PRODUCT INFORMATION

IA3112 lot 1937EC

Please note that analyte CA19-9 in Immunoassay Premium Plus Lot 1937EC does not meet the frozen stability claim and is therefore not suitable for freezing. Reconstituted, CA19-9 is stable for 7 days stored refrigerated at +2 - 8◦C, if kept capped in original container and free from contamination.

IA3112 lot 1942EC

Please note that analyte CA19-9 in Immunoassay Premium Plus Lot 1942EC does not meet the complete frozen stability claim and is therefore stable for 3 weeks frozen once stored at -20°C.

(OCC38148)

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

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

CAT. NO.	IA3109	**GTIN:**	05055273207255	**SIZE:**	12 x 5 ml
CAT. NO.	IA3112	**GTIN:**	05055273207286	**SIZE:**	4 x 5 ml
LOT NO.	1937EC	**EXPIRY:**	2022-12-28		

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. CA19-9 is stable for 7 days at +2°C to +8°C. CA19-9 in this lot is NOT suitable for freezing.
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 1: 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. Aldosterone is present in control levels 2 and level 3 only. 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 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112 Lot No. 1937EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Alpha-fetoprotein	KIU/l = IU/ml	8.83	7.06	10.6	Beckman Access / Access 2
	ng/ml	10.7	8.56	12.8	
	KIU/l = IU/ml	8.76	7.01	10.5	Beckman DxI600/800
	ng/ml	10.6	8.48	12.7	
CA 15-3	U/ml	7.43	5.94	8.92	Beckman Access / Access 2
	U/ml	7.30	5.84	8.76	Beckman DxI600/800
CA 19-9	U/ml	53.1	42.5	63.7	Beckman Access / Access 2
	U/ml	44.9	35.9	53.9	Beckman DxI600/800
CA125	U/ml	17.9	14.3	21.5	Beckman Access / Access 2
	U/ml	17.2	13.8	20.6	Beckman DxI600/800
Carcinoembryonic	ng/ml = µg/l	4.52	3.62	5.42	Beckman Access / Access 2
Antigen (CEA)	ng/ml = µg/l	4.34	3.47	5.21	Beckman DxI600/800
Cortisol	nmol/l	180	135	225	Beckman Access / Access 2
	µg/dl	6.48	4.86	8.10	
	nmol/l	178	134	222	Beckman DxI600/800
	µg/dl	6.41	4.81	8.01	
DHEA-S	µmol/l	2.29	1.83	2.75	Beckman Access / Access 2
	µg/dl	84.4	67.5	101	
	µmol/l	2.20	1.76	2.64	Beckman DxI600/800
	µg/dl	81.1	64.9	97.3	
Digoxin	nmol/l	0.838	0.670	1.01	Beckman Access / Access 2
	ng/ml	0.654	0.523	0.785	
	nmol/l	0.734	0.587	0.881	Beckman DxI600/800
	ng/ml	0.573	0.458	0.688	
Ferritin	ng/ml = µg/l	13.1	10.5	15.7	Beckman Access / Access 2
	ng/ml = µg/l	12.8	10.2	15.4	Beckman DxI600/800
Folate	nmol/l	3.53	2.68	4.38	Beckman Access / Access 2
	ng/ml	1.56	1.19	1.93	
	nmol/l	3.73	2.83	4.63	Beckman DxI600/800
	ng/ml	1.64	1.25	2.03	
Free T3	pmol/l	3.12	2.34	3.90	Beckman Access / Access 2
	ng/dl	0.203	0.152	0.254	
	pg/ml	2.03	1.52	2.54	
	pmol/l	3.13	2.35	3.91	Beckman DxI600/800
	ng/dl	0.203	0.152	0.254	
	pg/ml	2.04	1.53	2.55	
Free T4	pmol/l	9.37	7.03	11.7	Beckman Access / Access 2
	ng/dl	0.731	0.548	0.914	
	pg/ml	7.31	5.48	9.14	
	pmol/l	9.46	7.10	11.8	Beckman DxI600/800
	ng/dl	0.738	0.554	0.922	
	pg/ml	7.38	5.54	9.22	
FSH	mU/ml	6.90	5.52	8.28	Beckman Access / Access 2
	mU/ml	6.88	5.50	8.26	Beckman DxI600/800
Growth Hormone (GH)	µU/ml	3.64	2.91	4.37	Beckman Access / Access 2
	ng/ml	1.21	0.968	1.45	
	µU/ml	3.59	2.87	4.31	Beckman DxI600/800
	ng/ml	1.20	0.960	1.44	
Immunoglobulin E	KIU/l = IU/ml	TBC			Beckman Access / Access 2
	KIU/l = IU/ml	217	174	260	Beckman DxI600/800
Insulin	mU/l	0.823	0.617	1.03	Beckman Access / Access 2
	mU/l	0.780	0.585	0.975	Beckman DxI600/800
Luteinising Hormone (LH)	mU/ml	2.33	1.86	2.80	Beckman Access / Access 2
	mU/ml	2.26	1.81	2.71	Beckman DxI600/800

