

IMMUNOASSAY SPECIALITY I - LEVEL 2 (IA SPECIALITY I LEV 2)

CAT. NO. IAS3114 **LOT NO.** 2194EC
SIZE: 5 x 2 ml **EXPIRY:** 2024-05-28
GTIN: 05055273207309

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.

- 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 2 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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Cat. No. IAS3114 Lot. No. 2194EC Size 5 x 2ml Expiry 2024-05-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	200	140	260	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	62.0	46.5	77.5	Roche Vitamin D Total
	nmol/l	74.1	55.6	92.6	Diasorin Liaison
	nmol/l	70.6	53.0	88.3	Abbott Architect (3L52)
	nmol/l	95.5	71.6	119	Siemens Centaur XP/XPT/Classic
	nmol/l	72.7	54.5	90.9	BioMerieux Vidas
	nmol/l	59.3	44.5	74.1	Beckman Dxl 600/800
	nmol/l	70.4	52.8	88.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	72.6	54.5	90.8	Diasorin Liaison XL
	nmol/l	69.8	52.4	87.3	Roche Vitamin D Total II
	nmol/l	96.5	72.4	121	Siemens Atellica IM
	nmol/l	63.2	47.4	79.0	Roche Vitamin D Total II e801
nmol/l	62.2	46.7	77.8	Roche Vitamin D Total III	
Anti TG	kU/l	183	137	229	Siemens Immulite 2000/2500
	kU/l	130	97.5	163	Abbott Architect / Alinity
	kU/l	741	556	926	Roche Cobas 4000/E411
	kU/l	673	505	841	Roche Cobas e601/602
	kU/l	321	241	401	Beckman Dxl 600/800
	kU/l	197	148	246	Siemens Centaur XP/XPT/Classic
	kU/l	371	278	464	BioMerieux Vidas
	kU/l	205	154	256	Siemens Atellica IM
	kU/l	707	530	884	Roche Cobas e402/e801
	kU/l	212	159	265	Siemens Atellica IM aTgII
	kU/l	201	151	251	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	91.2	68.4	114	Abbott Architect / Alinity
	kU/l	97.1	72.8	121	Siemens Immulite 2000/2500
	kU/l	66.3	49.7	82.9	Roche Cobas 4000/E411
	kU/l	62.1	46.6	77.6	Roche Cobas c501/502 e601/602
	kU/l	61.6	46.2	77.0	Beckman Dxl 600/800
	kU/l	325	244	406	Siemens Centaur XP/XPT/Classic
	kU/l	66.5	49.9	83.1	BioMerieux Vidas
	kU/l	83.7	62.8	105	Roche Cobas e402/e801
	kU/l	314	236	393	Siemens Atellica IM
C-Peptide	nmol/l	0.753	0.565	0.941	Siemens Centaur XP/XPT/Classic
	ng/ml	2.27	1.71	2.83	
	nmol/l	1.090	0.818	1.360	Roche Cobas e601/602
	ng/ml	3.29	2.47	4.11	
	nmol/l	0.941	0.706	1.180	Abbott Architect / Alinity
	ng/ml	2.84	2.13	3.55	
	nmol/l	0.871	0.653	1.090	Siemens Immulite 2000/2500
	ng/ml	2.63	1.97	3.29	
	nmol/l	1.060	0.795	1.330	Roche Cobas 4000/E411
	ng/ml	3.20	2.40	4.00	

