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

CAT. NO. IA3110 **GTIN:** 05055273207262 **SIZE:** 12 x 5 ml
LOT NO. 2659EC/2 **EXPIRY:** 2028-11-28

INTENDED USE

The Immunoassay Premium Plus Control is intended for use with *in vitro* diagnostic assays for the quantitative determination of 17-OH-Progesterone, 25-OH Vitamin D, ACTH, Aldosterone, Alpha-fetoprotein, Amikacin, Androstenedione, Beta-2-microglobulin, C-Peptide, CA 15-3, CA 19-9, CA125, Carbamazepine, Carcinoembryonic Antigen, Cortisol, DHEA-S, Digoxin, Estriol, Ethosuximide, Ferritin, Folate, Free T3, Free T4, FSH, Gentamicin, Growth Hormone, Immunoglobulin E, Insulin, Luteinising Hormone, Oestradiol, Paracetamol, Phenobarbital, Phenytoin, Primidone, Progesterone, Prolactin, PSA Free, PSA Total, Salicylic Acid, SHBG, T Uptake, Testosterone, Theophylline, Thyroglobulin, Thyroid Stimulating Hormone, Tobramycin, Total Beta hCG, Total T3, Total T4, Valproic Acid, Vancomycin and Vitamin B12. The device is assayed with target values and is suitable for use on both Clinical Chemistry and Immunoassay analysers.

Immunoassay Premium Plus Control is for use by trained laboratory professionals and can be used in determining the precision of testing systems and in identifying sources of variation.

DEVICE DESCRIPTION

Immunoassay Premium Plus control is supplied at three levels – Level 1, 2 and 3. Immunoassay Premium Plus Level 2 is composed of human serum with added stabilisers and preservatives. This product is supplied lyophilised.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. For use only by trained personnel. Do not pipette by mouth. Wear PPE when handling this product. Any spillages must be treated immediately with a suitable disinfectant such as 1% Virkon solution. Exercise aerosol-minimizing techniques. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

Other hazards:



Biohazard

Biological source material. Treat as potentially infectious.
The product contains material of human origin. This material has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV and found to be non-reactive. However as 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 disease and disposed of accordingly.

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Safety Data Sheets are available on request.

If there is damage to the material upon arrival, the appearance is not as expected or the material is not performing as it should please contact Randox Laboratories Technical Services, Northern Ireland, telephone +44 (0) 28 9445 1070 or email technical.services@randox.com.

STORAGE AND STABILITY

OPENED: 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.

PREPARATION FOR USE
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

MATERIAL REQUIRED BUT NOT PROVIDED
Volumetric pipette
Distilled water

LIMITATIONS
1. This product is provided for quality assurance only and should not be used for calibration purposes.
2. This product should not be used beyond the expiration date.
3. This product should not be used in evidence of microbial contamination or high turbidity.
4. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide.
5. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

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.

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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

TECHNICAL ASSISTANCE
According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.
Contact Randox Laboratories Technical Services, Northern Ireland, telephone +44 (0) 28 9445 1070 or email technical.services@randox.com.

SUMMARY OF SAFETY AND PERFORMANCE
The summary of safety and performance for this *in vitro* diagnostic medical device is available to the public in the European database on medical devices (EUDAMED) when this database is available and the information has been uploaded by the Notified Body. The web address of the EUDAMED public website is: https://ec.europa.eu/tools/eudamed. The summary of safety and performance is also available on request. Contact Randox Laboratories Technical Services, Northern Ireland, telephone +44 (0) 28 9445 1070 or email technical.services@randox.com.

SYMBOL GLOSSARY
Randox Laboratories uses the following symbols, which may appear on the product labelling.

Symbol	Description
REF	Catalogue number
LOT	Batch code
CONTROL	Control
	Use-by date
	Manufacturer
EC REP	Authorized representative in the European Community
	Consult IFU
IVD	*In vitro* diagnostic medical device
CE	CE Marking
CE XXXX	CE Marking with Notified Body
RxOnly	Prescription device (US only)
	Temperature limit
	Do not re-use
YY/MM/DD	Date format (year/month/day)
UK CA	UK CA mark
	Keep away from sunlight
	Biological risks
	This way up
	Caution
	Do not use if package is damaged and consult instructions for use

24 Jun 26 fc

Table of Content

Method 2

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RANDOX

Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
25-OH-Vitamin D	ng/ml	29.1	21.8	36.4	3.65	7.30	Abbott Alinity i
	nmol/l	72.7	54.5	90.9	9.10	18.2	
	ng/ml	26.8	20.1	33.5	3.35	6.70	Abbott Architect (3L52)
	nmol/l	67.0	50.3	83.7	8.35	16.7	
	ng/ml	27.0	20.3	33.7	3.35	6.70	Abbott Architect (5P02)
	nmol/l	67.5	50.6	84.4	8.45	16.9	
	ng/ml	28.0	21.0	35.0	3.50	7.00	Beckman Access 25 OH Vitamin D Total
	nmol/l	70.0	52.5	87.5	8.75	17.5	
	ng/ml	26.2	19.7	32.7	3.25	6.50	Beckman DxI 9000
	nmol/l	65.3	49.0	81.6	8.15	16.3	
	ng/ml	29.9	22.4	37.4	3.75	7.50	Mindray VD CL (Excl. CL 900 Series)
	nmol/l	74.6	56.0	93.2	9.30	18.6	
	ng/ml	29.2	21.9	36.5	3.65	7.30	Mindray VD CL 900 Series
	nmol/l	73.0	54.8	91.2	9.10	18.2	
	ng/ml	32.0	24.0	40.0	4.00	8.00	Mindray VD II CL (Excl. 900 Series)
	nmol/l	79.9	59.9	99.9	10.0	20.0	
	ng/ml	32.2	24.2	40.2	4.00	8.00	Mindray VD II CL 900 Series
	nmol/l	80.4	60.3	101	10.3	20.6	
	ng/ml	25.0	18.8	31.2	3.10	6.20	Roche Vitamin D total III
	nmol/l	62.5	46.9	78.1	7.80	15.6	
	ng/ml	25.2	18.9	31.5	3.15	6.30	Roche Vitamin D Total III e402/e801
	nmol/l	62.8	47.1	78.5	7.85	15.7	
	ng/ml	36.7	27.5	45.9	4.60	9.20	Siemens Atellica IM
	nmol/l	91.5	68.6	114	11.3	22.5	
ACTH	pg/ml	33.4	25.1	41.7	4.15	8.30	Mindray CL 900 Series
	pmol/l	7.35	5.51	9.19	0.920	1.84	
	pg/ml	32.6	24.5	40.7	4.05	8.10	Mindray CL series (Excl. CL 900 series)
	pmol/l	7.17	5.38	8.96	0.895	1.79	
	pg/ml	42.6	32.0	53.2	5.30	10.6	Roche Cobas e402/e801
	pmol/l	9.37	7.03	11.7	1.17	2.33	
	pg/ml	41.5	31.1	51.9	5.20	10.4	Roche Cobas e601/ 602
	pmol/l	9.12	6.84	11.4	1.14	2.28	
	pg/ml	38.2	28.7	47.7	4.75	9.50	Siemens/DPC Immulite 2000/2500
	pmol/l	8.40	6.30	10.5	1.05	2.10	
Aldosterone	pg/ml	114	85.5	143	14.5	29.0	DiaSorin Liaison XL
	pmol/l	317	238	396	39.5	79.0	
	pg/ml	106	79.5	133	13.5	27.0	IDS iSYS
	pmol/l	295	221	369	37.0	74.0	