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

Cat. No. IA3109 / IA3112 Lot No. 1937EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Oestradiol	pmol/l	125	100	150	Beckman Access / Access 2
	pg/ml	34.0	27.2	40.8	
	pmol/l	135	108	162	Beckman Access / Access 2 Sensitive B84493
	pg/ml	36.7	29.4	44.0	
	pmol/l	123	98.4	148	Beckman DxI600/800
	pg/ml	33.5	26.8	40.2	
	pmol/l	128	102	154	Beckman DxI600/800 Sensitive B84493
	pg/ml	34.8	27.8	41.8	
Progesterone	nmol/l	3.08	2.46	3.70	Beckman Access / Access 2 Prog Cal 33555
	ng/ml	0.964	0.771	1.16	
	nmol/l	1.52	1.22	1.82	Beckman Access / Access 2 Prog DE Cal A80773
	ng/ml	0.476	0.381	0.571	
	nmol/l	2.71	2.17	3.25	Beckman DxI600/800 Prog Cal 33555
	ng/ml	0.848	0.678	1.02	
	nmol/l	1.64	1.31	1.97	Beckman DxI600/800 Prog DE Cal A80773
	ng/ml	0.513	0.410	0.616	
Prolactin	µU/ml	113	90.4	136	Beckman Access / Access 2
	µg/l	5.33	4.26	6.40	
	µU/ml	108	86.4	130	Beckman DxI600/800
	µg/l	5.10	4.08	6.12	
PSA Free	ng/ml = µg/l	1.50	1.13	1.87	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	1.48	1.11	1.85	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	1.39	1.04	1.74	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	1.29	0.968	1.61	Beckman DxI600/800 standardised to WHO IRP96/670
PSA Total	ng/ml = µg/l	2.10	1.58	2.62	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	2.06	1.55	2.57	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	2.05	1.54	2.56	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	1.71	1.28	2.14	Beckman DxI600/800 standardised to WHO IRP96/670
SHBG	nmol/l	11.5	9.20	13.8	Beckman Access / Access 2
	nmol/l	11.7	9.36	14.0	Beckman DxI600/800
Testosterone	nmol/l	1.70	1.36	2.04	Beckman Access / Access 2
	ng/ml	0.490	0.392	0.588	
	ng/dl	49.0	39.2	58.8	
	nmol/l	1.55	1.24	1.86	Beckman DxI600/800
	ng/ml	0.446	0.357	0.535	
	ng/dl	44.6	35.7	53.5	
Thyroglobulin	ng/ml	1.51	1.13	1.89	Beckman Access / Access 2
	ng/ml	1.44	1.08	1.80	Beckman DxI600/800
Thyroid Stimulating Hormone	µU/ml = mIU/l	0.080	0.064	0.096	Beckman Access / Access 2 Fast TSH
	µU/ml = mIU/l	0.078	0.062	0.094	Beckman Access / Access 2 hyperTSH 3rd Generation
	µU/ml = mIU/l	0.074	0.059	0.089	Beckman DxI600/800
	µU/ml = mIU/l	0.076	0.061	0.091	Beckman DxI600/800 Fast TSH
	µU/ml = mIU/l	0.074	0.059	0.089	Beckman DxI600/800 Hyper TSH
	µU/ml = mIU/l	0.075	0.060	0.090	Beckman DxI600/800 Access (3rd IS)

