

## IMMUNOASSAY SPECIALITY I - LEVEL I (IA SPECIALITY I LEV I)

**CAT NO.** IAS3113      **LOT NO.** 2064EC  
**SIZE** 5 x 2 ml      **EXPIRY:** 2023-03-28  
**GTIN:** 05055273207293

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of the accuracy of Immunoassays on clinical chemistry systems. This material can be used to monitor the control of accuracy or the control of reproducibility of immunoassays.

### SAFETY PRECAUTIONS AND WARNINGS

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

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

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

Health and Safety Data Sheets are available on request.

### STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 5 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. Anti-TG is stable for 3 days at +2°C to +8°C.

C-Peptide and Procalcitonin are stable for 1 day at +2°C to +8°C. IGF-I is stable for 8 hours at +2°C to +8°C.

Osteocalcin is stable for 4 hours at +2°C to +8°C. Parathyroid Hormone (PTH) should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored below -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

The Immunoassay Speciality I Control is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 2 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### MATERIALS PROVIDED

Immunoassay Speciality I - Level I 5 x 2 ml

### MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

### VALUE ASSIGNMENT

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.

Each batch of Immunoassay Speciality I Control is submitted to a number of reference laboratories and values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean  $\pm 2$  S.D.

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

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC	REP
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Randox Teoranta, Meenmore,  
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Cat. No. IAS3113 Lot. No. 2064EC

Size 5 x 2ml Expiry 2023-03-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) <sub>2</sub> Vitamin D	pmol/l	123	86.1	160	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	43.9	32.9	54.9	Diasorin Liaison
	nmol/l	24.0	18.0	30.0	Abbott Architect (3L52)
	nmol/l	49.3	37.0	61.6	Siemens Centaur XP/XPT/Classic
	nmol/l	42.1	31.6	52.6	BioMerieux Vidas
	nmol/l	29.9	22.4	37.4	Beckman Access 25 OH Vitamin D Total
	nmol/l	24.1	18.1	30.1	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	44.3	33.2	55.4	Diasorin Liaison XL
	nmol/l	29.8	22.4	37.3	Roche Vitamin D Total II
	nmol/l	44.1	33.1	55.1	Siemens Atellica IM
	nmol/l	29.3	22.0	36.6	Roche Vitamin D Total II e801
Anti TG	KU/l	24.3	18.2	30.4	Siemens Immulite 2000/2500
	KU/l	47.0	35.3	58.8	Abbott Architect / Alinity
	KU/l	70.2	52.7	87.8	Roche Cobas 4000/E411
	KU/l	69.0	51.8	86.3	Roche Cobas e601/602
	KU/l	54.3	40.7	67.9	Beckman Dxl 600/800
	KU/l	51.7	38.8	64.6	Siemens Centaur XP/XPT/Classic
	KU/l	63.4	47.6	79.3	BioMerieux Vidas
	KU/l	55.5	41.6	69.4	Siemens Atellica IM
	KU/l	64.5	48.4	80.6	Roche Cobas e801
	KU/l	53.2	39.9	66.5	Siemens Atellica IM aTgII
	KU/l	55.1	41.3	68.9	Siemens Centaur XP/XPT aTgII
Anti TPO	KU/l	35.5	26.6	44.4	Abbott Architect / Alinity
	KU/l	42.9	32.2	53.6	Siemens Immulite 2000/2500
	KU/l	25.2	18.9	31.5	Beckman Dxl 600/800
	KU/l	140	105	175	Siemens Centaur XP/XPT/Classic
	KU/l	27.8	20.9	34.8	BioMerieux Vidas
	KU/l	13.8	10.4	17.3	Roche Cobas e801
	KU/l	127	95.3	159	Siemens Atellica IM
C-Peptide	nmol/l	0.391	0.293	0.489	Siemens Centaur XP/XPT/Classic
	ng/ml	1.18	0.885	1.48	
	nmol/l	0.632	0.474	0.790	Roche Cobas e601/602
	ng/ml	1.91	1.43	2.39	
	nmol/l	0.634	0.476	0.793	Diasorin Liaison
	ng/ml	1.91	1.44	2.38	
	nmol/l	0.484	0.363	0.605	Abbott Architect / Alinity
	ng/ml	1.46	1.10	1.82	
	nmol/l	0.438	0.329	0.548	Siemens Immulite 2000/2500
	ng/ml	1.32	0.993	1.65	
	nmol/l	0.609	0.457	0.761	Roche Cobas 4000/E411
	ng/ml	1.84	1.38	2.30	
nmol/l	0.602	0.452	0.753	Roche Cobas e801	
ng/ml	1.82	1.36	2.28		

