	
	nmol/l	14.6	11.7	17.5	Tosoh Series
	ng/ml	4.20	3.37	5.03	
	ng/dl	420	337	503	
	nmol/l	15.9	12.7	19.1	Vitros ECI
	ng/ml	4.58	3.66	5.50	
	ng/dl	458	366	550	
	nmol/l	12.9	10.3	15.5	Roche Cobas e601/602 Test II
	ng/ml	3.72	2.97	4.47	
	ng/dl	372	297	447	
	nmol/l	12.6	10.1	15.1	Roche Elecsys Test II
	ng/ml	3.63	2.91	4.35	
	ng/dl	363	291	435	
	nmol/l	12.7	10.2	15.2	Roche Cobas 4000/e411 Test II
	ng/ml	3.66	2.94	4.38	
	ng/dl	366	294	438	
	nmol/l	12.3	9.84	14.8	Abbott Architect 2nd Generation
	ng/ml	3.54	2.83	4.25	
	ng/dl	354	283	425	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Testosterone	nmol/l	11.2	8.96	13.4	Siemens Centaur CP
	ng/ml	3.23	2.58	3.88	
	ng/dl	323	258	388	
	nmol/l	11.3	9.04	13.6	BioMerieux Vidas Testosterone II
	ng/ml	3.25	2.60	3.90	
	ng/dl	325	260	390	
	nmol/l	12.5	10.0	15.0	Siemens Centaur TST II
	ng/ml	3.60	2.88	4.32	
	ng/dl	360	288	432	
	nmol/l	7.11	5.69	8.53	Diasorin Liaison XL
	ng/ml	2.05	1.64	2.46	
	ng/dl	205	164	246	
	nmol/l	12.2	9.76	14.6	Siemens Atellica IM
	ng/ml	3.51	2.81	4.21	
	ng/dl	351	281	421	
	nmol/l	12.7	10.2	15.2	Roche Cobas e801 Test II
	ng/ml	3.66	2.94	4.38	
	ng/dl	366	294	438	
	nmol/l	17.2	13.8	20.6	Tosoh AIA-CL Series
	ng/ml	4.95	3.97	5.93	
	ng/dl	495	397	593	
	nmol/l	12.4	9.92	14.9	Abbott Alinity i
	ng/ml	3.57	2.86	4.28	
	ng/dl	357	286	428	
Theophylline	µmol/l	82.9	66.3	99.0	Siemens Centaur XP/XPT/Classic
	µg/ml	14.9	11.9	17.9	
	µmol/l	83.8	67.0	101	Roche Integra
	µg/ml	15.1	12.1	18.1	
	µmol/l	70.7	56.6	84.8	Abbott Architect (CMIA)
	µg/ml	12.7	10.2	15.2	
	µmol/l	80.0	64.0	96.0	Roche Cobas 6000/8000
	µg/ml	14.4	11.5	17.3	
	µmol/l	83.5	66.8	100	Beckman DxC
	µg/ml	15.0	12.0	18.0	
	µmol/l	77.2	61.8	92.6	Beckman AU400/600/640/2700/5400
	µg/ml	13.9	11.1	16.7	
	µmol/l	77.3	61.8	92.8	Abbott Alinity Enzyme-Immu
	µg/ml	13.9	11.1	16.7	
	µmol/l	83.8	67.0	101	Gravimetric
	µg/ml	15.1	12.1	18.2	
Thyroglobulin	ng/ml	14.7	11.0	18.4	Siemens Immulite 1000
	ng/ml	14.9	11.2	18.6	Siemens Immulite 2000
	ng/ml	36.7	27.5	45.9	Roche Elecsys
	ng/ml	30.8	23.1	38.5	Beckman Dxl800
	ng/ml	36.2	27.2	45.3	Roche Cobas 4000/E411