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

Cat. No. IA3109 / IA3112 Lot No. 1937EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Total Beta hCG	mU/ml = lU/l	10.2	8.16	12.2	Beckman Access / Access 2
	IU/ml	0.010	0.008	0.012	
	mU/ml = lU/l	10.3	8.24	12.4	Beckman Access / Access 2 Total BhCG (5th IS)
	IU/ml	0.010	0.008	0.012	
	mU/ml = lU/l	10.3	8.24	12.4	Beckman DxI600/800
	IU/ml	0.010	0.008	0.012	
	mU/ml = lU/l	10.3	8.24	12.4	Beckman DxI600/800 Total BhCG (5th IS)
	IU/ml	0.010	0.008	0.012	
Total T3	nmol/l	1.05	0.788	1.31	Beckman Access / Access 2
	ng/ml	0.684	0.513	0.855	
	ng/dl	68.4	51.3	85.5	
	nmol/l	0.902	0.677	1.13	Beckman DxI600/800
	ng/ml	0.587	0.440	0.734	
	ng/dl	58.7	44.0	73.4	
Total T4	nmol/l	21.6	16.2	27.0	Beckman Access / Access 2
	µg/dl	1.68	1.26	2.10	
	ng/ml	16.8	12.6	21.0	
	nmol/l	16.9	12.7	21.1	Beckman DxI600/800
	µg/dl	1.32	0.990	1.65	
	ng/ml	13.2	9.90	16.5	
Vitamin B12	pmol/l	86.8	69.4	104	Beckman Access / Access 2
	pg/ml	118	94.4	142	
	pmol/l	86.2	69.0	103	Beckman DxI600/800
	pg/ml	117	93.6	140	

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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. 1939EC **EXPIRY:** 2022-12-28

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. Aldosterone is present in control levels 2 and level 3 only. 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. 1939EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Alpha-fetoprotein	KIU/l = IU/ml	43.9	35.1	52.7	Beckman Access / Access 2
	ng/ml	53.1	42.5	63.7	
	KIU/l = IU/ml	41.3	33.0	49.6	Beckman DxI600/800
	ng/ml	50.0	40.0	60.0	
CA 15-3	U/ml	18.1	14.5	21.7	Beckman Access / Access 2
	U/ml	18.4	14.7	22.1	Beckman DxI600/800
CA 19-9	U/ml	82.2	65.8	98.6	Beckman Access / Access 2
	U/ml	70.8	56.6	85.0	Beckman DxI600/800
CA125	U/ml	70.1	56.1	84.1	Beckman Access / Access 2
	U/ml	67.9	54.3	81.5	Beckman DxI600/800
Carcinoembryonic	ng/ml = µg/l	24.9	19.9	29.9	Beckman Access / Access 2
Antigen (CEA)	ng/ml = µg/l	23.3	18.6	28.0	Beckman DxI600/800
Cortisol	nmol/l	607	455	759	Beckman Access / Access 2
	µg/dl	21.9	16.4	27.4	
	nmol/l	558	419	697	Beckman DxI600/800
	µg/dl	20.1	15.1	25.1	
DHEA-S	µmol/l	12.2	9.76	14.6	Beckman Access / Access 2
	µg/dl	450	360	540	
	µmol/l	11.5	9.20	13.8	Beckman DxI600/800
	µg/dl	424	339	509	
Digoxin	nmol/l	3.00	2.40	3.60	Beckman Access / Access 2
	ng/ml	2.34	1.87	2.81	
	nmol/l	3.03	2.42	3.64	Beckman DxI600/800
	ng/ml	2.37	1.90	2.84	
Ferritin	ng/ml = µg/l	69.1	55.3	82.9	Beckman Access / Access 2
	ng/ml = µg/l	67.0	53.6	80.4	Beckman DxI600/800
Folate	nmol/l	9.37	7.12	11.6	Beckman Access / Access 2
	ng/ml	4.13	3.14	5.12	
	nmol/l	9.75	7.41	12.1	Beckman DxI600/800
	ng/ml	4.30	3.27	5.33	
Free T3	pmol/l	10.8	8.10	13.5	Beckman Access / Access 2
	ng/dl	0.702	0.527	0.877	
	pg/ml	7.03	5.27	8.79	
	pmol/l	9.47	7.10	11.8	Beckman DxI600/800
	ng/dl	0.616	0.462	0.770	
	pg/ml	6.16	4.62	7.70	
Free T4	pmol/l	22.5	16.9	28.1	Beckman Access / Access 2
	ng/dl	1.76	1.32	2.20	
	pg/ml	17.6	13.2	22.0	
	pmol/l	21.8	16.4	27.2	Beckman DxI600/800
	ng/dl	1.70	1.28	2.12	
	pg/ml	17.0	12.8	21.2	
FSH	mU/ml	31.1	24.9	37.3	Beckman Access / Access 2
	mU/ml	31.8	25.4	38.2	Beckman DxI600/800
Growth Hormone (GH)	µU/ml	15.3	12.2	18.4	Beckman Access / Access 2
	ng/ml	5.09	4.07	6.11	
	µU/ml	14.4	11.5	17.3	Beckman DxI600/800
	ng/ml	4.80	3.84	5.76	
Immunoglobulin E	KIU/l = IU/ml	TBC			Beckman Access / Access 2
	KIU/l = IU/ml	TBC			Beckman DxI600/800
Insulin	mU/l	16.0	12.0	20.0	Beckman Access / Access 2
	mU/l	15.2	11.4	19.0	Beckman DxI600/800
Luteinising Hormone (LH)	mU/ml	25.7	20.6	30.8	Beckman Access / Access 2
	mU/ml	24.9	19.9	29.9	Beckman DxI600/800