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All enzyme values are quoted to a temperature of 37°C, unless otherwise stated

RANDOX

Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Aldosterone	pg/ml	137	103	171	17.0	34.0	Mindray ALD CL 900 Series
	pmol/l	380	285	475	47.5	95.0	
	pg/ml	86.6	65.0	108	10.7	21.4	Mindray ALD II (Excl. 900 Series)
	pmol/l	240	180	300	30.0	60.0	
Alpha-fetoprotein	ng/ml	52.2	41.8	62.6	5.20	10.4	3HB-GGG Start
	KIU/l = IU/ml	43.1	34.5	51.7	4.30	8.60	
	ng/ml	50.6	40.5	60.7	5.05	10.1	Abbott Alinity i
	KIU/l = IU/ml	41.8	33.4	50.2	4.20	8.40	
	ng/ml	60.1	48.1	72.1	6.00	12.0	Beckman DXI9000
	KIU/l = IU/ml	49.7	39.8	59.6	4.95	9.90	
	ng/ml	50.5	40.4	60.6	5.05	10.1	Mindray CL 900 Series
	KIU/l = IU/ml	41.7	33.4	50.0	4.15	8.30	
	ng/ml	49.9	39.9	59.9	5.00	10.0	Mindray CL series (Excl. CL 900 series)
	KIU/l = IU/ml	41.2	33.0	49.4	4.10	8.20	
	ng/ml	57.5	46.0	69.0	5.75	11.5	Roche Cobas 4000/e411
	KIU/l = IU/ml	47.5	38.0	57.0	4.75	9.50	
	ng/ml	56.8	45.4	68.2	5.70	11.4	Roche Cobas e402/e801
	KIU/l = IU/ml	46.9	37.5	56.3	4.70	9.40	
	ng/ml	57.5	46.0	69.0	5.75	11.5	Roche Cobas e601/ 602
	KIU/l = IU/ml	47.5	38.0	57.0	4.75	9.50	

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Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Alpha-fetoprotein	ng/ml	64.1	51.3	76.9	6.40	12.8	Siemens Atellica IM
	KIU/l = IU/ml	53.0	42.4	63.6	5.30	10.6	
Androstenedione	ng/ml	2.53	1.90	3.16	0.315	0.630	Beckman Coulter Active RIA
	nmol/l	8.82	6.62	11.0	1.09	2.18	
	ng/ml	2.37	1.78	2.96	0.295	0.590	Roche Elecsys
	nmol/l	8.27	6.20	10.3	1.02	2.03	
	ng/ml	5.65	4.24	7.06	0.705	1.41	Siemens/DPC Immulite 2000
	nmol/l	19.7	14.8	24.6	2.45	4.90	
Beta-2-Microglobulin	µg/ml = mg/l	2.53	2.02	3.04	0.255	0.510	Roche Cobas 6000/8000
C-Peptide	ng/ml	4.26	3.20	5.32	0.530	1.06	Mindray CL 900 Series
	nmol/l	1.41	1.06	1.76	0.175	0.350	
	ng/ml	4.17	3.13	5.21	0.520	1.04	Mindray CL series (Excl. CL 900 series)
	nmol/l	1.38	1.04	1.72	0.170	0.340	
	ng/ml	5.01	3.76	6.26	0.625	1.25	Roche Cobas e402/e801
	nmol/l	1.66	1.25	2.07	0.205	0.410	
CA 125	U/ml	126	101	151	12.5	25.0	Abbott Alinity
	U/ml	128	102	154	13.0	26.0	Abbott Architect
	U/ml	71.1	56.9	85.3	7.10	14.2	Beckman DxI 9000
	U/ml	91.2	73.0	109	8.90	17.8	BioMerieux VIDAS
	U/ml	103	82.4	124	10.5	21.0	Mindray CL (Excl. CL 900) <= lot 241101
	U/ml	48.3	38.6	58.0	4.85	9.70	Mindray CL (Excl. CL 900) >= lot 250501
	U/ml	103	82.4	124	10.5	21.0	Mindray CL 900 Series <= lot 241101
	U/ml	48.6	38.9	58.3	4.85	9.70	Mindray CL 900 Series >= lot 250501
	U/ml	89.4	71.5	107	8.80	17.6	Roche Cobas 4000/e411
	U/ml	84.0	67.2	101	8.50	17.0	Roche Cobas e402/e801
	U/ml	85.9	68.7	103	8.55	17.1	Roche Cobas e601/ 602
	U/ml	112	89.6	134	11.0	22.0	Siemens Atellica IM
CA 15-3	U/ml	36.7	29.4	44.0	3.65	7.30	Abbott Alinity i
	U/ml	37.4	29.9	44.9	3.75	7.50	Abbott Architect
	U/ml	19.8	15.8	23.8	2.00	4.00	Beckman DxI 600/800
	U/ml	19.4	15.5	23.3	1.95	3.90	Beckman DXI9000
	U/ml	25.0	20.0	30.0	2.50	5.00	Mindray CL 900 Series
	U/ml	24.5	19.6	29.4	2.45	4.90	Mindray CL series (Excl. CL 900 series)
	U/ml	38.9	31.1	46.7	3.90	7.80	Roche Cobas 4000/e411
	U/ml	38.6	30.9	46.3	3.85	7.70	Roche Cobas e402/e801
	U/ml	37.4	29.9	44.9	3.75	7.50	Roche Cobas e601/ 602

