

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

CAT. NO. IAS3114 **LOT NO.** 2219EC
SIZE: 5 x 2 ml **EXPIRY:** 2024-11-28
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.

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 2 5 x 2 ml

MATERIAL REQUIRED BUT NOT PROVIDED

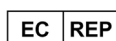
Volumetric pipette

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.



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

26 Jan '23 me

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

Cat. No. IAS3114 Lot. No. 2219EC Size 5 x 2ml Expiry 2024-11-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	195	137	254	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	70.0	52.5	87.5	Diasorin Liaison
	nmol/l	60.9	45.7	76.1	Abbott Architect (3L52)
	nmol/l	81.8	61.4	102	Siemens Centaur XP/XPT/Classic
	nmol/l	64.0	48.0	80.0	BioMerieux Vidas
	nmol/l	50.0	37.5	62.5	Beckman Dxl 600/800
	nmol/l	58.7	44.0	73.4	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	68.0	51.0	85.0	Diasorin Liaison XL
	nmol/l	56.8	42.6	71.0	Roche Vitamin D Total II
	nmol/l	85.7	64.3	107	Siemens Atellica IM
	nmol/l	55.7	41.8	69.6	Roche Vitamin D Total II e801
	nmol/l	53.6	40.2	67.0	Roche Vitamin D Total III
Anti TG	kU/l	113	84.8	141	Siemens Immulite 2000/2500
	kU/l	161	121	201	Abbott Architect / Alinity
	kU/l	711	533	889	Roche Cobas 4000/E411
	kU/l	753	565	941	Roche Cobas e601/602
	kU/l	242	182	303	Beckman Dxl 600/800
	kU/l	179	134	224	Siemens Centaur XP/XPT/Classic
	kU/l	242	182	303	Beckman Access/LXi725
	kU/l	240	180	300	BioMerieux Vidas
	kU/l	195	146	244	Siemens Atellica IM
	kU/l	679	509	849	Roche Cobas e402/e801
	kU/l	185	139	231	Siemens Atellica IM aTgII
kU/l	197	148	246	Siemens Centaur XP/XPT aTgII	
Anti TPO	kU/l	106	79.5	133	Abbott Architect / Alinity
	kU/l	119	89.3	149	Siemens Immulite 2000/2500
	kU/l	81.2	60.9	102	Roche Cobas 4000/E411
	kU/l	81.4	61.1	102	Roche Cobas c501/502 e601/602
	kU/l	61.6	46.2	77.0	Beckman Dxl 600/800
	kU/l	379	284	474	Siemens Centaur XP/XPT/Classic
	kU/l	89.8	67.4	112	BioMerieux Vidas
	kU/l	118	88.5	148	Roche Cobas e402/e801
	kU/l	373	280	466	Siemens Atellica IM
C-Peptide	nmol/l	0.997	0.748	1.250	Roche Cobas e601/602
	ng/ml	3.01	2.26	3.76	
	nmol/l	0.886	0.665	1.110	Abbott Architect / Alinity
	ng/ml	2.67	2.01	3.33	
	nmol/l	0.823	0.617	1.030	Siemens Immulite 2000/2500
	ng/ml	2.48	1.86	3.10	
	nmol/l	0.979	0.734	1.220	Roche Cobas 4000/E411
	ng/ml	2.96	2.22	3.70	
	nmol/l	0.990	0.743	1.240	Roche Cobas e402/e801
	ng/ml	2.99	2.24	3.74	