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Thyroglobulin	ng/ml	35.8	26.9	44.8	Roche Cobas e601/602
	ng/ml	32.0	24.0	40.0	Beckman Access
	ng/ml	39.5	29.6	49.4	Abbott Architect 2000i
	ng/ml	35.2	26.4	44.0	Tosoh Series
	ng/ml	35.6	26.7	44.5	Roche Cobas e601/602 Tg II
	ng/ml	36.3	27.2	45.4	Roche Elecsys TGII
	ng/ml	36.4	27.3	45.5	Roche Cobas 4000/E411 TGII
	ng/ml	37.2	27.9	46.5	Diasorin Liaison XL
	ng/ml	34.8	26.1	43.5	Roche Cobas e801 Tg II
	ng/ml	37.7	28.3	47.1	DiaSorin Liaison TG II Gen
	ng/ml	39.4	29.6	49.3	DiaSorin Liaison XL TG II Gen
	ng/ml	38.0	28.5	47.5	Abbott Alinity i
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.74	1.39	2.09	Abbott Architect
	µU/ml = mIU/l	2.02	1.62	2.42	bioMerieux VIDAS TSH
	µU/ml = mIU/l	1.85	1.48	2.22	bioMerieux VIDAS TSH3 Ultrasensitive
	µU/ml = mIU/l	2.13	1.70	2.56	Siemens Centaur XP/XPT/Classic
	µU/ml = mIU/l	2.67	2.14	3.20	CIS IRMA
	µU/ml = mIU/l	2.18	1.74	2.62	Siemens Centaur XP/XPT/Classic 3rd Generation
	µU/ml = mIU/l	2.09	1.67	2.51	Siemens Immulite 2000/2500
	µU/ml = mIU/l	2.01	1.61	2.41	Siemens Immulite 1000
	µU/ml = mIU/l	1.92	1.54	2.30	Beckman Dxl800 Fast TSH
	µU/ml = mIU/l	1.98	1.58	2.38	Beckman Dxl800
	µU/ml = mIU/l	2.33	1.86	2.80	Roche Elecsys
	µU/ml = mIU/l	2.71	2.17	3.25	Diasorin Liaison
	µU/ml = mIU/l	1.98	1.58	2.38	Beckman Access Fast TSH
	µU/ml = mIU/l	2.00	1.60	2.40	Beckman Access hyperTSH 3rd Generation
	µU/ml = mIU/l	2.18	1.74	2.62	Tosoh Series
	µU/ml = mIU/l	2.15	1.72	2.58	Vitros ECI
	µU/ml = mIU/l	2.34	1.87	2.81	Roche Cobas 4000/E411
	µU/ml = mIU/l	2.34	1.87	2.81	Roche Cobas e601/602
	µU/ml = mIU/l	2.25	1.80	2.70	ELISA
	µU/ml = mIU/l	1.92	1.54	2.30	Beckman Dxl800 Hyper TSH
	µU/ml = mIU/l	2.07	1.66	2.48	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml = mIU/l	1.97	1.58	2.36	Siemens Centaur CP
	µU/ml = mIU/l	1.96	1.57	2.35	Siemens Centaur CP TSH3-Ultra
	µU/ml = mIU/l	1.97	1.58	2.36	Beckman Dxl 600/800 Access (3rd IS)
	µU/ml = mIU/l	2.95	2.36	3.54	Diasorin Liaison XL
	µU/ml = mIU/l	2.09	1.67	2.51	Siemens Atellica IM
	µU/ml = mIU/l	1.76	1.41	2.11	Abbott Alinity i
	µU/ml = mIU/l	2.20	1.76	2.64	Roche Cobas e402/e801
Tobramycin	µmol/l	7.16	5.73	8.59	Gravimetric
	µg/ml	3.35	2.68	4.02	
Total Beta hCG	mU/ml=IU/l	22.5	18.0	27.0	BioMerieux Vidas
	IU/ml	0.023	0.018	0.028	
	mU/ml=IU/l	15.6	12.5	18.7	Siemens Centaur XP/XPT/Classic
	IU/ml	0.016	0.013	0.019	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Total Beta hCG	mU/ml=IU/l	25.1	20.1	30.1	Siemens Dimension
	IU/ml	0.025	0.020	0.030	
	mU/ml=IU/l	30.6	24.5	36.7	Siemens Immulite 2000
	IU/ml	0.031	0.025	0.037	
	mU/ml=IU/l	31.7	25.4	38.0	Siemens Immulite 1000
	IU/ml	0.032	0.025	0.039	
	mU/ml=IU/l	16.4	13.1	19.7	Beckman Dxl800
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	13.0	10.4	15.6	Diasorin Liaison
	IU/ml	0.013	0.010	0.016	
	mU/ml=IU/l	15.5	12.4	18.6	Roche Cobas Core EIA
	IU/ml	0.016	0.012	0.020	
	mU/ml=IU/l	16.0	12.8	19.2	Beckman Access
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	23.5	18.8	28.2	Tosoh Series
	IU/ml	0.024	0.019	0.029	
	mU/ml=IU/l	25.4	20.3	30.5	Vitros ECI
	IU/ml	0.025	0.020	0.030	
	mU/ml=IU/l	13.1	10.5	15.7	Roche hCG STAT (Intact)
	IU/ml	0.013	0.011	0.015	
	mU/ml=IU/l	15.9	12.7	19.1	Roche hCG+Beta
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	12.8	10.2	15.4	Fujirebio Lumipulse G Series
	IU/ml	0.013	0.010	0.016	
	mU/ml=IU/l	15.8	12.6	19.0	Beckman Access Total BhCG (5th IS)
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	16.2	13.0	19.4	Beckman Dxl Total BhCG (5th IS)
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	16.1	12.9	19.3	Siemens Centaur CP
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	14.0	11.2	16.8	Diasorin Liaison XL
	IU/ml	0.014	0.011	0.017	
	mU/ml=IU/l	16.6	13.3	19.9	Siemens Atellica IM
	IU/ml	0.017	0.013	0.021	
	mU/ml=IU/l	14.6	11.7	17.5	Abbott Alinity i
	IU/ml	0.015	0.012	0.018	
	mU/ml=IU/l	15.7	12.6	18.8	Roche hCG+Beta e801
	IU/ml	0.016	0.013	0.019	
	mU/ml=IU/l	28.9	23.1	34.7	Tosoh AIA-CL Series
	IU/ml	0.029	0.023	0.035	
Total T3	nmol/l	3.01	2.26	3.76	Abbott Architect
	ng/ml	1.96	1.47	2.45	
	ng/dl	196	147	245	
	nmol/l	3.49	2.62	4.36	BioMerieux Vidas
	ng/ml	2.27	1.71	2.83	
	ng/dl	227	171	283	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Total T3	nmol/l	3.70	2.78	4.63	Siemens Centaur XP/XPT/Classic
	ng/ml	2.41	1.81	3.01	
	ng/dl	241	181	301	
	nmol/l	3.15	2.36	3.94	Siemens Immulite 2000/2500
	ng/ml	2.05	1.54	2.56	
	ng/dl	205	154	256	
	nmol/l	2.84	2.13	3.55	Siemens Immulite 1000
	ng/ml	1.85	1.39	2.31	
	ng/dl	185	139	231	
	nmol/l	3.23	2.42	4.04	Beckman Dxl800
	ng/ml	2.10	1.58	2.62	
	ng/dl	210	158	262	
	nmol/l	3.70	2.78	4.63	Roche Elecsys
	ng/ml	2.41	1.81	3.01	
	ng/dl	241	181	301	
	nmol/l	3.39	2.54	4.24	Beckman Access
	ng/ml	2.21	1.65	2.77	
	ng/dl	221	165	277	
	nmol/l	3.34	2.51	4.18	Tosoh Series
	ng/ml	2.17	1.63	2.71	
	ng/dl	217	163	271	
	nmol/l	3.93	2.95	4.91	Vitros ECI
	ng/ml	2.56	1.92	3.20	
	ng/dl	256	192	320	
	nmol/l	2.41	1.81	3.01	CIS RIA Coated tube
	ng/ml	1.57	1.18	1.96	