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Analyte	unit	Target	Range		methods
			low	high	
C-Peptide	nmol/l	0.390	0.293	0.488	Siemens Atellica IM
	ng/ml	1.18	0.885	1.48	
	nmol/l	0.497	0.373	0.621	Ortho Vitros ECi
	ng/ml	1.50	1.13	1.87	
IGF 1	µg/l	78.9	59.2	98.6	Siemens Immulite 2000/2500
	µg/l	43.4	32.6	54.3	Diasorin Liaison
	µg/l	27.3	20.5	34.1	Roche Cobas 4000/E411
	µg/l	25.0	18.8	31.3	Roche Cobas 6000/8000
Insulin	mU/l	4.07	3.05	5.09	Abbott Architect
	µU/ml	4.07	3.05	5.09	
	mU/l	4.59	3.44	5.74	Roche Cobas 6000/8000
	µU/ml	4.59	3.44	5.74	
	mU/l	4.40	3.30	5.50	Siemens Centaur XP/XPT/Classic
	µU/ml	4.40	3.30	5.50	
	mU/l	3.72	2.79	4.65	Beckman Dxl 600/800
	µU/ml	3.72	2.79	4.65	
	mU/l	4.60	3.45	5.75	Roche Cobas 4000/E411
	µU/ml	4.60	3.45	5.75	
	mU/l	4.11	3.08	5.14	Siemens Atellica IM
	µU/ml	4.11	3.08	5.14	
Osteocalcin	µg/l	17.8	13.4	22.3	Siemens Immulite 2000/2500
	µg/l	30.6	23.0	38.3	Roche Elecsys
	µg/l	31.6	23.7	39.5	Roche Cobas 6000/8000
	µg/l	30.3	22.7	37.9	Roche Cobas 4000/E411
	µg/l	30.0	22.5	37.5	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	5.65	4.24	7.06	Abbott Architect / Alinity
	pg/ml	53.7	40.3	67.1	
	pmol/l	3.91	2.93	4.89	Beckman Dxl 600/800
	pg/ml	37.1	27.8	46.4	
	pmol/l	6.01	4.51	7.51	Siemens Immulite 2000/2500
	pg/ml	57.1	42.8	71.4	
	pmol/l	4.44	3.33	5.55	Roche Cobas e601/602 PTH
	pg/ml	42.2	31.6	52.8	
	pmol/l	4.73	3.55	5.91	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	44.9	33.7	56.1	
	pmol/l	4.60	3.45	5.75	Siemens Centaur XP/XPT/Classic
	pg/ml	43.7	32.8	54.6	
	pmol/l	4.35	3.26	5.44	Roche Cobas e601/602 PTH (1-84)
	pg/ml	41.3	31.0	51.6	
pmol/l	4.66	3.50	5.83	Roche Cobas 4000/E411 PTH (1-84)	
pg/ml	44.3	33.2	55.4		
pmol/l	4.44	3.33	5.55	Siemens Atellica IM	
pg/ml	42.2	31.6	52.8		

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Analyte	unit	Target	Range		methods
			low	high	
Parathyroid Hormone (PTH)	pmol/l	4.33	3.25	5.41	Roche Cobas e801 PTH
	pg/ml	41.1	30.9	51.3	
	pmol/l	4.37	3.28	5.46	Roche Cobas e801 PTH (1-84)
	pg/ml	41.5	31.2	51.8	
	pmol/l	4.62	3.47	5.78	Roche Cobas e801 PTH STAT
	pg/ml	43.9	33.0	54.8	
Procalcitonin	pmol/l	4.55	3.41	5.69	Roche Cobas e601/602 PTH STAT
	pg/ml	43.2	32.4	54.0	
	µg/l	1.09	0.818	1.36	Brahms Kryptor
	µg/l	1.87	1.40	2.34	BioMerieux Vidas
	µg/l	1.07	0.803	1.34	Roche Elecsys/Cobas/Modular
	µg/l	1.46	1.10	1.83	Siemens Centaur XP/XPT/Classic
	µg/l	1.61	1.21	2.01	Siemens Centaur CP 10378883
	µg/l	2.34	1.64	3.05	Diazyme PCT
	µg/l	1.20	0.900	1.50	Abbott Architect / Alinity Brahms PCT
	µg/l	1.06	0.795	1.33	Roche Cobas e801
	µg/l	1.50	1.13	1.88	Siemens Atellica IM 10995651
	µg/l	1.58	1.19	1.98	Beckman Access PCT
	µg/l	1.46	1.10	1.83	Siemens Centaur XP/XPT 11202697
	µg/l	1.63	1.22	2.04	Siemens Centaur CP 11202697
	µg/l	1.52	1.14	1.90	Siemens Atellica IM 11202699
	µg/l	1.17	0.843	1.50	Ortho Vitros ECi
	µg/l	0.920	0.643	1.20	Hipro HP Series (HP-083/4 / HP-AFS/1 / HP-AFS/3 / HP-AFS/1 Pro)
	µg/l	3.92	2.16	5.68	Nexus IB10