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

Cat. No. IA3110 / IA3112 Lot No. 1939EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Oestradiol	pmol/l	1336	1069	1603	Beckman Access / Access 2
	pg/ml	363	290	436	
	pmol/l	1147	918	1376	Beckman Access / Access 2 Sensitive B84493
	pg/ml	312	250	374	
	pmol/l	1285	1028	1542	Beckman DxI600/800
	pg/ml	350	280	420	
	pmol/l	1079	863	1295	Beckman DxI600/800 Sensitive B84493
	pg/ml	293	234	352	
Progesterone	nmol/l	37.9	30.3	45.5	Beckman Access / Access 2 Prog Cal 33555
	ng/ml	11.9	9.52	14.3	
	nmol/l	32.7	26.2	39.2	Beckman Access / Access 2 Prog DE Cal A80773
	ng/ml	10.2	8.16	12.2	
	nmol/l	36.3	29.0	43.6	Beckman DxI600/800 Prog Cal 33555
	ng/ml	11.4	9.12	13.7	
	nmol/l	31.7	25.4	38.0	Beckman DxI600/800 Prog DE Cal A80773
	ng/ml	9.92	7.94	11.9	
Prolactin	µU/ml	446	357	535	Beckman Access / Access 2
	µg/l	21.1	16.9	25.3	
	µU/ml	441	353	529	Beckman DxI600/800
	µg/l	20.8	16.6	25.0	
PSA Free	ng/ml = µg/l	11.1	8.33	13.9	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	11.0	8.25	13.8	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	10.5	7.88	13.1	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	8.95	6.71	11.2	Beckman DxI600/800 standardised to WHO IRP96/670
PSA Total	ng/ml = µg/l	16.5	12.4	20.6	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	16.4	12.3	20.5	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	16.2	12.2	20.2	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	12.5	9.38	15.6	Beckman DxI600/800 standardised to WHO IRP96/670
SHBG	nmol/l	47.4	37.9	56.9	Beckman Access / Access 2
	nmol/l	46.6	37.3	55.9	Beckman DxI600/800
Testosterone	nmol/l	12.7	10.2	15.2	Beckman Access / Access 2
	ng/ml	3.66	2.93	4.39	
	ng/dl	366	293	439	
	nmol/l	11.5	9.20	13.8	Beckman DxI600/800
	ng/ml	3.31	2.65	3.97	
	ng/dl	331	265	397	
Thyroglobulin	ng/ml	29.4	22.1	36.7	Beckman Access / Access 2
	ng/ml	28.0	21.0	35.0	Beckman DxI600/800
Thyroid Stimulating Hormone	µU/ml = mIU/l	2.09	1.67	2.51	Beckman Access / Access 2 Fast TSH
	µU/ml = mIU/l	2.15	1.72	2.58	Beckman Access / Access 2 hyperTSH 3rd Generation
	µU/ml = mIU/l	2.09	1.67	2.51	Beckman DxI600/800
	µU/ml = mIU/l	2.05	1.64	2.46	Beckman DxI600/800 Fast TSH
	µU/ml = mIU/l	2.10	1.68	2.52	Beckman DxI600/800 Hyper TSH
	µU/ml = mIU/l	2.09	1.67	2.51	Beckman DxI600/800 Access (3rd IS)