	ng/dl	157	118	196	
	nmol/l	3.57	2.68	4.46	Roche Cobas 4000/E411
	ng/ml	2.32	1.74	2.90	
	ng/dl	232	174	290	
	nmol/l	2.73	2.05	3.41	Immunotech RIA
	ng/ml	1.78	1.33	2.23	
	ng/dl	178	133	223	
	nmol/l	3.57	2.68	4.46	Roche Cobas e601/602
	ng/ml	2.32	1.74	2.90	
	ng/dl	232	174	290	
	nmol/l	3.94	2.96	4.93	Siemens Centaur CP
	ng/ml	2.56	1.93	3.19	
	ng/dl	256	193	319	
	nmol/l	2.38	1.79	2.98	Diasorin Liaison XL
	ng/ml	1.55	1.17	1.93	
	ng/dl	155	117	193	
	nmol/l	3.08	2.31	3.85	Abbott Alinity i
	ng/ml	2.01	1.50	2.52	
	ng/dl	201	150	252	
	nmol/l	3.72	2.79	4.65	Siemens Atellica IM
	ng/ml	2.42	1.82	3.02	
	ng/dl	242	182	302	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Total T3	nmol/l	3.88	2.91	4.85	Roche Cobas e402/e801
	ng/ml	2.53	1.89	3.17	
	ng/dl	253	189	317	
	nmol/l	3.31	2.48	4.14	Tosoh AIA-CL Series
	ng/ml	2.15	1.61	2.69	
	ng/dl	215	161	269	
Total T4	nmol/l	109	81.8	136	Abbott Architect
	µg/dl	8.50	6.38	10.6	
	ng/ml	85.0	63.8	106	
	nmol/l	119	89.3	149	BioMerieux Vidas
	µg/dl	9.28	6.97	11.6	
	ng/ml	92.8	69.7	116	
	nmol/l	114	85.5	143	Siemens Centaur XP/XPT/Classic
	µg/dl	8.89	6.67	11.1	
	ng/ml	88.9	66.7	111	
	nmol/l	111	83.3	139	Siemens Immulite 2000/2500
	µg/dl	8.66	6.50	10.8	
	ng/ml	86.6	65.0	108	
	nmol/l	108	81.0	135	Siemens Immulite 1000
	µg/dl	8.42	6.32	10.5	
	ng/ml	84.2	63.2	105	
	nmol/l	114	85.5	143	Beckman Dxl800
	µg/dl	8.89	6.67	11.1	
	ng/ml	88.9	66.7	111	
	nmol/l	108	81.0	135	Roche Elecsys
	µg/dl	8.42	6.32	10.5	
	ng/ml	84.2	63.2	105	
	nmol/l	116	87.0	145	Beckman Access
	µg/dl	9.05	6.79	11.3	
	ng/ml	90.5	67.9	113	
	nmol/l	109	81.8	136	Tosoh Series
	µg/dl	8.50	6.38	10.6	
	ng/ml	85.0	63.8	106	
	nmol/l	112	84.0	140	Vitros ECi
	µg/dl	8.74	6.55	10.9	
	ng/ml	87.4	65.5	109	
	nmol/l	108	81.0	135	CIS RIA Coated tube
	µg/dl	8.42	6.32	10.5	
	ng/ml	84.2	63.2	105	
	nmol/l	106	79.5	133	Roche Cobas 4000/E411
	µg/dl	8.27	6.20	10.3	
	ng/ml	82.7	62.0	103	
	nmol/l	104	78.0	130	Roche Cobas e601/602
	µg/dl	8.11	6.08	10.1	
	ng/ml	81.1	60.8	101	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Total T4	nmol/l	84.5	63.4	106	Immunotech IRMA
	µg/dl	6.59	4.95	8.23	
	ng/ml	65.9	49.5	82.3	
	nmol/l	123	92.3	154	Siemens Centaur CP
	µg/dl	9.59	7.20	12.0	
	ng/ml	95.9	72.0	120	
	nmol/l	92.5	69.4	116	Diasorin Liaison XL
	µg/dl	7.22	5.41	9.03	
	ng/ml	72.2	54.1	90.3	
	nmol/l	108	81.0	135	Abbott Alinity i
	µg/dl	8.42	6.32	10.5	
	ng/ml	84.2	63.2	105	
	nmol/l	123	92.3	154	Siemens Atellica IM
	µg/dl	9.59	7.20	12.0	
	ng/ml	95.9	72.0	120	
	nmol/l	104	78.0	130	Roche Cobas e402/e801
	µg/dl	8.11	6.08	10.1	
	ng/ml	81.1	60.8	101	
	nmol/l	125	93.8	156	Tosoh AIA-CL Series
	µg/dl	9.75	7.32	12.2	
	ng/ml	97.5	73.2	122	
Valproic Acid	µmol/l	529	423	635	Abbott Architect (CMIA)
	µg/ml	76.3	61.0	91.6	
	µmol/l	568	454	682	Siemens Centaur XP/XPT/Classic
	µg/ml	82.0	65.5	98.5	
	µmol/l	533	426	640	Siemens Dimension
	µg/ml	76.9	61.5	92.3	
	µmol/l	548	438	658	Siemens Immulite 2000/2500
	µg/ml	79.1	63.2	95.0	
	µmol/l	525	420	630	Roche Integra
	µg/ml	75.8	60.6	91.0	
	µmol/l	547	438	656	Vitros
	µg/ml	78.9	63.2	94.6	
	µmol/l	540	432	648	Roche Cobas 6000/8000
	µg/ml	77.9	62.3	93.5	
	µmol/l	570	456	684	Beckman AU400/600/640/2700/5400
	µg/ml	82.3	65.8	98.8	
	µmol/l	543	434	652	Siemens ADVIA 1200/1650/1800/2400
	µg/ml	78.4	62.6	94.2	
	µmol/l	512	410	614	Abbott Architect (PETINA)
	µg/ml	73.9	59.2	88.6	
	µmol/l	570	456	684	EMIT
	µg/ml	82.3	65.8	98.8	
	µmol/l	541	433	649	Siemens Atellica CH
	µg/ml	78.1	62.5	93.7	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Valproic Acid	μmol/l	514	411	617	Abbott Alinity (CMIA)
	μg/ml	74.2	59.3	89.1	
	μmol/l	528	422	634	Abbott Alinity (PETINA)
	μg/ml	76.2	60.9	91.5	
	μmol/l	638	510	766	Gravimetric
	μg/ml	92.1	73.6	111	
Vancomycin	μmol/l	6.73	5.38	8.08	Roche Integra
	μg/ml	10.0	7.99	12.0	
	μmol/l	6.22	4.98	7.46	Ortho Vitros Microslide Systems
	μg/ml	9.24	7.40	11.1	
	μmol/l	8.14	6.51	9.77	Abbott Architect (CMIA)
	μg/ml	12.1	9.67	14.5	
	μmol/l	6.54	5.23	7.85	Siemens Centaur XP/XPT/Classic
	μg/ml	9.72	7.77	11.7	
	μmol/l	7.49	5.99	8.99	Siemens Dimension
	μg/ml	11.1	8.90	13.3	
	μmol/l	7.36	5.89	8.83	Roche Cobas 6000/8000
	μg/ml	10.9	8.75	13.1	
	μmol/l	7.13	5.70	8.56	Thermo Scientific QMS Vancomycin
	μg/ml	10.6	8.47	12.7	
	μmol/l	7.58	6.06	9.10	Abbott Architect (PETINA)
	μg/ml	11.3	9.00	13.6	
	μmol/l	7.39	5.91	8.87	Siemens Atellica CH
	μg/ml	11.0	8.78	13.2	
	μmol/l	7.69	6.15	9.23	Abbott Alinity (CMIA)
	μg/ml	11.4	9.14	13.7	
	μmol/l	7.34	5.87	8.81	Abbott Alinity (PETINA)
	μg/ml	10.9	8.72	13.1	
	μmol/l	7.10	5.68	8.52	Gravimetric
	μg/ml	10.5	8.44	12.7	
Vitamin B12	pmol/l	363	290	436	Abbott Architect
	pg/ml	492	393	591	
	pmol/l	401	321	481	Siemens Centaur XP/XPT/Classic
	pg/ml	543	435	651	
	pmol/l	376	301	451	Siemens Immulite 2000
	pg/ml	509	408	610	
	pmol/l	300	240	360	Beckman DxI800
	pg/ml	407	325	489	
	pmol/l	416	333	499	Roche Elecsys
	pg/ml	564	451	677	
	pmol/l	314	251	377	Beckman Access
	pg/ml	425	340	510	
	pmol/l	508	406	610	Tosoh Series
	pg/ml	688	550	826	
	pmol/l	423	338	508	Vitros ECI
	pg/ml	573	458	688	

