

## IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)

**CAT NO.** IAS3115 **LOT NO.** 2014EC  
**SIZE** 5 x 2 ml **EXPIRY:** 2022-11-28  
**GTIN:** 05055273207316

### 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 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 3 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
----	-----

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

Rev. 11 Mar '22 me

## IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)

Cat. No. IAS3115 Lot. No. 2014EC Size 5 x 2ml Expiry 2022-11-28

Range					
Analyte	unit	Target	low	high	methods
1-25 (OH) <sub>2</sub> Vitamin D	pmol/l	375	263	488	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	99.0	74.3	124	Roche Vitamin D Total
	nmol/l	116	87.0	145	Roche Elecsys
	nmol/l	119	89.3	149	Diasorin Liaison
	nmol/l	114	85.5	143	Abbott Architect (3L52)
	nmol/l	162	122	203	Siemens Centaur XP/XPT/Classic
	nmol/l	101	75.8	126	BioMerieux Vidas
	nmol/l	113	84.8	141	Beckman Dxl 600/800
	nmol/l	118	88.5	148	Beckman Access 25 OH Vitamin D Total
	nmol/l	116	87.0	145	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	121	90.8	151	Diasorin Liaison XL
	nmol/l	119	89.3	149	Roche Vitamin D Total II
	nmol/l	165	124	206	Siemens Atellica IM
	nmol/l	123	92.3	154	Roche Vitamin D Total II e801
Anti TG	kU/l	257	193	321	Siemens Immulite 2000/2500
	kU/l	373	280	466	Abbott Architect / Alinity
	kU/l	1763	1322	2204	Roche Cobas 4000/E411
	kU/l	1735	1301	2169	Roche Cobas e601/602
	kU/l	447	335	559	Beckman Dxl 600/800
	kU/l	461	346	576	Siemens Centaur XP/XPT/Classic
	kU/l	442	332	553	Beckman Access/LXi725
	kU/l	463	347	579	BioMerieux Vidas
	kU/l	430	323	538	Siemens Atellica IM
	kU/l	1698	1274	2123	Roche Cobas e801
	kU/l	434	326	543	Siemens Atellica IM aTgII
	kU/l	410	308	513	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	158	119	198	Abbott Architect / Alinity
	kU/l	187	140	234	Siemens Immulite 2000/2500
	kU/l	109	81.8	136	Roche Cobas 4000/E411
	kU/l	107	80.3	134	Roche Cobas c501/502 e601/602
	kU/l	116	87.0	145	Beckman Dxl 600/800
	kU/l	522	392	653	Siemens Centaur XP/XPT/Classic
	kU/l	471	353	589	Brahms RIA
	kU/l	125	93.8	156	BioMerieux Vidas
	kU/l	144	108	180	Roche Cobas e801
C-Peptide	nmol/l	1.640	1.230	2.050	Siemens Centaur XP/XPT/Classic
	ng/ml	4.95	3.71	6.19	
	nmol/l	2.140	1.610	2.680	Roche Cobas e601/602
	ng/ml	6.46	4.86	8.06	
	nmol/l	1.990	1.490	2.490	Abbott Architect / Alinity
	ng/ml	6.01	4.50	7.52	

