

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

CAT NO. IAS3113 **LOT NO.** 2193EC
SIZE: 5 x 2 ml **EXPIRY:** 2024-05-28
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 ± 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.

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

Cat. No. IAS3113 Lot. No. 2193EC Size 5 x 2 ml Expiry 2024-05-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	75.9	53.1	98.7	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	10.8	8.10	13.5	Roche Vitamin D Total
	nmol/l	39.8	29.9	49.8	Diasorin Liaison
	nmol/l	23.3	17.5	29.1	Abbott Architect (3L52)
	nmol/l	47.7	35.8	59.6	Siemens Centaur XP/XPT/Classic
	nmol/l	39.1	29.3	48.9	BioMerieux Vidas
	nmol/l	23.3	17.5	29.1	Beckman Dxl 600/800
	nmol/l	22.1	16.6	27.6	Beckman Access 25 OH Vitamin D Total
	nmol/l	22.4	16.8	28.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	40.6	30.5	50.8	Diasorin Liaison XL
	nmol/l	43.5	32.6	54.4	Siemens Atellica IM
	nmol/l	11.7	8.78	14.6	Roche Vitamin D Total III
Anti TG	kU/l	64.0	48.0	80.0	Siemens Immulite 2000/2500
	kU/l	60.7	45.5	75.9	Abbott Architect / Alinity
	kU/l	275	206	344	Roche Cobas 4000/E411
	kU/l	263	197	329	Roche Cobas e601/602
	kU/l	132	99.0	165	Beckman Dxl 600/800
	kU/l	91.2	68.4	114	Siemens Centaur XP/XPT/Classic
	kU/l	137	103	171	Beckman Access/LXi725
	kU/l	145	109	181	BioMerieux Vidas
	kU/l	91.7	68.8	115	Siemens Atellica IM
	kU/l	255	191	319	Roche Cobas e402/e801
	kU/l	95.2	71.4	119	Siemens Atellica IM aTgII
Anti TPO	kU/l	41.8	31.4	52.3	Abbott Architect / Alinity
	kU/l	40.8	30.6	51.0	Siemens Immulite 2000/2500
	kU/l	18.4	13.8	23.0	Roche Cobas 4000/E411
	kU/l	16.8	12.6	21.0	Roche Cobas c501/502 e601/602
	kU/l	27.7	20.8	34.6	Beckman Dxl 600/800
	kU/l	151	113	189	Siemens Centaur XP/XPT/Classic
	kU/l	32.8	24.6	41.0	BioMerieux Vidas
	kU/l	24.5	18.4	30.6	Roche Cobas e402/e801
	kU/l	136	102	170	Siemens Atellica IM
C-Peptide	nmol/l	0.309	0.232	0.386	Siemens Centaur XP/XPT/Classic
	ng/ml	0.933	0.700	1.17	
	nmol/l	0.498	0.374	0.623	Roche Cobas e601/602
	ng/ml	1.50	1.13	1.87	
	nmol/l	0.406	0.305	0.508	Abbott Architect / Alinity
	ng/ml	1.23	0.921	1.54	
	nmol/l	0.335	0.251	0.419	Siemens Immulite 2000/2500
	ng/ml	1.01	0.758	1.26	
	nmol/l	0.512	0.384	0.640	Roche Cobas 4000/E411
	ng/ml	1.55	1.16	1.94	