IMMUNOASSAY PREMIUM PLUS LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot. No. 2107EC Size 12 x 5ml / 4 x 5ml Expiry 2024-12-28

Range					
Analyte	unit	Target	low	high	methods
Vitamin B12	pmol/l	366	293	439	Siemens Dimension
	pg/ml	496	397	595	
	pmol/l	413	330	496	Siemens Centaur CP
	pg/ml	560	447	673	
	pmol/l	406	325	487	Roche Cobas 4000/e411 Gen II
	pg/ml	550	440	660	
	pmol/l	430	344	516	Roche Cobas e601/602 Gen II
	pg/ml	583	466	700	
	pmol/l	328	262	394	Diasorin Liaison XL
	pg/ml	444	355	533	
	pmol/l	413	330	496	Siemens Atellica IM
	pg/ml	560	447	673	
	pmol/l	360	288	432	Abbott Alinity i
	pg/ml	488	390	586	
	pmol/l	422	338	506	Roche Cobas e801 Gen II
	pg/ml	572	458	686	

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

CAT. NO.	IA3110	GTIN:	05055273207262	SIZE	12 x 5 ml
CAT. NO.	IA3112	GTIN:	05055273207286	SIZE	4 x 5 ml
LOT NO.	2107EC	EXPIRY:	2024-12-28		

INTENDED USE

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

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

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

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

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

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

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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 Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

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

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

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Dungloe, Donegal,
F94 TV06, Ireland

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

Cat. No. IA3110 / IA3112		Lot No. 2107EC	Size: 12 x 5ml / 4 x 5ml		Expiry: 2024-12-28
Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	KIU/l = IU/ml	42.8	34.2	51.4	Beckman Access / Access 2
	ng/ml	51.8	41.4	62.2	
	KIU/l = IU/ml	40.6	32.5	48.7	Beckman Dxl600/800
	ng/ml	49.1	39.3	58.9	
CA 15-3	U/ml	19.2	15.4	23.0	Beckman Access / Access 2
	U/ml	19.2	15.4	23.0	Beckman Dxl600/800
CA 19-9	U/ml	170	136	204	Beckman Access / Access 2
	U/ml	152	122	182	Beckman Dxl600/800
CA125	U/ml	71.1	56.9	85.3	Beckman Access / Access 2
	U/ml	69.6	55.7	83.5	Beckman Dxl600/800
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	25.8	20.6	31.0	Beckman Access / Access 2
	ng/ml = µg/l	24.4	19.5	29.3	Beckman Dxl600/800
Cortisol	nmol/l	678	509	847	Beckman Access / Access 2
	µg/dl	24.4	18.3	30.5	
	nmol/l	626	470	782	Beckman Dxl600/800
	µg/dl	22.5	16.9	28.1	
DHEA-S	µmol/l	12.3	9.84	14.8	Beckman Access / Access 2
	µg/dl	453	362	544	
	µmol/l	11.5	9.20	13.8	Beckman Dxl600/800
	µg/dl	424	339	509	
Digoxin	nmol/l	2.96	2.37	3.55	Beckman Access / Access 2
	ng/ml	2.31	1.85	2.77	
	nmol/l	2.81	2.25	3.37	Beckman Dxl600/800
	ng/ml	2.19	1.75	2.63	
Ferritin	ng/ml = µg/l	60.1	48.1	72.1	Beckman Access / Access 2
	ng/ml = µg/l	58.9	47.1	70.7	Beckman Dxl600/800
Folate	nmol/l	11.8	8.97	14.6	Beckman Access / Access 2
	ng/ml	5.20	3.95	6.45	Beckman Dxl600/800 - A14208
	nmol/l	11.5	8.74	14.3	
	ng/ml	5.07	3.85	6.29	Beckman Dxl600/800 - A98032
	nmol/l	11.9	9.04	14.8	
	ng/ml	5.25	3.99	6.51	
Free T3	pmol/l	9.44	7.08	11.8	Beckman Access / Access 2
	ng/dl	0.614	0.461	0.767	
	pg/ml	6.15	4.61	7.69	
	pmol/l	8.46	6.35	10.6	Beckman Dxl600/800
	ng/dl	0.550	0.413	0.687	
	pg/ml	5.51	4.13	6.89	
Free T4	pmol/l	24.8	18.6	31.0	Beckman Access / Access 2
	ng/dl	1.93	1.45	2.41	
	pg/ml	19.3	14.5	24.1	
	pmol/l	23.9	17.9	29.9	Beckman Dxl600/800
	ng/dl	1.86	1.40	2.32	
	pg/ml	18.6	14.0	23.2	
FSH	mU/ml	27.9	22.3	33.5	Beckman Access / Access 2
	mU/ml	28.6	22.9	34.3	Beckman Dxl600/800
Growth Hormone (GH)	µU/ml	14.6	11.7	17.5	Beckman Access / Access 2
	ng/ml	4.86	3.89	5.83	
	µU/ml	13.5	10.8	16.2	Beckman Dxl600/800
	ng/ml	4.50	3.60	5.40	
Insulin	mU/l	10.7	8.03	13.4	Beckman Access / Access 2
	mU/l	10.2	7.65	12.8	Beckman Dxl600/800
Luteinising Hormone (LH)	mU/ml	27.1	21.7	32.5	Beckman Access / Access 2
	mU/ml	26.2	21.0	31.4	Beckman Dxl600/800