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RANDOX

Method				Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)			
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
CA 15-3	U/ml	34.3	27.4	41.2	3.45	6.90	Siemens Atellica IM
CA 19-9	U/ml	157	126	188	15.5	31.0	Abbott Alinity XR
	U/ml	165	132	198	16.5	33.0	Abbott Architect XR
	U/ml	318	254	382	32.0	64.0	Beckman DxI 9000
	U/ml	61.6	49.3	73.9	6.15	12.3	bioMerieux, VIDAS
	U/ml	53.6	42.9	64.3	5.35	10.7	Mindray CL 900 Series
	U/ml	52.9	42.3	63.5	5.30	10.6	Mindray CL series (Excl. CL 900 series)
	U/ml	75.8	60.6	91.0	7.60	15.2	Roche Cobas 4000/e411
	U/ml	77.9	62.3	93.5	7.80	15.6	Roche Cobas e402/e801
	U/ml	77.9	62.3	93.5	7.80	15.6	Roche Cobas e601/ 602
	U/ml	132	106	158	13.0	26.0	Siemens Atellica IM
Carbamazepine	µg/ml	9.22	7.38	11.1	0.940	1.88	Beckman AU Instruments
	µmol/l	39.0	31.2	46.8	3.90	7.80	
	µg/ml	9.08	7.26	10.9	0.910	1.82	Roche Cobas 6000/8000
	µmol/l	38.4	30.7	46.1	3.85	7.70	
CEA	ng/ml = µg/l	27.6	22.1	33.1	2.75	5.50	Abbott Alinity i
	ng/ml = µg/l	28.5	22.8	34.2	2.85	5.70	Abbott Architect
	ng/ml = µg/l	25.4	20.3	30.5	2.55	5.10	Beckman DxI 9000
	ng/ml = µg/l	18.0	14.4	21.6	1.80	3.60	Mindray CL 900 Series
	ng/ml = µg/l	17.9	14.3	21.5	1.80	3.60	Mindray CL series (Excl. CL 900 series)
	ng/ml = µg/l	26.6	21.3	31.9	2.65	5.30	Ortho Vitros 3600/5600/ECi/XT 7600
	ng/ml = µg/l	22.9	18.3	27.5	2.30	4.60	Roche Cobas 4000/e411
	ng/ml = µg/l	22.6	18.1	27.1	2.25	4.50	Roche Cobas e402/e801
	ng/ml = µg/l	22.8	18.2	27.4	2.30	4.60	Roche Cobas e601/ 602
	ng/ml = µg/l	28.4	22.7	34.1	2.85	5.70	Siemens Atellica IM
Cortisol	nmol/l	547	410	684	68.5	137	Abbott Alinity i
	µg/dl	19.7	14.8	24.6	2.45	4.90	
	nmol/l	536	402	670	67.0	134	Abbott Architect
	µg/dl	19.3	14.5	24.1	2.40	4.80	

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Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Cortisol	nmol/l	573	430	716	71.5	143	Beckman DxI 600/800
	µg/dl	20.6	15.5	25.7	2.55	5.10	
	nmol/l	590	443	737	73.5	147	Beckman DXI9000
	µg/dl	21.2	15.9	26.5	2.65	5.30	
	nmol/l	670	503	837	83.5	167	Mindray CL 900 Series
	µg/dl	24.1	18.1	30.1	3.00	6.00	
	nmol/l	669	502	836	83.5	167	Mindray CL series (Excl. CL 900 series)
	µg/dl	24.1	18.1	30.1	3.00	6.00	
	nmol/l	545	409	681	68.0	136	Ortho Vitros 3600/5600/ECi/XT 7600
	µg/dl	19.6	14.7	24.5	2.45	4.90	
	nmol/l	600	450	750	75.0	150	Roche Cobas e402/e801
	µg/dl	21.6	16.2	27.0	2.70	5.40	
	nmol/l	597	448	746	74.5	149	Roche Cobas e402/e801 Gen II
	µg/dl	21.5	16.1	26.9	2.70	5.40	
	nmol/l	592	444	740	74.0	148	Roche Cobas e601/ 602
	µg/dl	21.3	16.0	26.6	2.65	5.30	
	nmol/l	601	451	751	75.0	150	Roche Cobas e601/602 Gen II
	µg/dl	21.6	16.2	27.0	2.70	5.40	
	nmol/l	623	467	779	78.0	156	Siemens Atellica IM
	µg/dl	22.4	16.8	28.0	2.80	5.60	
	nmol/l	518	389	647	64.5	129	Siemens/DPC Immulite 2000/2500
	µg/dl	18.6	14.0	23.2	2.30	4.60	
DHEA-S	µmol/l	10.5	8.40	12.6	1.05	2.10	Abbott Alinity i
	µmol/l	10.2	8.16	12.2	1.00	2.00	Abbott Architect
	µmol/l	8.94	7.15	10.7	0.880	1.76	Beckman Access/LXi725
	µmol/l	8.94	7.15	10.7	0.880	1.76	
	µmol/l	8.42	6.74	10.1	0.840	1.68	Beckman DxI 600/800
	µmol/l	8.31	6.65	9.97	0.830	1.66	Beckman DXI9000
	µmol/l	8.31	6.65	9.97	0.830	1.66	
	µmol/l	10.8	8.64	13.0	1.10	2.20	Mindray CL 900 Series
	µmol/l	10.8	8.64	13.0	1.10	2.20	
	µmol/l	10.7	8.56	12.8	1.05	2.10	Mindray CL series (Excl. CL 900 series)
	µmol/l	10.7	8.56	12.8	1.05	2.10	
	µmol/l	11.0	8.80	13.2	1.10	2.20	Roche Cobas e402/e801
	µmol/l	11.3	9.04	13.6	1.15	2.30	Roche Cobas e601/ 602
	µmol/l	8.14	6.51	9.77	0.815	1.63	Siemens/DPC Immulite 2000/2500
Digoxin	ng/ml	2.43	1.94	2.92	0.245	0.490	Beckman AU Instruments
	nmol/l	3.11	2.49	3.73	0.310	0.620	

