

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

CAT NO. IAS3115 **LOT NO.** 2283EC
SIZE 5 x 2 ml **EXPIRY:** 2025-04-28
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

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 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.



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Range					
Analyte	unit	Target	low	high	methods
1-25 (OH) ₂ Vitamin D	pmol/l	341	239	443	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	93.8	70.4	117	Diasorin Liaison
	nmol/l	100	75.0	125	Abbott Architect (3L52)
	nmol/l	129	96.8	161	Siemens Centaur XP/XPT/Classic
	nmol/l	117	87.8	146	Vitros ECI
	nmol/l	90.2	67.7	113	BioMerieux Vidas
	nmol/l	90.9	68.2	114	Beckman Dxl 600/800
	nmol/l	100	75.0	125	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	94.1	70.6	118	Diasorin Liaison XL
	nmol/l	92.1	69.1	115	Roche Vitamin D Total II
	nmol/l	129	96.8	161	Siemens Atellica IM
	nmol/l	91.0	68.3	114	Roche Vitamin D Total II e801
	nmol/l	93.5	70.1	117	Roche Vitamin D Total III
Anti TG	kU/l	174	131	218	Siemens Immulite 2000/2500
	kU/l	223	167	279	Abbott Architect / Alinity
	kU/l	1283	962	1604	Roche Cobas 4000/E411
	kU/l	1372	1029	1715	Roche Cobas e601/602
	kU/l	351	263	439	Beckman Dxl 600/800
	kU/l	234	176	293	Siemens Centaur XP/XPT/Classic
	kU/l	357	268	446	Beckman Access/LXi725
	kU/l	355	266	444	BioMerieux Vidas
	kU/l	922	692	1153	SNIBE Maglumi Analysers
	kU/l	259	194	324	Siemens Atellica IM
	kU/l	1221	916	1526	Roche Cobas e402/e801
	kU/l	257	193	321	Siemens Atellica IM aTgII
	kU/l	243	182	304	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	185	139	231	Abbott Architect / Alinity
	kU/l	207	155	259	Siemens Immulite 2000/2500
	kU/l	135	101	169	Roche Cobas 4000/E411
	kU/l	135	101	169	Roche Cobas c501/502 e601/602
	kU/l	107	80.3	134	Beckman Dxl 600/800
	kU/l	634	476	793	Siemens Centaur XP/XPT/Classic
	kU/l	112	84.0	140	Beckman Access/LXi725
	kU/l	167	125	209	BioMerieux Vidas
	kU/l	192	144	240	Roche Cobas e402/e801
	kU/l	643	482	804	Siemens Atellica IM
C-Peptide	nmol/l	1.550	1.160	1.940	Roche Cobas e601/602
	ng/ml	4.68	3.50	5.86	
	nmol/l	1.460	1.100	1.830	Abbott Architect / Alinity
	ng/ml	4.41	3.32	5.50	
	nmol/l	1.380	1.040	1.730	Siemens Immulite 2000/2500
	ng/ml	4.17	3.14	5.20	

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Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	1.560	1.170	1.950	Roche Cobas 4000/E411
	ng/ml	4.71	3.53	5.89	
	nmol/l	1.730	1.300	2.160	Diasorin Liaison XL
	ng/ml	5.22	3.92	6.52	
	nmol/l	1.530	1.150	1.910	Roche Cobas e402/e801
	ng/ml	4.62	3.47	5.77	
	nmol/l	1.250	0.938	1.560	Siemens Atellica IM
	ng/ml	3.77	2.83	4.71	
IGF 1	µg/l	335	251	419	Siemens Immulite 2000/2500
	µg/l	159	119	199	Diasorin Liaison
	µg/l	106	79.5	133	Roche Cobas 4000/E411
	µg/l	101	75.8	126	Roche Cobas 6000/8000
	µg/l	94.5	70.9	118	Roche Elecsys
Insulin	mU/l	22.8	17.1	28.5	Abbott Architect
	µU/ml	22.8	17.1	28.5	
	mU/l	30.4	22.8	38.0	Roche Cobas 6000/8000
	µU/ml	30.4	22.8	38.0	
	mU/l	29.4	22.1	36.8	Siemens Centaur XP/XPT/Classic
	µU/ml	29.4	22.1	36.7	
	mU/l	25.7	19.3	32.1	Beckman Dxl 600/800
	µU/ml	25.7	19.3	32.1	
	mU/l	31.3	23.5	39.1	Roche Cobas 4000/E411
	µU/ml	31.3	23.5	39.1	
	mU/l	28.8	21.6	36.0	Siemens Atellica IM
	µU/ml	28.8	21.6	36.0	
	mU/l	21.9	16.4	27.4	Abbott Alinity i
	µU/ml	21.9	16.4	27.4	
Osteocalcin	µg/l	75.3	56.5	94.1	Siemens Immulite 2000/2500
	µg/l	158	119	198	Roche Cobas 6000/8000
	µg/l	153	115	191	Roche Cobas 4000/E411
Parathyroid Hormone (PTH)	pmol/l	126	94.5	158	Abbott Architect / Alinity
	pg/ml	1197	897	1497	
	pmol/l	89.1	66.8	111	Beckman Dxl 600/800
	pg/ml	846	634	1058	
	pmol/l	155	116	194	Siemens Immulite 2000/2500
	pg/ml	1472	1102	1842	
	pmol/l	84.0	63.0	105	Roche Cobas e601/602 PTH
	pg/ml	798	598	998	
	pmol/l	87.7	65.8	110	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	833	625	1041	
	pmol/l	119	89.3	149	Siemens Centaur XP/XPT/Classic
	pg/ml	1130	848	1412	
	pmol/l	78.8	59.1	98.5	Roche Cobas e601/602 PTH (1-84)
	pg/ml	748	561	935	
	pmol/l	85.3	64.0	107	Roche Cobas 4000/E411 PTH (1-84)
	pg/ml	810	608	1012	

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Parathyroid Hormone (PTH)	pmol/l	118	88.5	148	Siemens Atellica IM
	pg/ml	1121	840	1402	
	pmol/l	78.0	58.5	97.5	Roche Cobas e801 PTH
	pg/ml	741	556	926	
	pmol/l	70.9	53.2	88.6	Roche Cobas e801 PTH (1-84)
	pg/ml	673	505	841	
	pmol/l	76.0	57.0	95.0	Roche Cobas e801 PTH STAT
	pg/ml	722	541	903	
Procalcitonin	pmol/l	72.1	54.1	90.1	Roche Cobas e601/602 PTH STAT
	pg/ml	685	514	856	
	µg/l	23.4	17.6	29.3	BioMerieux Vidas
	µg/l	17.6	13.2	22.0	Roche Elecsys/Cobas/Modular
	µg/l	22.2	16.7	27.8	Siemens Centaur XP/XPT/Classic
	µg/l	17.7	13.3	22.1	SNIBE Maglumi Analysers
	µg/l	21.2	15.9	26.5	Siemens Centaur CP 10378883
	µg/l	16.3	12.2	20.4	Abbott Architect / Alinity Brahms PCT
	µg/l	16.8	12.6	21.0	Roche Cobas e402/e801
	µg/l	20.9	15.7	26.1	Siemens Atellica IM 10995651
	µg/l	22.4	16.8	28.0	Beckman Access PCT
	µg/l	21.9	16.4	27.4	Siemens Centaur XP/XPT 11202697
	µg/l	22.0	16.5	27.5	Siemens Centaur CP 11202697
	µg/l	21.1	15.8	26.4	Siemens Atellica IM 11202699