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

Cat. No. IA3110 / IA3112		Lot No. 2107EC	Size: 12 x 5ml / 4 x 5ml		Expiry: 2024-12-28
Analyte	unit	Target	Range		methods
			low	high	
Oestradiol	pmol/l	808	646	970	Beckman Access / Access 2
	pg/ml	220	176	264	
	pmol/l	761	609	913	Beckman Access / Access 2 Sensitive B84493
	pg/ml	207	166	248	
	pmol/l	682	546	818	Beckman Dxl600/800
	pg/ml	186	149	223	
	pmol/l	682	546	818	Beckman Dxl600/800 Sensitive B84493
	pg/ml	186	149	223	
Progesterone	nmol/l	31.7	25.4	38.0	Beckman Access / Access 2 Prog Cal 33555
	ng/ml	9.92	7.94	11.9	
	nmol/l	29.6	23.7	35.5	Beckman Access / Access 2 Prog DE Cal A80773
	ng/ml	9.26	7.41	11.1	
	nmol/l	30.3	24.2	36.4	Beckman Dxl600/800 Prog Cal 33555
	ng/ml	9.48	7.58	11.4	
	nmol/l	25.9	20.7	31.1	Beckman Dxl600/800 Prog DE Cal A80773
	ng/ml	8.11	6.49	9.73	
Prolactin	µU/ml	589	471	707	Beckman Access / Access 2
	µg/l	27.8	22.2	33.4	
	µU/ml	559	447	671	Beckman Dxl600/800
	µg/l	26.4	21.1	31.7	
PSA Free	ng/ml = µg/l	10.3	7.73	12.9	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	10.2	7.65	12.8	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	10.3	7.73	12.9	Beckman Dxl600/800 standardised to Hybritech
	ng/ml = µg/l	9.37	7.03	11.7	Beckman Dxl600/800 standardised to WHO IRP96/670
PSA Total	ng/ml = µg/l	9.77	7.33	12.2	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	9.51	7.13	11.9	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	9.48	7.11	11.9	Beckman Dxl600/800 standardised to Hybritech
	ng/ml = µg/l	7.93	5.95	9.91	Beckman Dxl600/800 standardised to WHO IRP96/670
SHBG	nmol/l	43.6	34.9	52.3	Beckman Access / Access 2
	nmol/l	40.2	32.2	48.2	Beckman Dxl600/800
Testosterone	nmol/l	12.0	9.60	14.4	Beckman Access / Access 2
	ng/ml	3.46	2.77	4.15	
	ng/dl	346	277	415	
	nmol/l	11.0	8.80	13.2	Beckman Dxl600/800
	ng/ml	3.17	2.54	3.80	
	ng/dl	317	254	380	
Thyroglobulin	ng/ml	32.0	24.0	40.0	Beckman Access / Access 2
	ng/ml	30.8	23.1	38.5	Beckman Dxl600/800
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.98	1.58	2.38	Beckman Access / Access 2 Fast TSH
	µU/ml = mIU/l	2.00	1.60	2.40	Beckman Access / Access 2 hyperTSH 3rd Generation
	µU/ml = mIU/l	1.98	1.58	2.38	Beckman Dxl600/800
	µU/ml = mIU/l	1.92	1.54	2.30	Beckman Dxl600/800 Fast TSH
	µU/ml = mIU/l	1.92	1.54	2.30	Beckman Dxl600/800 Hyper TSH
	µU/ml = mIU/l	1.97	1.58	2.36	Beckman Dxl600/800 Access (3rd IS)

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

Cat. No. IA3110 / IA3112		Lot No. 2107EC	Size: 12 x 5ml / 4 x 5ml		Expiry: 2024-12-28
Analyte	unit	Target	Range		methods
			low	high	
Total Beta hCG	mU/ml = IU/l	16.0	12.8	19.2	Beckman Access / Access 2
	IU/ml	0.0160	0.0128	0.0192	
	mU/ml = IU/l	15.8	12.6	19.0	Beckman Access / Access 2 Total BhCG (5th IS)
	IU/ml	0.0158	0.0126	0.0190	
	mU/ml = IU/l	16.4	13.1	19.7	Beckman Dxl600/800
	IU/ml	0.0164	0.0131	0.0197	
Total T3	mU/ml = IU/l	16.2	13.0	19.4	Beckman Dxl600/800 Total BhCG (5th IS)
	IU/ml	0.0162	0.0130	0.0194	
	nmol/l	3.39	2.54	4.24	Beckman Access / Access 2
	ng/ml	2.21	1.66	2.76	
	ng/dl	221	166	276	
	nmol/l	3.23	2.42	4.04	Beckman Dxl600/800
Total T4	ng/ml	2.10	1.58	2.62	
	ng/dl	210	158	262	
	nmol/l	116	87.0	145	Beckman Access / Access 2
	µg/dl	9.05	6.79	11.3	
	ng/ml	90.5	67.9	113	
	nmol/l	114	85.5	143	Beckman Dxl600/800
Vitamin B12	µg/dl	8.89	6.67	11.1	
	ng/ml	88.9	66.7	111	
	pmol/l	314	251	377	Beckman Access / Access 2
	pg/ml	425	340	510	
	pmol/l	300	240	360	Beckman Dxl600/800
	pg/ml	407	326	488	