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Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Digoxin	ng/ml	2.33	1.86	2.80	0.235	0.470	Beckman DxI 600/800
	nmol/l	2.98	2.38	3.58	0.300	0.600	
	ng/ml	2.42	1.94	2.90	0.240	0.480	Roche Cobas e402/e801
	nmol/l	3.10	2.48	3.72	0.310	0.620	
Ferritin	ng/ml = µg/l	99.6	79.7	120	10.2	20.4	Abbott Architect Chemilum
	ng/ml = µg/l	61.4	49.1	73.7	6.15	12.3	Beckman DXI9000
	ng/ml = µg/l	76.6	61.3	91.9	7.65	15.3	bioMerieux, VIDAS
	ng/ml = µg/l	85.4	68.3	103	8.80	17.6	Mindray CL series (Excl. CL 900 series)
	ng/ml = µg/l	59.5	47.6	71.4	5.95	11.9	Ortho Vitros 3600/5600/ECi/XT/7600
	ng/ml = µg/l	92.1	73.7	111	9.45	18.9	Roche Cobas C303/501/502/503/701/702
	ng/ml = µg/l	98.3	78.6	118	9.85	19.7	Roche Cobas e402/e801
	ng/ml = µg/l	107	85.6	128	10.5	21.0	Roche Elecsys / Cobas e411
	ng/ml = µg/l	102	81.6	122	10.0	20.0	Roche Modular E170 /Cobas e601/602
	ng/ml = µg/l	64.0	51.2	76.8	6.40	12.8	Siemens Atellica IM
	ng/ml = µg/l	67.3	53.8	80.8	6.75	13.5	Siemens Centaur
Folate	ng/ml	5.12	3.89	6.35	0.615	1.23	Abbott Alinity i
	nmol/l	11.6	8.82	14.4	1.40	2.80	
	ng/ml	4.31	3.28	5.34	0.515	1.03	Abbott Architect
	nmol/l	9.78	7.43	12.1	1.16	2.32	
	ng/ml	5.38	4.09	6.67	0.645	1.29	Beckman DxI 600/800 - A14208
	nmol/l	12.2	9.27	15.1	1.45	2.90	
	ng/ml	5.38	4.09	6.67	0.645	1.29	Beckman DxI 600/800 - A98032
	nmol/l	12.2	9.27	15.1	1.45	2.90	
	ng/ml	6.00	5.04	6.96	0.480	0.960	Beckman DXI9000
	nmol/l	13.6	11.4	15.8	1.10	2.20	
	ng/ml	3.08	2.34	3.82	0.370	0.740	Ortho Vitros 3600/5600/ECi/XT/7600
	nmol/l	6.99	5.31	8.67	0.840	1.68	

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Method				Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)			
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Folate	ng/ml	4.25	3.23	5.27	0.510	1.02	Roche e402/e801
	nmol/l	9.64	7.33	12.0	1.18	2.36	
	ng/ml	9.22	7.01	11.4	1.09	2.18	Siemens Atellica IM
	nmol/l	20.9	15.9	25.9	2.50	5.00	
	ng/ml	3.55	2.70	4.40	0.425	0.850	Siemens/DPC Immulite 2000
	nmol/l	8.04	6.11	9.97	0.965	1.93	
Free T3	ng/dl	0.767	0.575	0.959	0.096	0.192	Abbott Alinity, 2 point cal
	pg/ml	7.68	5.76	9.60	0.960	1.92	
	pmol/l	11.8	8.85	14.8	1.50	3.00	
	ng/dl	0.761	0.571	0.951	0.095	0.190	Abbott Alinity, 6 point cal
	pg/ml	7.62	5.72	9.52	0.950	1.90	
	pmol/l	11.7	8.78	14.6	1.45	2.90	
	ng/dl	0.722	0.542	0.902	0.090	0.180	Abbott Architect, 2 point cal
	pg/ml	7.23	5.42	9.04	0.905	1.81	
	pmol/l	11.1	8.33	13.9	1.40	2.80	
	ng/dl	0.741	0.556	0.926	0.093	0.185	Abbott Architect, 6 point cal
	pg/ml	7.42	5.57	9.27	0.925	1.85	
	pmol/l	11.4	8.55	14.3	1.45	2.90	
	ng/dl	0.657	0.493	0.821	0.082	0.164	Beckman DXI9000
	pg/ml	6.58	4.94	8.22	0.820	1.64	
	pmol/l	10.1	7.58	12.6	1.25	2.50	
	ng/dl	1.72	1.29	2.15	0.215	0.430	Ortho Vitros 3600/5600/ECi/XT 7600
	pg/ml	17.3	13.0	21.6	2.15	4.30	
	pmol/l	26.5	19.9	33.1	3.30	6.60	
	ng/dl	0.884	0.663	1.11	0.113	0.226	Roche Cobas 4000/e411
	pg/ml	8.85	6.64	11.1	1.13	2.25	
	pmol/l	13.6	10.2	17.0	1.70	3.40	
	ng/dl	0.878	0.659	1.10	0.111	0.222	Roche Cobas e402/e801
	pg/ml	8.79	6.59	11.0	1.11	2.21	
	pmol/l	13.5	10.1	16.9	1.70	3.40	
	ng/dl	0.878	0.659	1.10	0.111	0.222	Roche Cobas e601/ 602
	pg/ml	8.79	6.59	11.0	1.11	2.21	
	pmol/l	13.5	10.1	16.9	1.70	3.40	
	ng/dl	0.826	0.620	1.03	0.102	0.204	Siemens Atellica IM
	pg/ml	8.27	6.20	10.3	1.02	2.03	
	pmol/l	12.7	9.53	15.9	1.60	3.20	
Free T4	ng/dl	1.63	1.22	2.04	0.205	0.410	Abbott Alinity i
	pg/ml	16.3	12.2	20.4	2.05	4.10	
	pmol/l	20.9	15.7	26.1	2.60	5.20	