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

Cat. No. IA3110 / IA3112 Lot No. 1939EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Total Beta hCG	mU/ml = lU/l	14.7	11.8	17.6	Beckman Access / Access 2
	IU/ml	0.015	0.012	0.018	
	mU/ml = lU/l	15.0	12.0	18.0	Beckman Access / Access 2 Total BhCG (5th IS)
	IU/ml	0.015	0.012	0.018	
	mU/ml = lU/l	15.1	12.1	18.1	Beckman DxI600/800
	IU/ml	0.015	0.012	0.018	
	mU/ml = lU/l	15.1	12.1	18.1	Beckman DxI600/800 Total BhCG (5th IS)
	IU/ml	0.015	0.012	0.018	
Total T3	nmol/l	3.69	2.77	4.61	Beckman Access / Access 2
	ng/ml	2.40	1.80	3.00	
	ng/dl	240	180	300	
	nmol/l	3.62	2.72	4.52	Beckman DxI600/800
	ng/ml	2.36	1.77	2.95	
	ng/dl	236	177	295	
Total T4	nmol/l	113	84.8	141	Beckman Access / Access 2
	µg/dl	8.81	6.61	11.0	
	ng/ml	88.1	66.1	110	
	nmol/l	107	80.3	134	Beckman DxI600/800
	µg/dl	8.35	6.26	10.4	
	ng/ml	83.5	62.6	104	
Vitamin B12	pmol/l	373	298	448	Beckman Access / Access 2
	pg/ml	505	404	606	
	pmol/l	356	285	427	Beckman DxI600/800
	pg/ml	482	386	578	

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

CAT. NO.	IA3111	**GTIN:**	05055273207279	**SIZE:**	12 x 5 ml
CAT. NO.	IA3112	**GTIN:**	05055273207286	**SIZE:**	4 x 5 ml
LOT NO.	1942EC	**EXPIRY:**	2022-12-28		

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. CA19-9 is stable for 3 weeks when frozen once at –20°C
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 3: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED
Volumetric pipette

VALUE ASSIGNMENT
Each batch of Immunoassay Premium 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. Aldosterone is present in control levels 2 and level 3 only. 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