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

CAT. NO.	IA3110	GTIN:	05055273207262	SIZE	12 x 5 ml
CAT. NO.	IA3112	GTIN:	05055273207286	SIZE	4 x 5 ml
LOT NO.	2107EC	EXPIRY:	2024-12-28		

INTENDED USE

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

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

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

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

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

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

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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 Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

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

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



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

Cat. No. IA3110 / IA3112 Lot No. 2107EC Size: 12 x 5ml / 4 x 5ml Expiry: 2024-12-28

Analyte	unit	Target	Range		methods
			low	high	
25-OH Vitamin D	nmol/l	80.3	60.2	100	Vitros Eci
Alpha-fetoprotein	KIU/l = IU/ml	43.8	35.0	52.6	Vitros Eci
CA 125	U/ml	81.2	65.0	97.4	Vitros Eci
CA 15-3	U/ml	35.9	28.7	43.1	Vitros Eci
CA 19-9	U/ml	151	121	181	Vitros Eci
C-Peptide	nmol/l	1.930	1.450	2.410	Vitros Eci
	ng/ml	5.83	4.38	7.28	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	29.0	23.2	34.8	Vitros Eci
Cortisol	nmol/l	586	440	733	Vitros Eci
	µg/dl	21.1	15.8	26.4	
Ferritin	ng/ml = µg/l	54.2	43.4	65.0	Vitros Eci
Folate	nmol/l	7.68	5.84	9.52	Vitros Eci
	ng/ml	3.39	2.58	4.20	
Free T3	pmol/l	28.4	21.3	35.5	Vitros Eci
	ng/dl	1.85	1.38	2.32	
	pg/ml	18.5	13.9	23.1	
Free T4	pmol/l	63.5	47.6	79.4	Vitros Eci
	ng/dl	4.95	3.71	6.19	
	pg/ml	49.5	37.1	61.9	
FSH	mU/ml	20.0	16.0	24.0	Vitros Eci
Insulin	mU/l	10.9	8.18	13.6	Vitros Eci
	µU/ml	10.9	8.18	13.6	
Luteinising Hormone (LH)	mU/ml	41.5	33.2	49.8	Vitros Eci
Oestradiol	pmol/l	1095	876	1314	Vitros Eci
	pg/ml	298	238	358	
Progesterone	nmol/l	36.1	28.9	43.3	Vitros Eci
	ng/ml	11.3	9.05	13.6	
Prolactin	µU/ml	582	466	698	Vitros Eci
PSA Free	ng/ml = µg/l	6.78	5.09	8.48	Ortho Vitros 3600/5600/ECi PSA II
PSA Total	ng/ml = µg/l	9.89	7.42	12.4	Vitros Eci
Testosterone	nmol/l	15.9	12.7	19.1	Vitros Eci
	ng/ml	4.58	3.66	5.50	
	ng/dl	458	366	550	
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.15	1.72	2.58	Vitros Eci
Total Beta hCG	mU/ml=IU/l	25.4	20.3	30.5	Vitros Eci
	IU/ml	0.025	0.020	0.030	
Vitamin B12	pmol/l	423	338	508	Vitros Eci
	pg/ml	573	458	688	

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS - LEVEL 2
(IA PREMIUM PLUS 2)
Cat No. IA3110 / IA3112
Lot No. 2107EC
GTIN: 05055273207262 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
17-OH-Progesterone	nmol/l	28.7	20.1 – 37.3	Autobio CLIA
	ng/ml	9.50	6.65 - 12.4	
25-OH Vitamin D	ng/ml	65.0	45.5 - 84.5	Autobio CLIA
ACTH	pmol/l	11.6	8.12 - 15.1	Autobio CLIA
	pg/ml	52.7	36.9 - 68.5	
Alphafoetoprotein	KIU/l = IU/ml	45.6	31.9 - 59.3	Autobio CLIA
	ng/ml	55.2	38.6 - 71.8	
Beta-2-microglobulin	ug/l	3.26	2.28 - 4.24	Autobio CLIA
C-Peptide	nmol/l	3.03	2.12 - 3.94	Autobio CLIA
	ng/ml	9.15	6.41 - 11.9	
CA 15-3	U/ml	42.3	29.6 - 55.0	Autobio CLIA
CA 19-9	U/ml	94.9	66.4 - 123	Autobio CLIA
CA125	U/ml	70.1	49.1 - 91.1	Autobio CLIA
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	35.8	25.1 - 46.5	Autobio CLIA
Cortisol	nmol/l	803	562 - 1044	Autobio CLIA
	µg/dl	28.9	20.2 - 37.6	
DHEA-S	ng/dl	18.5	13.0 - 24.0	Autobio CLIA
Ferritin	ng/ml = µg/l	78.5	55.0 - 102	Autobio CLIA
Folate	nmol/l	13.5	9.45 - 17.6	Autobio CLIA
	ng/ml	5.95	4.17 - 7.73	
Free T3	pmol/l	12.4	8.68 - 16.1	Autobio CLIA
	ng/dl	0.806	0.564 - 1.05	
	pg/ml	8.07	5.65 - 10.5	
Free T4	pmol/l	31.7	22.2 - 41.2	Autobio CLIA
	ng/dl	2.47	1.73 - 3.21	
	pg/ml	24.7	17.3 - 32.1	
FSH	mU/ml	34.1	23.9 - 44.3	Autobio CLIA
Growth Hormone (GH)	µU/ml	18.6	13.0 - 24.2	Autobio CLIA
	ng/ml	6.19	4.33 - 8.05	
Immunoglobulin E	KIU/l = IU/ml	119	83.3 - 155	Autobio CLIA
Insulin	mU/l	17.5	12.3 - 22.7	Autobio CLIA
	µU/ml	17.5	12.3 - 22.7	
Luteinising Hormone (LH)	mU/ml	37.4	26.2 - 48.6	Autobio CLIA