IAAI BC5 GG5 MGD97-5 @HM=!'@J9@' f15 GD97-5 @HM=@J' t

Cat. No. IAS3115 Lot. No. 2014EC Size 5 x 2ml Expiry 2022-11-28

Analyte	unit	Target	Range		methods	
			low	high		
C-Peptide	nmol/l	2.100	1.580	2.630	Siemens Immulite 2000/2500	
	ng/ml	6.34	4.77	7.91		
	nmol/l	2.150	1.610	2.690	Roche Cobas 4000/E411	
	ng/ml	6.49	4.86	8.12		
	nmol/l	2.100	1.580	2.630	Roche Cobas e801	
	ng/ml	6.34	4.77	7.91		
	nmol/l	1.630	1.220	2.040	Siemens Atellica IM	
	ng/ml	4.92	3.68	6.16		
	IGF 1	µg/l	524	393	655	Siemens Immulite 2000/2500
		µg/l	254	191	318	Diasorin Liaison
		µg/l	162	122	203	Roche Cobas 4000/E411
		µg/l	173	130	216	Roche Cobas 6000/8000
Insulin	mU/l	21.7	16.3	27.1	Abbott Architect	
	µU/ml	21.7	16.3	27.1		
	mU/l	32.9	24.7	41.1	Roche Cobas 6000/8000	
	µU/ml	32.9	24.7	41.1		
	mU/l	24.4	18.3	30.5	Siemens Centaur XP/XPT/Classic	
	µU/ml	24.4	18.3	30.5		
	mU/l	22.2	16.7	27.8	Beckman Dxl 600/800	
	µU/ml	22.2	16.7	27.7		
	mU/l	32.6	24.5	40.8	Roche Elecsys	
	µU/ml	32.6	24.5	40.7		
Osteocalcin	mU/l	32.3	24.2	40.4	Roche Cobas 4000/E411	
	µU/ml	32.3	24.2	40.4		
	mU/l	26.6	20.0	33.3	Siemens Atellica IM	
	µU/ml	26.6	20.0	33.2		
	Osteocalcin	µg/l	76.3	57.2	95.4	Siemens Immulite 2000/2500
		µg/l	148	111	185	Roche Cobas 6000/8000
		µg/l	139	104	174	Roche Cobas 4000/E411
		µg/l	176	132	220	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	145	109	181	Abbott Architect / Alinity	
	pg/ml	1377	1035	1719		
	pmol/l	104	78.0	130	Beckman Dxl 600/800	
	pg/ml	988	741	1235		
	pmol/l	94.8	71.1	119	Roche Elecsys PTH/PTH STAT	
	pg/ml	900	675	1125		
	pmol/l	94.8	71.1	119	Roche Cobas e601/602 PTH	
	pg/ml	900	675	1125		
	pmol/l	99.0	74.3	124	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	940	706	1174		
	pmol/l	128	96.0	160	Siemens Centaur XP/XPT/Classic	
	pg/ml	1216	912	1520		
pmol/l	87.6	65.7	110	Roche Cobas e601/602 PTH (1-84)		
pg/ml	832	624	1040			
pmol/l	93.5	70.1	117	Roche Cobas 4000/E411 PTH (1-84)		
pg/ml	888	666	1110			

IAAI BC5 GG5 MGD97-5 @HM=!'@J9@' f15 GD97-5 @HM=@J' Ł

Cat. No. IAS3115 Lot. No. 2014EC Size 5 x 2ml Expiry 2022-11-28

Range						
Analyte	unit	Target	low	high	methods	
Parathyroid Hormone (PTH)	pmol/l	124	93.0	155	Siemens Atellica IM	
	pg/ml	1178	883	1473		
	pmol/l	95.6	71.7	120	Roche Cobas e801 PTH	
	pg/ml	908	681	1135		
	pmol/l	88.4	66.3	111	Roche Cobas e801 PTH (1-84)	
	pg/ml	840	630	1050		
	pmol/l	87.4	65.6	109	Roche Cobas e801 PTH STAT	
	pg/ml	830	623	1037		
	pmol/l	92.5	69.4	116	Roche Cobas e601/602 PTH STAT	
	pg/ml	878	659	1097		
	Procalcitonin	µg/l	11.7	8.78	14.6	Brahms Kryptor
		µg/l	19.8	14.9	24.8	BioMerieux Vidas
µg/l		15.1	11.3	18.9	Roche Elecsys/Cobas/Modular	
µg/l		20.0	15.0	25.0	Siemens Centaur XP/XPT/Classic	
µg/l		19.5	14.6	24.4	Siemens Centaur CP 10378883	
µg/l		15.4	11.6	19.3	Abbott Architect / Alinity Brahms PCT	
µg/l		15.1	11.3	18.9	Roche Cobas e801	
µg/l		18.2	13.7	22.8	Siemens Atellica IM 10995651	
µg/l		20.5	15.4	25.6	Beckman Access PCT	
µg/l		19.5	14.6	24.4	Siemens Centaur XP/XPT 11202697	
µg/l		20.5	15.4	25.6	Siemens Centaur CP 11202697	
µg/l		20.0	15.0	25.0	Siemens Atellica IM 11202699	