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Method				Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)			
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Free T4	ng/dl	1.70	1.28	2.12	0.210	0.420	Abbott Architect
	pg/ml	17.0	12.8	21.2	2.10	4.20	
	pmol/l	21.8	16.4	27.2	2.70	5.40	
	ng/dl	1.66	1.25	2.07	0.205	0.410	Beckman Access REF C76421
	pg/ml	16.6	12.5	20.7	2.05	4.10	
	pmol/l	21.3	16.0	26.6	2.65	5.30	
	ng/dl	1.67	1.25	2.09	0.210	0.420	Beckman DXI 600/800 REF C76421
	pg/ml	16.7	12.5	20.9	2.10	4.20	
	pmol/l	21.4	16.1	26.7	2.65	5.30	
	ng/dl	1.68	1.26	2.10	0.210	0.420	Beckman DXI9000
	pg/ml	16.8	12.6	21.0	2.10	4.20	
	pmol/l	21.5	16.1	26.9	2.70	5.40	
	ng/dl	4.59	3.44	5.74	0.575	1.15	Ortho Vitros 3600/5600/ECi/XT/7600
	pg/ml	45.9	34.4	57.4	5.75	11.5	
	pmol/l	58.9	44.2	73.6	7.35	14.7	
	ng/dl	2.15	1.61	2.69	0.270	0.540	Roche Cobas 4000/e411
	pg/ml	21.5	16.1	26.9	2.70	5.40	
	pmol/l	27.6	20.7	34.5	3.45	6.90	
	ng/dl	2.20	1.65	2.75	0.275	0.550	Roche Cobas e402/e801
	pg/ml	22.0	16.5	27.5	2.75	5.50	
	pmol/l	28.2	21.2	35.2	3.50	7.00	
	ng/dl	2.19	1.64	2.74	0.275	0.550	Roche Cobas e601/ 602
	pg/ml	21.9	16.4	27.4	2.75	5.50	
	pmol/l	28.1	21.1	35.1	3.50	7.00	
	ng/dl	1.70	1.28	2.12	0.210	0.420	Siemens Atellica IM
	pg/ml	17.0	12.8	21.2	2.10	4.20	
	pmol/l	21.8	16.4	27.2	2.70	5.40	
	ng/dl	1.66	1.25	2.07	0.205	0.410	Siemens Centaur
	pg/ml	16.6	12.5	20.7	2.05	4.10	
	pmol/l	21.3	16.0	26.6	2.65	5.30	
FSH	mU/ml	22.5	18.0	27.0	2.25	4.50	Abbott Alinity i
	mU/ml	22.8	18.2	27.4	2.30	4.60	Abbott Architect
	mU/ml	28.2	22.6	33.8	2.80	5.60	Beckman DXI9000
	mU/ml	28.3	22.6	34.0	2.85	5.70	bioMerieux, VIDAS
	mU/ml	22.1	17.7	26.5	2.20	4.40	Roche Cobas e402/e801
	mU/ml	22.5	18.0	27.0	2.25	4.50	Roche Cobas e601/602
	mU/ml	29.9	23.9	35.9	3.00	6.00	Siemens Atellica IM
Gentamicin	µg/ml	2.55	2.04	3.06	0.255	0.510	Beckman Coulter Analysers
	µmol/l	5.33	4.26	6.40	0.535	1.07	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Growth Hormone (GH)	ng/ml	5.39	4.31	6.47	0.540	1.08	Beckman Access/LXi725
	µU/ml	16.2	13.0	19.4	1.60	3.20	
	ng/ml	5.56	4.45	6.67	0.555	1.11	Beckman DXI9000
	µU/ml	16.7	13.4	20.0	1.65	3.30	
	ng/ml	5.63	4.50	6.76	0.565	1.13	DiaSorin Liaison XL
	µU/ml	16.9	13.5	20.3	1.70	3.40	
	ng/ml	6.59	5.27	7.91	0.660	1.32	Roche Cobas e402/e801
	µU/ml	19.8	15.8	23.8	2.00	4.00	
	ng/ml	7.09	5.67	8.51	0.710	1.42	Siemens/DPC Immulite 2000/2500
	µU/ml	21.3	17.0	25.6	2.15	4.30	
Immunoglobulin E	KIU/l = IU/ml	80.4	64.3	96.5	8.05	16.1	Abbott Architect
	KIU/l = IU/ml	90.2	72.2	108	8.90	17.8	bioMerieux, VIDAS
	KIU/l = IU/ml	113	90.4	136	11.5	23.0	Roche Cobas 4000/e411
	KIU/l = IU/ml	105	84.0	126	10.5	21.0	Roche Cobas e402/e801
	KIU/l = IU/ml	103	82.4	124	10.5	21.0	Roche Cobas e601/ 602
	KIU/l = IU/ml	95.4	76.3	115	9.80	19.6	Siemens Atellica IM
Insulin	mU/l	9.84	7.38	12.3	1.23	2.46	Abbott Alinity i
	µU/ml	9.84	7.38	12.3	1.23	2.46	
	mU/l	10.8	8.10	13.5	1.35	2.70	Abbott Architect
	µU/ml	10.8	8.10	13.5	1.35	2.70	
	mU/l	10.9	8.72	13.1	1.10	2.20	Beckman Access/LXi725
	µU/ml	10.9	8.72	13.1	1.10	2.20	
	mU/l	10.5	8.40	12.6	1.05	2.10	Beckman DxI 600/800
	µU/ml	10.5	8.40	12.6	1.05	2.10	