COMPONENT	UNITS	TARGET	RANGE	METHOD
Oestradiol	pmol/l	1165	816 - 1514	Autobio CLIA
	pg/ml	317	222 - 412	
Progesterone	nmol/l	34.4	24.1 - 44.7	Autobio CLIA
	ng/ml	10.8	7.56 - 14.0	
Prolactin	μU/ml	930	651 - 1209	Autobio CLIA
PSA Free	ng/ml = μg/l	9.08	6.36 - 11.8	Autobio CLIA
PSA Total	ng/ml = μg/l	9.32	6.52 - 12.1	Autobio CLIA
SHBG	nmol/l	34.6	24.2 - 45.0	Autobio CLIA
Testosterone	nmol/l	13.2	9.24 - 17.2	Autobio CLIA
	ng/ml	3.80	2.66 - 4.94	
	ng/dl	380	266 - 494	
Thyroglobulin	ng/ml	8.20	5.74 - 10.7	Autobio CLIA
Thyroid Stimulating Hormone	μU/ml = mIU/l	2.28	1.60 - 2.96	Autobio CLIA
Total Beta hCG	mU/ml=IU/l	14.3	10.0 - 18.6	Autobio CLIA
	IU/ml	0.014	0.010 - 0.018	
Total T3	nmol/l	3.12	2.18 - 4.06	Autobio CLIA
	ng/ml	2.03	1.42 - 2.64	
	ng/dl	203	142 - 264	
Total T4	nmol/l	119	83.3 - 155	Autobio CLIA
	μg/dl	9.28	6.50 - 12.1	
	ng/ml	92.8	65.0 - 121	
Vitamin B12	pmol/l	458	321 - 595	Autobio CLIA
	pg/ml	621	435 - 807	

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

Rev. 28 Feb '23 me

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS - LEVEL 2
(IA PREMIUM PLUS 2)
Cat No. IA3110 / IA3112
Lot No. 2107EC
GTIN: 05055273207262 / 05055273207286**

COMPONENTS	UNITS	TARGET	RANGE	METHOD
C-Peptide	nmol/l	1.98	1.48 – 2.48	Ortho Vitros ECI
	ng/ml	5.98	4.47 – 7.49	
Insulin	mU/l	10.8	6.84 – 14.8	Ortho Vitros ECI
	µU/ml	10.8	6.84 – 14.8	

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

11 Apr '22 me

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS - LEVEL 2
(IA PREMIUM PLUS 2)
Cat No. IA3110 / IA3112
Lot No. 2107EC
GTIN: 05055273207262 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
17-OH Progesterone	nmol/l	16.1	11.2 – 20.9	SNIBE Maglumi Analysers
	ng/ml	5.32	3.72 – 6.92	
25-OH Vitamin D	nmol/l	70.4	49.3 – 91.5	SNIBE Maglumi Analysers
25-OH Vitamin D	nmol/l	80.9	56.6 – 105	SNIBE Maglumi Analysers II
ACTH	pmol/l	9.18	6.43 – 11.9	SNIBE Maglumi Analysers
	pg/ml	41.7	29.2 – 54.2	
Aldosterone	pmol/l	226	158 – 294	SNIBE Maglumi Analysers
	pg/ml	81.5	57.1 – 106	
Alpha-foetoprotein	KIU/l = IU/ml	46.3	32.4 – 60.2	SNIBE Maglumi Analysers
	ng/ml	56.0	39.2 – 72.8	
Androstenedione	nmol/l	10.9	7.63 – 14.2	SNIBE Maglumi Analysers
	ng/ml	3.13	2.19 – 4.07	
Beta-2-microglobulin	µg/ml = mg/l	2.66	1.86 – 3.46	SNIBE Maglumi Analysers
C-Peptide	nmol/l	2.09	1.46 – 2.72	SNIBE Maglumi Analysers
	ng/ml	6.31	4.42 – 8.20	
CA 15-3	U/ml	54.6	38.2 – 71.0	SNIBE Maglumi Analysers
CA 19-9	U/ml	58.2	40.7 – 75.7	SNIBE Maglumi Analysers
CA125	U/ml	77.5	54.3 – 101	SNIBE Maglumi Analysers
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	23.1	16.2 – 30.0	SNIBE Maglumi Analysers
Cortisol	nmol/l	693	485 – 901	SNIBE Maglumi Analysers
	µg/dl	24.9	17.4 – 32.4	
DHEA-S	µmol/l	12.5	8.75 – 16.3	SNIBE Maglumi Analysers
	µg/dl	461	323 – 599	
Digoxin	nmol/l	2.86	2.00 – 3.72	SNIBE Maglumi Analysers
	ng/ml	2.23	1.56 – 2.90	
Ferritin	ng/ml = µg/l	97.2	68.0 – 126	SNIBE Maglumi Analysers
Free T3	pmol/l	13.1	9.14 – 17.0	SNIBE Maglumi Analysers
	ng/dl	0.848	0.594 – 1.10	
	pg/ml	8.50	5.95 – 11.1	

COMPONENT	UNITS	TARGET	RANGE	METHOD
Free T4	pmol/l	32.9	23.0 – 42.8	SNIBE Maglumi Analysers
	ng/dl	2.57	1.80 – 3.34	
	pg/ml	25.7	18.0 – 33.4	
FSH	mU/ml	28.2	19.7 – 36.7	SNIBE Maglumi Analysers
Growth Hormone (GH)	µU/ml	23.6	16.5 – 30.6	SNIBE Maglumi Analysers
	ng/ml	7.85	5.50 – 10.2	
Immunoglobulin E	KIU/l = IU/ml	112	78.4 – 146	SNIBE Maglumi Analysers
Insulin	mU/l	16.1	11.3 – 20.9	SNIBE Maglumi Analysers
	µU/ml	16.1	11.3 – 20.9	
Luteinising Hormone (LH)	mU/ml	52.8	37.0 – 68.6	SNIBE Maglumi Analysers
Oestradiol	pmol/l	1518	1063 – 1973	SNIBE Maglumi Analysers
	pg/ml	413	289 – 537	
Progesterone	nmol/l	30.4	21.3 – 39.5	SNIBE Maglumi Analysers
	ng/ml	9.52	6.66 – 12.4	
Prolactin	µU/ml	680	476 – 884	SNIBE Maglumi Analysers
PSA Free	ng/ml = µg/l	7.60	5.32 – 9.88	SNIBE Maglumi Analysers
PSA Total	ng/ml = µg/l	8.27	5.79 – 10.8	SNIBE Maglumi Analysers
SHBG	nmol/l	45.8	32.1 – 59.5	SNIBE Maglumi Analysers
Testosterone	nmol/l	12.6	8.82 – 16.4	SNIBE Maglumi Analysers
	ng/ml	3.63	2.54 – 4.72	
	ng/dl	363	254 – 472	
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.90	1.33 – 2.47	SNIBE Maglumi Analysers
Total Beta hCG	mU/ml=IU/l	25.2	17.6 – 32.8	SNIBE Maglumi Analysers
	IU/ml	0.0252	0.0176 – 0.0328	
Total T3	nmol/l	2.73	1.91 – 3.55	SNIBE Maglumi Analysers
	ng/ml	1.78	1.25 – 2.31	
	ng/dl	178	125 – 231	
Total T4	nmol/l	126	88.4 – 164	SNIBE Maglumi Analysers
	µg/dl	9.85	6.90 – 12.8	
	ng/ml	98.5	69.0 – 128	
Vitamin B12	pmol/l	361	253 – 469	SNIBE Maglumi Analysers
	pg/ml	489	342 – 636	

