

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

CAT NO.	IAS3115	LOT NO.	2195EC
SIZE:	5 x 2 ml	EXPIRY:	2024-05-28
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-1 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 ± 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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Dungloe, Donegal,
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28 Jul '22 me

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Cat. No. IAS3115 Lot. No. 2195EC Size 5 x 2ml Expiry 2024-05-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	293	205	381	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	102	76.5	128	Roche Vitamin D Total
	nmol/l	105	78.8	131	Diasorin Liaison
	nmol/l	105	78.8	131	Abbott Architect (3L52)
	nmol/l	136	102	170	Siemens Centaur XP/XPT/Classic
	nmol/l	93.7	70.3	117	BioMerieux Vidas
	nmol/l	89.7	67.3	112	Beckman Dxl 600/800
	nmol/l	103	77.3	129	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	102	76.5	128	Diasorin Liaison XL
	nmol/l	102	76.5	128	Roche Vitamin D Total II
	nmol/l	138	104	173	Siemens Atellica IM
	nmol/l	97.5	73.1	122	Roche Vitamin D Total II e801
nmol/l	95.6	71.7	120	Roche Vitamin D Total III	
Anti TG	kU/l	400	300	500	Siemens Immulite 2000/2500
	kU/l	218	164	273	Abbott Architect / Alinity
	kU/l	1185	889	1481	Roche Cobas 4000/E411
	kU/l	1026	770	1283	Roche Cobas e601/602
	kU/l	565	424	706	Beckman Dxl 600/800
	kU/l	359	269	449	Siemens Centaur XP/XPT/Classic
	kU/l	674	506	843	BioMerieux Vidas
	kU/l	389	292	486	Siemens Atellica IM
	kU/l	1056	792	1320	Roche Cobas e402/e801
	kU/l	378	284	473	Siemens Atellica IM aTgII
	kU/l	358	269	448	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	140	105	175	Abbott Architect / Alinity
	kU/l	153	115	191	Siemens Immulite 2000/2500
	kU/l	98.5	73.9	123	Roche Cobas 4000/E411
	kU/l	97.5	73.1	122	Roche Cobas c501/502 e601/602
	kU/l	95.8	71.9	120	Beckman Dxl 600/800
	kU/l	477	358	596	Siemens Centaur XP/XPT/Classic
	kU/l	101	75.8	126	BioMerieux Vidas
	kU/l	129	96.8	161	Roche Cobas e402/e801
	kU/l	461	346	576	Siemens Atellica IM
C-Peptide	nmol/l	1.190	0.893	1.490	Siemens Centaur XP/XPT/Classic
	ng/ml	3.59	2.70	4.48	
	nmol/l	1.710	1.280	2.140	Roche Cobas e601/602
	ng/ml	5.16	3.86	6.46	
	nmol/l	1.530	1.150	1.910	Abbott Architect / Alinity
	ng/ml	4.62	3.47	5.77	
	nmol/l	1.470	1.100	1.840	Siemens Immulite 2000/2500
	ng/ml	4.44	3.32	5.56	
	nmol/l	1.710	1.280	2.140	Roche Cobas 4000/E411
	ng/ml	5.16	3.86	6.46	

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			low	high		
C-Peptide	nmol/l	1.620	1.220	2.030	Roche Cobas e402/e801	
	ng/ml	4.89	3.68	6.10		
	nmol/l	1.120	0.840	1.400	Siemens Atellica IM	
	ng/ml	3.38	2.54	4.22		
	nmol/l	1.850	1.388	2.313	Diasorin Liaison XL	
	ng/ml	5.59	4.19	6.98		
	IGF 1	µg/l	504	378	630	Siemens Immulite 2000/2500
		µg/l	128	96.0	160	Roche Cobas 4000/E411
µg/l		124	93.0	155	Roche Cobas 6000/8000	
Insulin	mU/l	23.4	17.6	29.3	Abbott Architect	
	µU/ml	23.4	17.6	29.2		
	mU/l	30.1	22.6	37.6	Roche Cobas 6000/8000	
	µU/ml	30.1	22.6	37.6		
	mU/l	28.1	21.1	35.1	Siemens Centaur XP/XPT/Classic	
	µU/ml	28.1	21.1	35.1		
	mU/l	26.2	19.7	32.8	Beckman Dxl 600/800	
	µU/ml	26.2	19.7	32.7		
	mU/l	30.6	23.0	38.3	Roche Cobas 4000/E411	
	µU/ml	30.6	23.0	38.2		
	mU/l	28.2	21.2	35.3	Siemens Atellica IM	
	µU/ml	28.2	21.2	35.2		
Osteocalcin	mU/l	21.5	16.1	26.9	Abbott Alinity i	
	µU/ml	21.5	16.1	26.9		
	µg/l	45.1	33.8	56.4	Siemens Immulite 2000/2500	
	µg/l	99.0	74.3	124	Roche Cobas 6000/8000	
Parathyroid Hormone (PTH)	µg/l	95.4	71.6	119	Roche Cobas 4000/E411	
	µg/l	111	83.3	139	Diasorin Liaison	
	pmol/l	126	94.5	158	Abbott Architect / Alinity	
	pg/ml	1197	897	1497		
	pmol/l	96.7	72.5	121	Beckman Dxl 600/800	
	pg/ml	918	689	1147		
	pmol/l	77.4	58.1	96.8	Roche Cobas e601/602 PTH	
	pg/ml	735	552	918		
	pmol/l	85.0	63.8	106	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	807	606	1008		
	pmol/l	124	93.0	155	Siemens Centaur XP/XPT/Classic	
	pg/ml	1178	883	1473		
	pmol/l	73.9	55.4	92.4	Roche Cobas e601/602 PTH (1-84)	
	pg/ml	702	526	878		
	pmol/l	82.7	62.0	103	Roche Cobas 4000/E411 PTH (1-84)	
	pg/ml	785	589	981		
pmol/l	117	87.8	146	Siemens Atellica IM		
pg/ml	1111	834	1388			
pmol/l	82.9	62.2	104	Roche Cobas e801 PTH		
pg/ml	787	591	983			

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Analyte	unit	Target	Range		methods
			low	high	
Parathyroid Hormone (PTH)	pmol/l	70.7	53.0	88.4	Roche Cobas e801 PTH (1-84)
	pg/ml	671	503	839	
	pmol/l	78.6	59.0	98.3	Roche Cobas e801 PTH STAT
	pg/ml	746	560	932	
	pmol/l	76.6	57.5	95.8	Roche Cobas e601/602 PTH STAT
Procalcitonin	µg/l	14.3	10.7	17.9	Brahms Kryptor
	µg/l	24.0	18.0	30.0	BioMerieux Vidas
	µg/l	20.6	15.5	25.8	Roche Elecsys/Cobas/Modular
	µg/l	24.9	18.7	31.1	Siemens Centaur XP/XPT/Classic
	µg/l	23.4	17.6	29.3	Siemens Centaur CP 10378883
	µg/l	19.7	14.8	24.6	Abbott Architect / Alinity Brahms PCT
	µg/l	20.6	15.5	25.8	Roche Cobas e402/e801
	µg/l	24.9	18.7	31.1	Siemens Atellica IM 10995651
	µg/l	26.5	19.9	33.1	Beckman Access PCT
	µg/l	25.2	18.9	31.5	Siemens Centaur XP/XPT 11202697
	µg/l	25.3	19.0	31.6	Siemens Centaur CP 11202697
	µg/l	25.3	19.0	31.6	Siemens Atellica IM 11202699