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Method				Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)			
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Insulin	mU/l	10.9	8.72	13.1	1.10	2.20	Beckman DXI9000
	µU/ml	10.9	8.72	13.1	1.10	2.20	
	mU/l	10.9	8.72	13.1	1.10	2.20	
	µU/ml	10.9	8.72	13.1	1.10	2.20	
	mU/l	14.0	10.5	17.5	1.75	3.50	Roche Cobas 6000/8000
	µU/ml	14.0	10.5	17.5	1.75	3.50	
	mU/l	12.6	9.45	15.8	1.60	3.20	Siemens Atellica IM
	µU/ml	12.6	9.45	15.8	1.60	3.20	
Luteinising Hormone (LH)	mU/ml	25.4	20.3	30.5	2.55	5.10	Abbott Alinity i
	mU/ml	26.3	21.0	31.6	2.65	5.30	Abbott Architect
	mU/ml	29.2	23.4	35.0	2.90	5.80	Beckman DXI9000
	mU/ml	32.1	25.7	38.5	3.20	6.40	bioMerieux, VIDAS
	mU/ml	34.9	27.9	41.9	3.50	7.00	Roche Cobas 4000/e411
	mU/ml	32.7	26.2	39.2	3.25	6.50	Roche Cobas e402/e801
	mU/ml	34.6	27.7	41.5	3.45	6.90	Roche Cobas e601/ 602
	mU/ml	32.6	26.1	39.1	3.25	6.50	Siemens Atellica IM
Oestradiol	pg/ml	194	155	233	19.5	39.0	Abbott Alinity i
	pmol/l	712	570	854	71.0	142	
	pg/ml	195	156	234	19.5	39.0	Abbott Architect
	pmol/l	718	574	862	72.0	144	
	pg/ml	255	204	306	25.5	51.0	Beckman Access/LXi725 Sensitive B84493
	pmol/l	937	750	1124	93.5	187	
	pg/ml	229	183	275	23.0	46.0	Beckman DxI 600/800 Sensitive B84493
	pmol/l	843	674	1012	84.5	169	
	pg/ml	239	191	287	24.0	48.0	Beckman DxI 9000
	pmol/l	877	702	1052	87.5	175	
	pg/ml	396	317	475	39.5	79.0	bioMerieux, VIDAS
	pmol/l	1455	1164	1746	146	291	
	pg/ml	198	158	238	20.0	40.0	Roche Cobas 4000/e411 (Estradiol III)
	pmol/l	728	582	874	73.0	146	
	pg/ml	212	170	254	21.0	42.0	Roche Cobas e402/e801 (Estradiol III)
	pmol/l	778	622	934	78.0	156	
	pg/ml	205	164	246	20.5	41.0	Roche Cobas e601/ 602 (Estradiol III)
	pmol/l	753	602	904	75.5	151	
	pg/ml	309	247	371	31.0	62.0	Siemens Atellica IM
	pmol/l	1137	910	1364	114	227	
Paracetamol	mg/l	51.8	41.4	62.2	5.20	10.4	Beckman AU Instruments
	mmol/l	0.342	0.274	0.410	0.034	0.068	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Phenobarbital	µg/ml	16.4	13.1	19.7	1.65	3.30	Beckman AU Instruments
	µmol/l	70.7	56.6	84.8	7.05	14.1	
	µg/ml	17.0	13.6	20.4	1.70	3.40	Roche Cobas C303/501/502/503/701
	µmol/l	73.3	58.6	88.0	7.35	14.7	
	µg/ml	17.1	13.7	20.5	1.70	3.40	Siemens/DPC Immulite 2000/2500
	µmol/l	73.7	59.0	88.4	7.35	14.7	
Phenytoin	µg/ml	16.9	13.5	20.3	1.70	3.40	Beckman AU Instruments
	µmol/l	66.9	53.5	80.3	6.70	13.4	
	µg/ml	16.8	13.4	20.2	1.70	3.40	Roche Cobas 6000/8000
	µmol/l	66.5	53.2	79.8	6.65	13.3	
Progesterone	ng/ml	6.64	5.31	7.97	0.665	1.33	Abbott Alinity i
	nmol/l	21.2	17.0	25.4	2.10	4.20	
	ng/ml	7.17	5.74	8.60	0.715	1.43	Abbott Architect
	nmol/l	22.9	18.3	27.5	2.30	4.60	
	ng/ml	8.80	7.04	10.6	0.900	1.80	Beckman Access Prog. Cal 33555
	nmol/l	28.1	22.5	33.7	2.80	5.60	
	ng/ml	8.04	6.43	9.65	0.805	1.61	Beckman Access Prog.DE Cal. A80773
	nmol/l	25.7	20.6	30.8	2.55	5.10	
	ng/ml	8.70	6.96	10.4	0.850	1.70	Beckman Access Progesterone II
	nmol/l	27.8	22.2	33.4	2.80	5.60	
	ng/ml	8.42	6.74	10.1	0.840	1.68	Beckman DXI Prog. Cal 33555
	nmol/l	26.9	21.5	32.3	2.70	5.40	
	ng/ml	8.14	6.51	9.77	0.815	1.63	Beckman DXI Progesterone II
	nmol/l	26.0	20.8	31.2	2.60	5.20	
	ng/ml	7.20	5.76	8.64	0.720	1.44	Beckman DXI9000
	nmol/l	23.0	18.4	27.6	2.30	4.60	
	ng/ml	8.36	6.69	10.0	0.820	1.64	Roche Cobas 4000/e411 (Prog. III)
	nmol/l	26.7	21.4	32.0	2.65	5.30	
	ng/ml	8.54	6.83	10.3	0.880	1.76	Roche Cobas e402/e801 (Prog III)
	nmol/l	27.3	21.8	32.8	2.75	5.50	
	ng/ml	8.73	6.98	10.5	0.885	1.77	Roche Cobas e601/ 602 (Prog. III)
	nmol/l	27.9	22.3	33.5	2.80	5.60	
	ng/ml	6.48	5.18	7.78	0.650	1.30	Siemens Atellica IM
	nmol/l	20.7	16.6	24.8	2.05	4.10	
	ng/ml	6.89	5.51	8.27	0.690	1.38	Siemens/DPC Immulite 2000/2500
	nmol/l	22.0	17.6	26.4	2.20	4.40	
Prolactin	µIU/mL	719	575	863	72.0	144	Abbott Alinity i
	µIU/mL	701	561	841	70.0	140	Abbott Architect
	µIU/mL	576	461	691	57.5	115	Beckman DXI9000

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Prolactin	µIU/mL	779	623	935	78.0	156	bioMerieux, VIDAS
	µIU/mL	755	604	906	75.5	151	Roche Cobas 4000/e411
	µIU/mL	699	559	839	70.0	140	Roche Cobas e402/e801 PRL II
	µIU/mL	731	585	877	73.0	146	Roche Cobas e601/ 602
	µIU/mL	451	361	541	45.0	90.0	Siemens Atellica IM
PSA Free	ng/ml = µg/l	12.7	9.53	15.9	1.60	3.20	Abbott Alinity i
	ng/ml = µg/l	12.6	9.45	15.8	1.60	3.20	Abbott Architect
	ng/ml = µg/l	12.6	9.45	15.8	1.60	3.20	Beckman Access standardised to Hybritech
	ng/ml = µg/l	12.5	9.38	15.6	1.55	3.10	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	12.5	9.38	15.6	1.55	3.10	Beckman DXI9000
	ng/ml = µg/l	9.44	7.08	11.8	1.18	2.36	Roche Cobas 4000/e411
	ng/ml = µg/l	8.81	6.61	11.0	1.10	2.19	Roche Cobas e402/e801
	ng/ml = µg/l	9.22	6.92	11.5	1.14	2.28	Roche Cobas e601/602
PSA Total	ng/ml = µg/l	10.1	7.58	12.6	1.25	2.50	Abbott Alinity i
	ng/ml = µg/l	10.5	7.88	13.1	1.30	2.60	Abbott Architect
	ng/ml = µg/l	12.9	9.68	16.1	1.60	3.20	Beckman DXI standard to WHO IRP96/670
	ng/ml = µg/l	16.2	12.2	20.2	2.00	4.00	Beckman DXI standardised to Hybritech
	ng/ml = µg/l	16.7	12.5	20.9	2.10	4.20	Beckman DXI9000
	ng/ml = µg/l	13.4	10.1	16.7	1.65	3.30	Ortho Vitros 3600/5600/ECi PSA II/XT7600
	ng/ml = µg/l	14.6	11.0	18.2	1.80	3.60	Roche Cobas 4000/e411
	ng/ml = µg/l	13.6	10.2	17.0	1.70	3.40	Roche Cobas e402/e801
	ng/ml = µg/l	13.9	10.4	17.4	1.75	3.50	Roche Cobas e601/602