EC REP

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

Rev. 30 Sep '22 me

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS - LEVEL 2
(IA PREMIUM PLUS 2)
Cat No. IA3110 / IA3112
Lot No. 2107EC
GTIN: 05055273207262 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Thyroid Stimulating Hormone	µU/ml	2.09	1.67 – 2.51	Ortho Vitros ECI
	mIU/l	2.09	1.67 – 2.51	

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

02 Dec '22 me

**ADDITIONAL VALUES FOR
IMMUNOASSAY PREMIUM PLUS LEVEL 2
(IA PREMIUM PLUS 2)
Cat No. IA3110 / IA3112
Lot No. 2107EC
GTIN: 05055273207262 / 05055273207286**

COMPONENT	UNITS	TARGET	RANGE	METHOD
Total Beta hCG	mU/ml=IU/l	14.5	11.6 – 17.4	Abbott Architect
	IU/ml	0.015	0.012 – 0.017	



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

12 Jan '23 me

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

CAT. NO. IA3110	GTIN: 05055273207262	SIZE: 12 x 5 ml
CAT. NO. IA3112	GTIN: 05055273207286	SIZE: 4 x 5 ml
LOT NO. 2107EC	EXPIRY: 2024-12-28	

INTENDED USE

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

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

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

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

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

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

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

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

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

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 Plus - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

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

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

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

(S). 05 Nov '24 me

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

Cat. No. IA3110 / IA3112 Lot No.2107EC Size: 12 x 5ml / 4 x 5ml Expiry: 2024-12-28

Analyte	unit	Target	Range		methods
			low	high	
Alphafoetoprotein	ng/ml	53.1	38.8	67.5	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		57.0	41.6	72.3	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 15-3	U/ml	24.6	16.7	32.4	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		25.5	17.3	33.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA 19-9	U/ml	65.0	47.5	82.6	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		66.7	48.7	84.7	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
CA125	U/ml	138	101	175	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		142	104	181	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	20.3	14.8	25.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		20.8	15.2	26.4	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
DHEA-S	µg/dl	560	409	711	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		578	422	734	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Oestradiol	pg/mL	228	155	302	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501
		224	152	296	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501
		272	185	359	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001
		272	185	359	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001
Ferritin	ng/ml	77.7	56.7	98.7	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		80.4	58.7	102	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Folate	ng/ml	14.6	10.6	18.5	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		14.8	10.8	18.8	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
FSH	mIU/mL	31.3	22.9	39.8	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101
		31.6	23.0	40.1	Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101
		26.6	16.0	37.2	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401
		26.6	16.0	37.2	Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401
Insulin	µIU/ml	13.6	9.25	18.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		15.6	10.6	20.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Luteinising Hormone (LH)	mIU/ml	36.3	26.5	46.1	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		35.1	25.6	44.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Progesterone	ng/mL	12.6	9.20	16.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		12.6	9.23	16.1	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
		9.36	6.36	12.4	Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i
		9.36	6.36	12.4	Wiener Lab CLIA Series & Mindray PROG II CL 900i
Prolactin	ng/ml	34.5	25.2	43.8	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		34.8	25.4	44.2	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Free	ng/ml	10.2	7.46	13.0	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		10.9	7.96	13.8	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
PSA Total	ng/ml	10.7	7.83	13.6	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		10.7	7.84	13.6	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i

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

Cat. No. IA3110 / IA3112 Lot No.2107EC Size: 12 x 5ml / 4 x 5ml Expiry: 2024-12-28

Analyte	unit	Target	Range		methods
			low	high	
Testosterone	ng/mL	5.15	3.76	6.54	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X
		5.14	3.75	6.53	Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X
		4.16	2.83	5.49	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00
		4.22	2.87	5.57	Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00
		3.29	2.24	4.34	Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i
		3.29	2.24	4.34	Wiener Lab CLIA Series & Mindray TESTO II CL 900i
Total Beta hCG	mIU/mL	29.2	17.5	40.9	Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i
		29.2	17.5	40.9	Wiener Lab CLIA Series & Mindray hCG2 CL 900i
		14.1	9.58	18.6	Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i
		12.7	8.65	16.8	Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i
Vitamin B12	pg/mL	599	437	761	Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i
		595	434	755	Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i
Thyroid Stimulating Hormone	µIU/mL	2.73	1.86	3.61	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X
		2.76	1.87	3.64	Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X
		1.92	1.30	2.53	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00
		1.92	1.30	2.53	Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00
Free T3	pg/mL	7.58	5.15	10.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X
		7.37	5.01	9.72	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X
		7.58	5.15	10.0	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00
		7.37	5.01	9.72	Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00
Free T4	ng/dL	2.16	1.47	2.84	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X
		1.98	1.35	2.61	Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X
		2.81	1.91	3.71	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00
		2.83	1.93	3.74	Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00
Total T3	ng/mL	1.93	1.31	2.55	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X
		1.84	1.25	2.43	Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X
		1.84	1.25	2.44	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00
		1.82	1.24	2.40	Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00
Total T4	µg/dL	9.16	6.23	12.1	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X
		9.34	6.35	12.3	Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X
		8.25	5.61	10.9	Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00
		8.16	5.55	10.8	Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00