

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

CAT NO. IAS3113 **LOT NO.** 2218EC
SIZE: 5 x 2 ml **EXPIRY:** 2024-11-28
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-1 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.

1. 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.
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 Speciality I - Level I 5 x 2 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Values should be assigned by each laboratory.



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

Rev. 20 Feb '23 me

IMMUNOASSAY SPECIALITY I - LEVEL 1 (IA SPECIALITY I LEV 1)

Cat. No. IAS3113 Lot. No. 2218EC Size 5 x 2 ml Expiry 2024-11-28

Analyte	unit	Target	Range		methods
			low	high	
1-25(OH) vitamin D	pmol/L	77.1	54.0	100	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	19.6	14.7	24.5	Abbott Architect (3L52)
	nmol/l	38.0	28.5	47.5	Siemens Centaur XP/XPT/Classic
	nmol/l	32.1	24.1	40.1	BioMerieux Vidas
	nmol/l	19.6	14.7	24.5	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	35.1	26.3	43.9	Diasorin Liaison XL
	nmol/l	42.0	31.5	52.5	Siemens Atellica IM
Anti TG	kU/l	41.3	31.0	51.6	Siemens Immulite 2000/2500
	kU/l	63.1	47.3	78.9	Abbott Architect / Alinity
	kU/l	223	167	279	Roche Cobas 4000/E411
	kU/l	223	167	279	Roche Cobas e601/602
	kU/l	102	76.5	128	Beckman Dxl 600/800
	kU/l	78.7	59.0	98.4	Siemens Centaur XP/XPT/Classic
	kU/l	135	101	169	BioMerieux Vidas
	kU/l	70.0	52.5	87.5	Siemens Atellica IM
	kU/l	209	157	261	Roche Cobas e402/e801
	kU/l	72.0	54.0	90.0	Siemens Atellica IM aTgII
	kU/l	75.7	56.8	94.6	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	43.7	32.8	54.6	Abbott Architect / Alinity
	kU/l	44.7	33.5	55.9	Siemens Immulite 2000/2500
	kU/l	22.9	17.2	28.6	Roche Cobas 4000/E411
	kU/l	22.2	16.7	27.8	Roche Cobas c501/502 e601/602
	kU/l	27.0	20.3	33.8	Beckman Dxl 600/800
	kU/l	178	134	223	Siemens Centaur XP/XPT/Classic
	kU/l	43.6	32.7	54.5	BioMerieux Vidas
	kU/l	33.7	25.3	42.1	Roche Cobas e402/e801
C-Peptide	nmol/l	0.420	0.315	0.525	Roche Cobas e601/602
	ng/ml	1.27	0.951	1.59	
	nmol/l	0.340	0.255	0.425	Abbott Architect / Alinity
	ng/ml	1.03	0.770	1.29	
	nmol/l	0.270	0.203	0.338	Siemens Immulite 2000/2500
	ng/ml	0.815	0.613	1.02	
	nmol/l	0.420	0.315	0.525	Roche Cobas 4000/E411
	ng/ml	1.27	0.951	1.59	
	nmol/l	0.410	0.308	0.513	Roche Cobas e402/e801
ng/ml	1.24	0.930	1.55		
IGF 1	nmol/l	0.300	0.225	0.375	Siemens Atellica IM
	ng/ml	0.906	0.679	1.13	
	µg/l	87.7	65.8	110	Siemens Immulite 2000/2500
	µg/l	37.5	28.1	46.9	Diasorin Liaison
	µg/l	22.0	16.5	27.5	Roche Cobas 4000/E411

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			low	high	
IGF 1	µg/l	22.0	16.5	27.5	Roche Cobas 6000/8000
	µg/l	19.8	14.9	24.8	Roche Elecsys
Insulin	mU/l	5.74	4.31	7.18	Abbott Architect
	µU/ml	5.74	4.31	7.17	
	mU/l	6.23	4.67	7.79	Roche Cobas 6000/8000
	µU/ml	6.23	4.67	7.79	
	mU/l	6.86	5.15	8.58	Siemens Centaur XP/XPT/Classic
	µU/ml	6.86	5.15	8.57	
	mU/l	5.48	4.11	6.85	Beckman Dxl 600/800
	µU/ml	5.48	4.11	6.85	
	mU/l	6.54	4.91	8.18	Roche Cobas 4000/E411
	µU/ml	6.54	4.91	8.17	
	mU/l	6.53	4.90	8.16	Siemens Atellica IM
	µU/ml	6.53	4.90	8.16	
Osteocalcin	mU/l	5.33	4.00	6.66	Abbott Alinity i
	µU/ml	5.33	4.00	6.66	
	µg/l	12.7	9.53	15.9	Siemens Immulite 2000/2500
	µg/l	27.6	20.7	34.5	Roche Cobas 6000/8000
	µg/l	27.5	20.6	34.4	Roche Cobas 4000/E411
Parathyroid Hormone (PTH)	pmol/l	4.90	3.68	6.13	Abbott Architect / Alinity
	pg/ml	46.5	34.9	58.1	
	pmol/l	3.47	2.60	4.34	Beckman Dxl 600/800
	pg/ml	33.0	24.7	41.3	
	pmol/l	4.74	3.56	5.93	Siemens Immulite 2000/2500
	pg/ml	45.0	33.8	56.2	
	pmol/l	3.59	2.69	4.49	Roche Cobas e601/602 PTH
	pg/ml	34.1	25.5	42.7	
	pmol/l	3.87	2.90	4.84	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	36.8	27.5	46.1	
	pmol/l	4.36	3.27	5.45	Siemens Centaur XP/XPT/Classic
	pg/ml	41.4	31.1	51.7	
	pmol/l	3.67	2.75	4.59	Roche Cobas e601/602 PTH (1-84)
	pg/ml	34.9	26.1	43.7	
	pmol/l	3.98	2.99	4.98	Roche Cobas 4000/E411 PTH (1-84)
	pg/ml	37.8	28.4	47.2	
	pmol/l	4.19	3.14	5.24	Siemens Atellica IM
	pg/ml	39.8	29.8	49.8	
	pmol/l	3.66	2.75	4.58	Roche Cobas e801 PTH
	pg/ml	34.8	26.1	43.5	
pmol/l	4.02	3.02	5.03	Roche Cobas e801 PTH (1-84)	
pg/ml	38.2	28.7	47.7		
pmol/l	3.72	2.79	4.65	Roche Cobas e801 PTH STAT	
pg/ml	35.3	26.5	44.1		
pmol/l	3.49	2.62	4.36	Roche Cobas e601/602 PTH STAT	
pg/ml	33.1	24.9	41.3		
Procalcitonin	µg/l	2.18	1.64	2.73	BioMerieux Vidas

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Procalcitonin	µg/l	1.09	0.818	1.36	Roche Elecsys/Cobas/Modular
	µg/l	2.28	1.71	2.85	Siemens Centaur XP/XPT/Classic
	µg/l	2.21	1.66	2.76	Siemens Centaur CP 10378883
	µg/l	1.56	1.09	2.03	Diazyme PCT
	µg/l	1.07	0.803	1.34	Abbott Architect / Alinity Brahms PCT
	µg/l	1.10	0.825	1.38	Roche Cobas e402/e801
	µg/l	2.05	1.54	2.56	Siemens Atellica IM 10995651
	µg/l	1.46	1.10	1.83	Beckman Access PCT
	µg/l	2.17	1.63	2.71	Siemens Centaur XP/XPT 11202697
	µg/l	2.38	1.79	2.98	Siemens Centaur CP 11202697
	µg/l	1.87	1.40	2.34	Siemens Atellica IM 11202699