Rev. 30 July '21 me

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

Cat. No. IA3111 / IA3112 Lot No. 1942EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Alpha-fetoprotein	KIU/l = lU/ml	170	136	204	Beckman Access / Access 2
	ng/ml	206	165	247	
	KIU/l = lU/ml	161	129	193	Beckman DxI600/800
	ng/ml	195	156	234	
CA 15-3	U/ml	26.8	21.4	32.2	Beckman Access / Access 2
	U/ml	27.8	22.2	33.4	Beckman DxI600/800
CA 19-9	U/ml	238	190	286	Beckman Access / Access 2
	U/ml	200	160	240	Beckman DxI600/800
CA125	U/ml	161	129	193	Beckman Access / Access 2
	U/ml	157	126	188	Beckman DxI600/800
Carcinoembryonic	ng/ml = µg/l	60.2	48.2	72.2	Beckman Access / Access 2
Antigen (CEA)	ng/ml = µg/l	57.2	45.8	68.6	Beckman DxI600/800
Cortisol	nmol/l	969	727	1211	Beckman Access / Access 2
	µg/dl	34.9	26.2	43.6	
	nmol/l	907	680	1134	Beckman DxI600/800
	µg/dl	32.7	24.5	40.9	
DHEA-S	µmol/l	17.5	14.0	21.0	Beckman Access / Access 2
	µg/dl	645	516	774	
	µmol/l	17.5	14.0	21.0	Beckman DxI600/800
	µg/dl	645	516	774	
Digoxin	nmol/l	4.92	3.94	5.90	Beckman Access / Access 2
	ng/ml	3.84	3.07	4.61	
	nmol/l	4.92	3.94	5.90	Beckman DxI600/800
	ng/ml	3.84	3.07	4.61	
Ferritin	ng/ml = µg/l	243	194	292	Beckman Access / Access 2
	ng/ml = µg/l	232	186	278	Beckman DxI600/800
Folate	nmol/l	19.0	14.4	23.6	Beckman Access / Access 2
	ng/ml	8.38	6.37	10.4	
	nmol/l	19.3	14.7	23.9	Beckman DxI600/800
	ng/ml	8.51	6.47	10.6	
Free T3	pmol/l	19.0	14.3	23.7	Beckman Access / Access 2
	ng/dl	1.24	0.930	1.55	
	pg/ml	12.4	9.30	15.5	
	pmol/l	17.4	13.1	21.7	Beckman DxI600/800
	ng/dl	1.13	0.848	1.41	
	pg/ml	11.3	8.48	14.1	
Free T4	pmol/l	45.1	33.8	56.4	Beckman Access / Access 2
	ng/dl	3.52	2.64	4.40	
	pg/ml	35.2	26.4	44.0	
	pmol/l	48.4	36.3	60.5	Beckman DxI600/800
	ng/dl	3.78	2.84	4.72	
	pg/ml	37.8	28.4	47.2	
FSH	mU/ml	62.3	49.8	74.8	Beckman Access / Access 2
	mU/ml	62.7	50.2	75.2	Beckman DxI600/800
Growth Hormone (GH)	µU/ml	38.3	30.6	46.0	Beckman Access / Access 2
	ng/ml	12.8	10.2	15.4	
	µU/ml	36.9	29.5	44.3	Beckman DxI600/800
	ng/ml	12.3	9.84	14.8	
Immunoglobulin E	KlU/l = lU/ml	TBC			Beckman Access / Access 2
	KlU/l = lU/ml	TBC			Beckman DxI600/800
Insulin	mU/l	26.4	19.8	33.0	Beckman Access / Access 2
	mU/l	25.1	18.8	31.4	Beckman DxI600/800
Luteinising Hormone (LH)	mU/ml	39.2	31.4	47.0	Beckman Access / Access 2
	mU/ml	38.2	30.6	45.8	Beckman DxI600/800