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
PSA Total	ng/ml = µg/l	12.9	9.68	16.1	1.60	3.20	Siemens Atellica IM
	ng/ml = µg/l	13.1	9.83	16.4	1.65	3.30	Siemens Centaur
SHBG	nmol/l	36.3	29.0	43.6	3.65	7.30	Abbott Alinity i
	nmol/l	35.0	28.0	42.0	3.50	7.00	Abbott Architect
	nmol/l	32.4	25.9	38.9	3.25	6.50	Beckman Access
	nmol/l	32.6	26.1	39.1	3.25	6.50	Beckman DxI 600/800
	nmol/l	33.2	26.6	39.8	3.30	6.60	Roche analysers
	nmol/l	30.8	24.6	37.0	3.10	6.20	Roche e402/e801
	nmol/l	31.8	25.4	38.2	3.20	6.40	Siemens/DPC Immulite 2000/2500
Testosterone	ng/dl	363	290	436	36.5	73.0	Abbott Alinity i
	ng/ml	3.63	2.90	4.36	0.365	0.730	
	nmol/l	12.6	10.1	15.1	1.25	2.50	
	ng/dl	363	290	436	36.5	73.0	Abbott Architect 2nd gen
	ng/ml	3.63	2.90	4.36	0.365	0.730	
	nmol/l	12.6	10.1	15.1	1.25	2.50	
	ng/dl	354	283	425	35.5	71.0	Beckman Access/LXi725
	ng/ml	3.54	2.83	4.25	0.355	0.710	
	nmol/l	12.3	9.84	14.8	1.25	2.50	
	ng/dl	331	265	397	33.0	66.0	Beckman DXI9000
	ng/ml	3.31	2.65	3.97	0.330	0.660	
	nmol/l	11.5	9.20	13.8	1.15	2.30	
	ng/dl	389	311	467	39.0	78.0	Roche Cobas 4000/e411 Test II
	ng/ml	3.89	3.11	4.67	0.390	0.780	
	nmol/l	13.5	10.8	16.2	1.35	2.70	
	ng/dl	395	316	474	39.5	79.0	Roche Cobas e402/e801 Test II
	ng/ml	3.95	3.16	4.74	0.395	0.790	
	nmol/l	13.7	11.0	16.4	1.35	2.70	
	ng/dl	389	311	467	39.0	78.0	Roche Cobas e601/ 602 Test II
	ng/ml	3.89	3.11	4.67	0.390	0.780	
	nmol/l	13.5	10.8	16.2	1.35	2.70	
	ng/dl	363	290	436	36.5	73.0	Siemens Atellica IM
	ng/ml	3.63	2.90	4.36	0.365	0.730	
	nmol/l	12.6	10.1	15.1	1.25	2.50	
	ng/dl	392	314	470	39.0	78.0	Siemens/DPC Immulite 2000/2500
	ng/ml	3.92	3.14	4.70	0.390	0.780	
	nmol/l	13.6	10.9	16.3	1.35	2.70	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Theophylline	µg/ml	14.0	11.2	16.8	1.40	2.80	Beckman AU Instruments
	µmol/l	77.8	62.2	93.4	7.80	15.6	
Thyroglobulin	ng/ml	32.2	24.2	40.2	4.00	8.00	Abbott Alinity i
	ng/ml	27.4	20.6	34.2	3.40	6.80	Beckman Access
	ng/ml	29.6	22.2	37.0	3.70	7.40	Beckman Access (C71762)
	ng/ml	27.2	20.4	34.0	3.40	6.80	Beckman DxI 600/800
	ng/ml	33.3	25.0	41.6	4.15	8.30	Beckman IRMA
	ng/ml	32.2	24.2	40.2	4.00	8.00	Roche Cobas e402/e801 Tg II
	ng/ml	14.3	10.7	17.9	1.80	3.60	Siemens/DPC Immulite 2000/2500
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.34	1.87	2.81	0.235	0.470	Abbott Alinity i
	µU/ml = mIU/l	2.36	1.89	2.83	0.235	0.470	Abbott Architect
	µU/ml = mIU/l	2.53	2.02	3.04	0.255	0.510	Beckman DxI 600/800 1st generation
	µU/ml = mIU/l	2.53	2.02	3.04	0.255	0.510	
	µU/ml = mIU/l	2.52	2.02	3.02	0.250	0.500	Beckman DXI 600/800 Fast TSH
	µU/ml = mIU/l	2.52	2.02	3.02	0.250	0.500	
	µU/ml = mIU/l	2.59	2.07	3.11	0.260	0.520	Beckman DXI 600/800 Hyper TSH
	µU/ml = mIU/l	2.59	2.07	3.11	0.260	0.520	
	µU/ml = mIU/l	2.53	2.02	3.04	0.255	0.510	Beckman DXI 600/800/ Access 2 (3rd IS)
	µU/ml = mIU/l	2.53	2.02	3.04	0.255	0.510	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.56	2.05	3.07	0.255	0.510	Beckman DXI600/800/ Access 2 (3rd IS)
	µU/ml = mIU/l	2.76	2.21	3.31	0.275	0.550	Beckman DXI9000
	µU/ml = mIU/l	2.76	2.21	3.31	0.275	0.550	
	µU/ml = mIU/l	2.51	2.01	3.01	0.250	0.500	Ortho Vitros TSH3
	µU/ml = mIU/l	2.87	2.30	3.44	0.285	0.570	Roche Cobas 4000/e411
	µU/ml = mIU/l	2.72	2.18	3.26	0.270	0.540	Roche Cobas e402/e801
	µU/ml = mIU/l	2.93	2.34	3.52	0.295	0.590	Roche Cobas e601/ 602
	µU/ml = mIU/l	2.59	2.07	3.11	0.260	0.520	Siemens Atellica IM
	µU/ml = mIU/l	2.60	2.08	3.12	0.260	0.520	Siemens Centaur TSH3-Ultra
Total Beta hCG	IU/ml	0.019	0.015	0.023	0.002	0.004	Abbott Alinity i
	mU/ml = IU/l	18.5	14.8	22.2	1.85	3.70	
	IU/ml	0.018	0.014	0.022	0.002	0.004	Abbott Architect
	mU/ml = IU/l	18.2	14.6	21.8	1.80	3.60	
	IU/ml	0.047	0.038	0.056	0.005	0.009	Ortho Vitros 3600/5600/ECi/XT 7600
	mU/ml = IU/l	47.4	37.9	56.9	4.75	9.50	
	IU/ml	0.026	0.021	0.031	0.003	0.005	Roche hCG + Beta e402/e801
	mU/ml = IU/l	25.5	20.4	30.6	2.55	5.10	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Total Beta hCG	IU/ml	0.026	0.021	0.031	0.003	0.005	Roche hCG+Beta
