

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

CAT. NO. IAS3114 **LOT NO.** 2282EC
SIZE 5 x 2 ml **EXPIRY:** 2025-04-28
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

Unopened: Unreconstituted control is stable up to the expiry date shown on the side of each individual bottle.

Opened: Once reconstituted, the components of the control are stable for 5 days at +2°C to +8°C and 28 days at -20°C when frozen once. Except:

Analyte	+2°C to +8°C	Aliquoted and frozen once at -20°C
Anti-TG	3 days	-
C-Peptide	1 day	-
IGF-I	8 hours	-
Osteocalcin	4 hours	-
Parathyroid Hormone (PTH)	4 hours	14 days
Procalcitonin	1 day	

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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	Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland
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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	184	129	239	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	54.2	40.7	67.8	Diasorin Liaison
	nmol/l	52.7	39.5	65.9	Abbott Architect (3L52)
	nmol/l	76.3	57.2	95.4	Siemens Centaur XP/XPT/Classic
	nmol/l	73.7	55.3	92.1	Vitros ECi
	nmol/l	62.1	46.6	77.6	BioMerieux Vidas
	nmol/l	49.0	36.8	61.3	Beckman Dxl 600/800
	nmol/l	52.0	39.0	65.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	54.4	40.8	68.0	Diasorin Liaison XL
	nmol/l	49.1	36.8	61.4	Roche Vitamin D Total II
	nmol/l	75.9	56.9	94.9	Siemens Atellica IM
	nmol/l	45.9	34.4	57.4	Roche Vitamin D Total II e801
nmol/l	50.4	37.8	63.0	Roche Vitamin D Total III	
Anti TG	kU/l	91.7	68.8	115	Siemens Immulite 2000/2500
	kU/l	127	95.3	159	Abbott Architect / Alinity
	kU/l	510	383	638	Roche Cobas 4000/E411
	kU/l	546	410	683	Roche Cobas e601/602
	kU/l	199	149	249	Beckman Dxl 600/800
	kU/l	132	99.0	165	Siemens Centaur XP/XPT/Classic
	kU/l	219	164	274	Beckman Access/LXi725
	kU/l	207	155	259	BioMerieux Vidas
	kU/l	140	105	175	Siemens Atellica IM
	kU/l	484	363	605	Roche Cobas e402/e801
	kU/l	143	107	179	Siemens Atellica IM aTgII
	kU/l	136	102	170	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	114	85.5	143	Abbott Architect / Alinity
	kU/l	127	95.3	159	Siemens Immulite 2000/2500
	kU/l	85.2	63.9	107	Roche Cobas 4000/E411
	kU/l	81.7	61.3	102	Roche Cobas c501/502 e601/602
	kU/l	67.0	50.3	83.8	Beckman Dxl 600/800
	kU/l	437	328	546	Siemens Centaur XP/XPT/Classic
	kU/l	74.4	55.8	93.0	Beckman Access/LXi725
	kU/l	102	76.5	128	BioMerieux Vidas
	kU/l	109	81.8	136	Roche Cobas e402/e801
	kU/l	419	314	524	Siemens Atellica IM
C-Peptide	nmol/l	0.890	0.668	1.110	Siemens Centaur XP/XPT/Classic
	ng/ml	2.69	2.02	3.36	
	nmol/l	0.970	0.728	1.210	Roche Cobas e601/602
	ng/ml	2.93	2.20	3.66	
	nmol/l	0.870	0.653	1.090	Abbott Architect / Alinity
	ng/ml	2.63	1.97	3.29	
	nmol/l	0.800	0.600	1.000	Siemens Immulite 2000/2500
	ng/ml	2.42	1.81	3.03	