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Analyte	unit	Target	Range		methods	
			low	high		
C-Peptide	nmol/l	0.571	0.428	0.714	Diasorin Liaison XL	
	ng/ml	1.72	1.29	2.15		
	nmol/l	0.493	0.370	0.616	Roche Cobas e402/e801	
	ng/ml	1.49	1.12	1.86		
	nmol/l	0.297	0.223	0.371	Siemens Atellica IM	
	ng/ml	0.897	0.673	1.12		
	IGF 1	µg/l	86.1	64.6	108	Siemens Immulite 2000/2500
		µg/l	35.9	26.9	44.9	Diasorin Liaison
µg/l		25.2	18.9	31.5	Roche Cobas 4000/E411	
µg/l		22.1	16.6	27.6	Roche Cobas 6000/8000	
µg/l		23.1	17.3	28.9	Roche Elecsys	
Insulin	mU/l	4.39	3.29	5.49	Abbott Architect	
	µU/ml	4.39	3.29	5.49		
	mU/l	4.92	3.69	6.15	Roche Cobas 6000/8000	
	µU/ml	4.92	3.69	6.15		
	mU/l	4.91	3.68	6.14	Siemens Centaur XP/XPT/Classic	
	µU/ml	4.91	3.68	6.14		
	mU/l	4.27	3.20	5.34	Beckman Dxl 600/800	
	µU/ml	4.27	3.20	5.34		
	mU/l	5.38	4.04	6.73	Roche Cobas 4000/E411	
	µU/ml	5.38	4.04	6.72		
	mU/l	4.82	3.62	6.03	Siemens Atellica IM	
µU/ml	4.82	3.62	6.02			
Osteocalcin	mU/l	4.17	3.13	5.21	Abbott Alinity i	
	µU/ml	4.17	3.13	5.21		
	Osteocalcin	µg/l	8.73	6.55	10.9	Siemens Immulite 2000/2500
		µg/l	19.5	14.6	24.4	Roche Cobas 6000/8000
µg/l		18.9	14.2	23.6	Roche Cobas 4000/E411	
µg/l		19.4	14.6	24.3	Diasorin Liaison	
Parathyroid Hormone (PTH)	pmol/l	5.97	4.48	7.46	Abbott Architect / Alinity	
	pg/ml	56.7	42.5	70.9		
	pmol/l	4.28	3.21	5.35	Beckman Dxl 600/800	
	pg/ml	40.6	30.5	50.7		
	pmol/l	4.29	3.22	5.36	Roche Cobas e601/602 PTH	
	pg/ml	40.7	30.6	50.8		
	pmol/l	4.60	3.45	5.75	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	43.7	32.8	54.6		
	pmol/l	5.14	3.86	6.43	Siemens Centaur XP/XPT/Classic	
	pg/ml	48.8	36.7	60.9		
	pmol/l	4.58	3.44	5.73	Roche Cobas e601/602 PTH (1-84)	
	pg/ml	43.5	32.7	54.3		
	pmol/l	4.82	3.62	6.03	Roche Cobas 4000/E411 PTH (1-84)	
pg/ml	45.8	34.4	57.2			
pmol/l	4.94	3.71	6.18	Siemens Atellica IM		
pg/ml	46.9	35.2	58.6			

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			low	high	
Parathyroid Hormone (PTH)	pmol/l	4.44	3.33	5.55	Roche Cobas e801 PTH
	pg/ml	42.2	31.6	52.8	
	pmol/l	4.61	3.46	5.76	Roche Cobas e801 PTH (1-84)
	pg/ml	43.8	32.9	54.7	
	pmol/l	4.33	3.25	5.41	Roche Cobas e801 PTH STAT
	pg/ml	41.1	30.9	51.3	
Procalcitonin	pmol/l	4.14	3.11	5.18	Roche Cobas e601/602 PTH STAT
	pg/ml	39.3	29.5	49.1	
	µg/l	2.43	1.82	3.04	BioMerieux Vidas
	µg/l	1.42	1.07	1.78	Roche Elecsys/Cobas/Modular
	µg/l	2.07	1.55	2.59	Siemens Centaur XP/XPT/Classic
	µg/l	2.19	1.64	2.74	Siemens Centaur CP 10378883
	µg/l	1.60	1.20	2.00	Abbott Architect / Alinity Brahms PCT
	µg/l	1.45	1.09	1.81	Roche Cobas e402/e801
	µg/l	2.11	1.58	2.64	Siemens Atellica IM 10995651
	µg/l	2.21	1.66	2.76	Beckman Access PCT
	µg/l	2.12	1.59	2.65	Siemens Centaur XP/XPT 11202697
	µg/l	2.21	1.66	2.76	Siemens Centaur CP 11202697
µg/l	2.14	1.61	2.68	Siemens Atellica IM 11202699	