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Analyte	unit	Target	Range		methods	
			low	high		
C-Peptide	nmol/l	1.180	0.885	1.480	Diasorin Liaison XL	
	ng/ml	3.56	2.67	4.45		
	nmol/l	1.050	0.788	1.310	Roche Cobas e402/e801	
	ng/ml	3.17	2.38	3.96		
	nmol/l	0.708	0.531	0.885	Siemens Atellica IM	
	ng/ml	2.14	1.60	2.68		
	IGF 1	µg/l	262	197	328	Siemens Immulite 2000/2500
		µg/l	114	85.5	143	Diasorin Liaison
µg/l		77.5	58.1	96.9	Roche Cobas 4000/E411	
µg/l		79.9	59.9	100	Roche Cobas 6000/8000	
µg/l		72.7	54.5	90.9	Roche Elecsys	
Insulin	mU/l	8.44	6.33	10.6	Abbott Architect	
	µU/ml	8.44	6.33	10.6		
	mU/l	10.4	7.80	13.0	Roche Cobas 6000/8000	
	µU/ml	10.4	7.80	13.0		
	mU/l	10.4	7.80	13.0	Siemens Centaur XP/XPT/Classic	
	µU/ml	10.4	7.80	13.0		
	mU/l	8.54	6.41	10.7	Beckman Dxl 600/800	
	µU/ml	8.54	6.41	10.7		
	mU/l	10.6	7.95	13.3	Roche Cobas 4000/E411	
	µU/ml	10.6	7.95	13.3		
	mU/l	9.89	7.42	12.4	Siemens Atellica IM	
µU/ml	9.89	7.42	12.4			
Osteocalcin	mU/l	7.90	5.93	9.88	Abbott Alinity i	
	µU/ml	7.90	5.93	9.87		
	µg/l	15.2	11.4	19.0	Siemens Immulite 2000/2500	
	µg/l	32.5	24.4	40.6	Roche Cobas 6000/8000	
	µg/l	31.4	23.6	39.3	Roche Cobas 4000/E411	
	µg/l	35.8	26.9	44.8	Diasorin Liaison	
	Parathyroid Hormone (PTH)	pmol/l	41.1	30.8	51.4	Abbott Architect / Alinity
		pg/ml	390	293	487	
pmol/l		31.3	23.5	39.1	Beckman Dxl 600/800	
pg/ml		297	223	371		
pmol/l		26.1	19.6	32.6	Roche Cobas e601/602 PTH	
pg/ml		248	186	310		
pmol/l		28.0	21.0	35.0	Roche Cobas 4000/e411 PTH/PTH STAT	
pg/ml		266	199	333		
pmol/l		40.2	30.2	50.3	Siemens Centaur XP/XPT/Classic	
pg/ml		382	287	477		
pmol/l		25.8	19.4	32.3	Roche Cobas e601/602 PTH (1-84)	
pg/ml		245	184	306		
pmol/l		28.3	21.2	35.4	Roche Cobas 4000/E411 PTH (1-84)	
pg/ml	269	201	337			
pmol/l	39.1	29.3	48.9	Siemens Atellica IM		
pg/ml	371	278	464			

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Analyte	unit	Target	Range		methods
			low	high	
Parathyroid Hormone (PTH)	pmol/l	26.8	20.1	33.5	Roche Cobas e801 PTH
	pg/ml	255	191	319	
	pmol/l	25.6	19.2	32.0	Roche Cobas e801 PTH (1-84)
	pg/ml	243	182	304	
	pmol/l	24.5	18.4	30.6	Roche Cobas e801 PTH STAT
	pg/ml	233	175	291	
Procalcitonin	pmol/l	24.7	18.5	30.9	Roche Cobas e601/602 PTH STAT
	pg/ml	235	176	294	
	µg/l	2.51	1.88	3.14	Brahms Kryptor
	µg/l	4.53	3.40	5.66	BioMerieux Vidas
	µg/l	3.19	2.39	3.99	Roche Elecsys/Cobas/Modular
	µg/l	4.01	3.01	5.01	Siemens Centaur XP/XPT/Classic
	µg/l	3.97	2.98	4.96	Siemens Centaur CP 10378883
	µg/l	3.33	2.50	4.16	Abbott Architect / Alinity Brahms PCT
	µg/l	3.26	2.45	4.08	Roche Cobas e402/e801
	µg/l	4.13	3.10	5.16	Siemens Atellica IM 10995651
	µg/l	4.45	3.34	5.56	Beckman Access PCT
	µg/l	3.96	2.97	4.95	Siemens Centaur XP/XPT 11202697
	µg/l	4.34	3.26	5.43	Siemens Centaur CP 11202697
	µg/l	4.14	3.11	5.18	Siemens Atellica IM 11202699