	mU/ml = IU/l	25.9	20.7	31.1	2.60	5.20	
	IU/ml	0.017	0.014	0.020	0.002	0.003	Siemens Atellica IM
	mU/ml = IU/l	17.2	13.8	20.6	1.70	3.40	
	IU/ml	0.016	0.013	0.019	0.002	0.003	Siemens Centaur
	mU/ml = IU/l	16.4	13.1	19.7	1.65	3.30	
Total T3	ng/dl	210	158	262	26.0	52.0	Abbott Alinity i
	ng/ml	2.10	1.58	2.62	0.260	0.520	
	nmol/l	3.23	2.42	4.04	0.405	0.810	
	ng/dl	203	152	254	25.5	51.0	Abbott Architect
	ng/ml	2.03	1.52	2.54	0.255	0.510	
	nmol/l	3.12	2.34	3.90	0.390	0.780	
	ng/dl	232	174	290	29.0	58.0	Beckman DxI 600/800
	ng/ml	2.32	1.74	2.90	0.290	0.580	
	nmol/l	3.57	2.68	4.46	0.445	0.890	
	ng/dl	266	200	332	33.0	66.0	Ortho Vitros 3600/5600/ECi/XT/7600
	ng/ml	2.66	2.00	3.32	0.330	0.660	
	nmol/l	4.09	3.07	5.11	0.510	1.02	
	ng/dl	275	206	344	34.5	69.0	Roche Cobas e402/e801
	ng/ml	2.76	2.07	3.45	0.345	0.690	
	nmol/l	4.24	3.18	5.30	0.530	1.06	
	ng/dl	271	203	339	34.0	68.0	Siemens Atellica IM
	ng/ml	2.72	2.04	3.40	0.340	0.680	
	nmol/l	4.18	3.14	5.22	0.520	1.04	
Total T4	ng/ml	80.3	60.2	100	9.85	19.7	Abbott Alinity i
	nmol/l	103	77.3	129	13.0	26.0	
	µg/dl	8.03	6.02	10.0	0.985	1.97	
	ng/ml	79.6	59.7	99.5	9.95	19.9	Abbott Architect
	nmol/l	102	76.5	128	13.0	26.0	
	µg/dl	7.96	5.97	9.95	0.995	1.99	
	ng/ml	81.1	60.8	101	9.95	19.9	Beckman DxI 600/800
	nmol/l	104	78.0	130	13.0	26.0	
	µg/dl	8.11	6.08	10.1	0.995	1.99	
	ng/ml	88.1	66.1	110	11.0	21.9	Roche Cobas 4000/e411
	nmol/l	113	84.8	141	14.0	28.0	
	µg/dl	8.81	6.61	11.0	1.10	2.19	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Total T4	ng/ml	77.5	58.1	96.9	9.70	19.4	Roche Cobas e402/e801
	nmol/l	99.4	74.6	124	12.3	24.6	
	µg/dl	7.75	5.81	9.69	0.970	1.94	
	ng/ml	86.6	65.0	108	10.7	21.4	Siemens Atellica IM
	nmol/l	111	83.3	139	14.0	28.0	
	µg/dl	8.66	6.50	10.8	1.07	2.14	
	ng/ml	85.8	64.4	107	10.6	21.2	Siemens/DPC Immulite 2000/2500
	nmol/l	110	82.5	138	14.0	28.0	
	µg/dl	8.58	6.44	10.7	1.06	2.12	
Valproic Acid	µg/ml	83.0	66.4	99.6	8.30	16.6	Abbott Architect (CMIA)
	µmol/l	575	460	690	57.5	115	
	µg/ml	93.1	74.5	112	9.45	18.9	Beckman AU Instruments
	µmol/l	645	516	774	64.5	129	
	µg/ml	85.0	68.0	102	8.50	17.0	Roche Cobas 6000/8000
	µmol/l	589	471	707	59.0	118	
Vancomycin	µg/ml	11.3	9.04	13.6	1.15	2.30	Abbott Architect (CMIA)
	µmol/l	7.60	6.08	9.12	0.760	1.52	
	µg/ml	9.82	7.86	11.8	0.990	1.98	Beckman Coulter Synchron LX / Unicel
	µmol/l	6.61	5.29	7.93	0.660	1.32	
Vitamin B12	pg/ml	400	320	480	40.0	80.0	Abbott Alinity i
	pmol/l	295	236	354	29.5	59.0	
	pg/ml	453	362	544	45.5	91.0	Abbott Architect
	pmol/l	334	267	401	33.5	67.0	
	pg/ml	527	422	632	52.5	105	Beckman Access Vit B12 II Cal Ref D06116
	pmol/l	389	311	467	39.0	78.0	
	pg/ml	393	314	472	39.5	79.0	Beckman DxI 600/800
	pmol/l	290	232	348	29.0	58.0	
	pg/ml	523	418	628	52.5	105	Beckman DXI 600/800 B12 II Cal D06116
	pmol/l	386	309	463	38.5	77.0	
	pg/ml	412	330	494	41.0	82.0	Beckman DXI9000
	pmol/l	304	243	365	30.5	61.0	
	pg/ml	511	409	613	51.0	102	Ortho Vitros 3600/5600/ECi/XT 7600
	pmol/l	377	302	452	37.5	75.0	
	pg/ml	554	443	665	55.5	111	Roche Cobas 4000/e411 Gen II
	pmol/l	409	327	491	41.0	82.0	
	pg/ml	539	431	647	54.0	108	Roche Cobas e402/e801 Gen II
	pmol/l	398	318	478	40.0	80.0	
	pg/ml	557	446	668	55.5	111	Roche Cobas e601/ 602 Gen II
	pmol/l	411	329	493	41.0	82.0	

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Method							Immunoassay Premium Plus - Level 2 (IA PREMIUM PLUS 2)
Lot. No: 2659EC/2 Cat. No: IA3110 Expiry: 2028/11/28							
Size: 12 x 5 ml / 4 x 5 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
Vitamin B12	pg/ml	547	438	656	54.5	109	Siemens Atellica IM lot <=13290
	pmol/l	404	323	485	40.5	81.0	
	pg/ml	524	419	629	52.5	105	Siemens Atellica IM lot 13291 and above
	pmol/l	387	310	464	38.5	77.0	
	pg/ml	509	407	611	51.0	102	Siemens/DPC Immulite 2000
	pmol/l	376	301	451	37.5	75.0	

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