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

Cat. No. IA3111 / IA3112 Lot No. 1942EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Oestradiol	pmol/l	2394	1915	2873	Beckman Access / Access 2
	pg/ml	651	521	781	
	pmol/l	1916	1533	2299	Beckman Access / Access 2 Sensitive B84493
	pg/ml	521	417	625	
	pmol/l	2204	1763	2645	Beckman DxI600/800
	pg/ml	599	479	719	
	pmol/l	1832	1466	2198	Beckman DxI600/800 Sensitive B84493
	pg/ml	498	398	598	
Progesterone	nmol/l	100	80.0	120	Beckman Access / Access 2 Prog Cal 33555
	ng/ml	31.3	25.0	37.6	
	nmol/l	101	80.8	121	Beckman Access / Access 2 Prog DE Cal A80773
	ng/ml	31.6	25.3	37.9	
	nmol/l	100	80.0	120	Beckman DxI600/800 Prog Cal 33555
	ng/ml	31.3	25.0	37.6	
	nmol/l	99.0	79.2	119	Beckman DxI600/800 Prog DE Cal A80773
	ng/ml	31.0	24.8	37.2	
Prolactin	µU/ml	879	703	1055	Beckman Access / Access 2
	µg/l	41.5	33.2	49.8	
	µU/ml	856	685	1027	Beckman DxI600/800
	µg/l	40.4	32.3	48.5	
PSA Free	ng/ml = µg/l	25.7	19.3	32.1	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	29.0	21.8	36.2	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	25.1	18.8	31.4	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	25.3	19.0	31.6	Beckman DxI600/800 standardised to WHO IRP96/670
PSA Total	ng/ml = µg/l	40.0	30.0	50.0	Beckman Access / Access 2 standardised to Hybritech
	ng/ml = µg/l	40.0	30.0	50.0	Beckman Access / Access 2 standardised to WHO IRP96/670
	ng/ml = µg/l	39.3	29.5	49.1	Beckman DxI600/800 standardised to Hybritech
	ng/ml = µg/l	34.3	25.7	42.9	Beckman DxI600/800 standardised to WHO IRP96/670
SHBG	nmol/l	43.7	35.0	52.4	Beckman Access / Access 2
	nmol/l	41.6	33.3	49.9	Beckman DxI600/800
Testosterone	nmol/l	25.9	20.7	31.1	Beckman Access / Access 2
	ng/ml	7.46	5.97	8.95	
	ng/dl	746	597	895	
	nmol/l	23.2	18.6	27.8	Beckman DxI600/800
	ng/ml	6.68	5.34	8.02	
	ng/dl	668	534	802	
Thyroglobulin	ng/ml	52.4	39.3	65.5	Beckman Access / Access 2
	ng/ml	50.1	37.6	62.6	Beckman DxI600/800
Thyroid Stimulating Hormone	µU/ml = mlU/l	18.8	15.0	22.6	Beckman Access / Access 2 Fast TSH
	µU/ml = mlU/l	19.4	15.5	23.3	Beckman Access / Access 2 hyperTSH 3rd Generation
	µU/ml = mlU/l	19.0	15.2	22.8	Beckman DxI600/800
	µU/ml = mlU/l	19.4	15.5	23.3	Beckman DxI600/800 Fast TSH
	µU/ml = mlU/l	18.7	15.0	22.4	Beckman DxI600/800 Hyper TSH
	µU/ml = mlU/l	19.0	15.2	22.8	Beckman DxI600/800 Access (3rd IS)

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

Cat. No. IA3111 / IA3112 Lot No. 1942EC Size: 12 x 5ml / 4 x 5ml Expiry: 2022-12-28

Analyte	unit	Target	Range low	Range high	methods
Total Beta hCG	mU/ml = lU/l	135	108	162	Beckman Access / Access 2
	IU/ml	0.135	0.108	0.162	
	mU/ml = lU/l	141	113	169	Beckman Access / Access 2 Total BhCG (5th IS)
	IU/ml	0.141	0.113	0.169	
	mU/ml = lU/l	146	117	175	Beckman DxI600/800
	IU/ml	0.146	0.117	0.175	
	mU/ml = lU/l	146	117	175	Beckman DxI600/800 Total BhCG (5th IS)
	IU/ml	0.146	0.117	0.175	
Total T3	nmol/l	6.09	4.57	7.61	Beckman Access / Access 2
	ng/ml	3.96	2.97	4.95	
	ng/dl	396	297	495	
	nmol/l	5.94	4.46	7.42	Beckman DxI600/800
	ng/ml	3.87	2.90	4.84	
	ng/dl	387	290	484	
Total T4	nmol/l	182	137	227	Beckman Access / Access 2
	µg/dl	14.2	10.7	17.7	
	ng/ml	142	107	177	
	nmol/l	179	134	224	Beckman DxI600/800
	µg/dl	14.0	10.5	17.5	
	ng/ml	140	105	175	
Vitamin B12	pmol/l	659	527	791	Beckman Access / Access 2
	pg/ml	893	714	1072	
	pmol/l	643	514	772	Beckman DxI600/800
	pg/ml	871	697	1045	

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