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

Cat. No. IAS3114 Lot. No. 2219EC Size 5 x 2ml Expiry 2024-11-28

Range					
Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	0.813	0.610	1.020	Siemens Atellica IM
	ng/ml	2.45	1.84	3.06	
IGF 1	µg/l	251	188	314	Siemens Immulite 2000/2500
	µg/l	106	79.5	133	Diasorin Liaison
	µg/l	77.5	58.1	96.9	Roche Cobas 4000/E411
	µg/l	69.7	52.3	87.1	Roche Cobas 6000/8000
	µg/l	70.6	53.0	88.3	Roche Elecsys
Insulin	mU/l	10.4	7.80	13.0	Abbott Architect
	µU/ml	10.4	7.80	13.0	
	mU/l	12.2	9.15	15.3	Roche Cobas 6000/8000
	µU/ml	12.2	9.15	15.3	
	mU/l	12.6	9.45	15.8	Siemens Centaur XP/XPT/Classic
	µU/ml	12.6	9.45	15.8	
	mU/l	11.2	8.40	14.0	Beckman Dxl 600/800
	µU/ml	11.2	8.40	14.0	
	mU/l	12.2	9.15	15.3	Roche Cobas 4000/E411
	µU/ml	12.2	9.15	15.3	
	mU/l	12.8	9.60	16.0	Siemens Atellica IM
	µU/ml	12.8	9.60	16.0	
	mU/l	9.06	6.80	11.3	Abbott Alinity i
µU/ml	9.06	6.80	11.3		
Osteocalcin	µg/l	43.8	32.9	54.8	Siemens Immulite 2000/2500
	µg/l	93.4	70.1	117	Roche Cobas 6000/8000
	µg/l	93.2	69.9	117	Roche Cobas 4000/E411
Parathyroid Hormone (PTH)	pmol/l	38.6	29.0	48.3	Abbott Architect / Alinity
	pg/ml	367	275	459	
	pmol/l	30.1	22.6	37.6	Beckman Dxl 600/800
	pg/ml	286	215	357	
	pmol/l	23.9	17.9	29.9	Roche Cobas e601/602 PTH
	pg/ml	227	170	284	
	pmol/l	26.2	19.7	32.8	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	249	187	311	
	pmol/l	34.8	26.1	43.5	Siemens Centaur XP/XPT/Classic
	pg/ml	330	248	412	
	pmol/l	23.5	17.6	29.4	Roche Cobas e601/602 PTH (1-84)
	pg/ml	223	167	279	
	pmol/l	26.2	19.7	32.8	Roche Cobas 4000/E411 PTH (1-84)
	pg/ml	249	187	311	
	pmol/l	32.9	24.7	41.1	Siemens Atellica IM
	pg/ml	312	235	389	
pmol/l	24.0	18.0	30.0	Roche Cobas e801 PTH	
pg/ml	228	171	285		
pmol/l	22.6	17.0	28.3	Roche Cobas e801 PTH (1-84)	
pg/ml	215	161	269		
pmol/l	23.2	17.4	29.0	Roche Cobas e801 PTH STAT	
pg/ml	220	165	275		

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

Cat. No. IAS3114 Lot. No. 2219EC Size 5 x 2ml Expiry 2024-11-28

Analyte	unit	Target	Range		methods
			low	high	
Parathyroid Hormone (PTH)	pmol/l	22.6	17.0	28.3	Roche Cobas e601/602 PTH STAT
	pg/ml	215	161	269	
Procalcitonin	µg/l	4.19	3.14	5.24	BioMerieux Vidas
	µg/l	2.60	1.95	3.25	Roche Elecsys/Cobas/Modular
	µg/l	4.10	3.08	5.13	Siemens Centaur XP/XPT/Classic
	µg/l	4.24	3.18	5.30	Siemens Centaur CP 10378883
	µg/l	2.48	1.86	3.10	Abbott Architect / Alinity Brahms PCT
	µg/l	2.62	1.97	3.28	Roche Cobas e402/e801
	µg/l	3.17	2.38	3.96	Beckman Access PCT
	µg/l	4.16	3.12	5.20	Siemens Centaur XP/XPT 11202697
	µg/l	4.30	3.23	5.38	Siemens Centaur CP 11202697
	µg/l	3.81	2.86	4.76	Siemens Atellica IM 11202699