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			low	high		
C-Peptide	nmol/l	0.960	0.720	1.200	Roche Cobas 4000/E411	
	ng/ml	2.90	2.17	3.63		
	nmol/l	1.140	0.855	1.430	Diasorin Liaison XL	
	ng/ml	3.44	2.58	4.30		
	nmol/l	0.960	0.720	1.200	Roche Cobas e402/e801	
	ng/ml	2.90	2.17	3.63		
	nmol/l	0.770	0.578	0.963	Siemens Atellica IM	
	ng/ml	2.32	1.74	2.90		
	IGF 1	µg/l	212	159	265	Siemens Immulite 2000/2500
		µg/l	64.8	48.6	81.0	Roche Cobas 4000/E411
µg/l		70.9	53.2	88.6	Roche Cobas 6000/8000	
µg/l		63.9	47.9	79.9	Roche Elecsys	
Insulin	mU/l	8.74	6.56	10.9	Abbott Architect	
	µU/ml	8.74	6.56	10.9		
	mU/l	10.2	7.65	12.8	Roche Cobas 6000/8000	
	µU/ml	10.2	7.65	12.8		
	mU/l	11.4	8.55	14.3	Siemens Centaur XP/XPT/Classic	
	µU/ml	11.4	8.55	14.3		
	mU/l	9.19	6.89	11.5	Beckman Dxl 600/800	
	µU/ml	9.19	6.89	11.5		
	mU/l	10.7	8.03	13.4	Roche Cobas 4000/E411	
	µU/ml	10.7	8.03	13.4		
Osteocalcin	µg/l	36.2	27.2	45.3	Siemens Immulite 2000/2500	
	µg/l	78.6	59.0	98.3	Roche Cobas 6000/8000	
	µg/l	75.0	56.3	93.8	Roche Cobas 4000/E411	
Parathyroid Hormone (PTH)	pmol/l	42.4	31.8	53.0	Abbott Architect / Alinity	
	pg/ml	403	302	504		
	pmol/l	31.3	23.5	39.1	Beckman Dxl 600/800	
	pg/ml	297	223	371		
	pmol/l	27.1	20.3	33.9	Roche Cobas e601/602 PTH	
	pg/ml	257	193	321		
	pmol/l	29.1	21.8	36.4	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	276	207	345		
	pmol/l	38.1	28.6	47.6	Siemens Centaur XP/XPT/Classic	
	pg/ml	362	272	452		
	pmol/l	26.8	20.1	33.5	Roche Cobas e601/602 PTH (1-84)	
	pg/ml	255	191	319		
pmol/l	29.2	21.9	36.5	Roche Cobas 4000/E411 PTH (1-84)		
pg/ml	277	208	346			
pmol/l	37.8	28.4	47.3	Siemens Atellica IM		
pg/ml	359	270	448			

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			low	high	
Parathyroid Hormone (PTH)	pmol/l	26.1	19.6	32.6	Roche Cobas e801 PTH
	pg/ml	248	186	310	
	pmol/l	25.5	19.1	31.9	Roche Cobas e801 PTH (1-84)
	pg/ml	242	181	303	
	pmol/l	24.9	18.7	31.1	Roche Cobas e801 PTH STAT
	pg/ml	236	178	294	
Procalcitonin	pmol/l	25.3	19.0	31.6	Roche Cobas e601/602 PTH STAT
	pg/ml	240	180	300	
	µg/l	1.76	1.32	2.20	Brahms Kryptor
	µg/l	4.67	3.50	5.84	BioMerieux Vidas
	µg/l	2.77	2.08	3.46	Roche Elecsys/Cobas/Modular
	µg/l	4.01	3.01	5.01	Siemens Centaur XP/XPT/Classic
	µg/l	2.74	2.06	3.43	SNIBE Maglumi Analysers
	µg/l	3.88	2.91	4.85	Siemens Centaur CP 10378883
	µg/l	2.69	2.02	3.36	Abbott Architect / Alinity Brahms PCT
	µg/l	2.72	2.04	3.40	Roche Cobas e402/e801
	µg/l	3.98	2.99	4.98	Siemens Atellica IM 10995651
	µg/l	3.63	2.72	4.54	Beckman Access PCT
	µg/l	3.93	2.95	4.91	Siemens Centaur XP/XPT 11202697
	µg/l	4.13	3.10	5.16	Siemens Centaur CP 11202697
µg/l	4.05	3.04	5.06	Siemens Atellica IM 11202699	