

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

CAT. NO. IAS3114

LOT NO. 1988EC

SIZE: 5 x 2 ml

EXPIRY: 2022-06-28

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, IGF-I and Procalcitonin are stable for 1 day 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

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. This results in extremely accurate values, which may be confidently used by laboratories to ensure the accuracy of their methods.

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,
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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	218	153	283	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	60.5	45.4	75.6	Roche Vitamin D Total
	nmol/l	69.0	51.8	86.3	Diasorin Liaison
	nmol/l	60.3	45.2	75.4	Abbott Architect
	nmol/l	89.7	67.3	112	Siemens Centaur XP/XPT/Classic
	nmol/l	67.6	50.7	84.5	BioMerieux Vidas
	nmol/l	64.4	48.3	80.5	Beckman Dxl 600/800
	nmol/l	71.8	53.9	89.8	Beckman Access 25 OH Vitamin D Total
	nmol/l	60.8	45.6	76.0	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	74.9	56.2	93.6	Diasorin Liaison XL
	nmol/l	65.6	49.2	82.0	Roche Vitamin D Total II
	nmol/l	91.4	68.6	114	Siemens Atellica IM
Anti-TG	kU/l	153	115	191	Siemens Immulite 2000/2500
	kU/l	145	109	181	Abbott Architect
	kU/l	801	601	1001	Roche Cobas E411
	kU/l	753	565	941	Roche Cobas 6000/8000
	kU/l	311	233	389	Beckman Dxl 600/800
	kU/l	498	374	623	Siemens Centaur XP/XPT/Classic
	kU/l	285	214	356	Beckman Access/LXi725
	kU/l	313	235	391	BioMerieux Vidas
	kU/l	539	404	674	Siemens Atellica IM
Anti-TPO	kU/l	112	84.0	140	Abbott Architect
	kU/l	130	97.5	163	Siemens Immulite 2000/2500
	kU/l	76.6	57.5	95.8	Roche Cobas E411
	kU/l	78.2	58.7	97.8	Roche Cobas 6000/8000
	kU/l	88.1	66.1	110	Beckman Dxl 600/800
	kU/l	368	276	460	Siemens Centaur XP/XPT/Classic
	kU/l	96.7	72.5	121	BioMerieux Vidas
	kU/l	364	273	455	Siemens Atellica IM
C-Peptide	nmol/l	1.050	0.788	1.310	Siemens Centaur XP/XPT/Classic
	ng/ml	3.17	2.38	3.96	
	nmol/l	1.420	1.070	1.780	Roche Cobas 6000/8000
	ng/ml	4.29	3.23	5.35	
	nmol/l	1.480	1.110	1.850	Diasorin Liaison
	ng/ml	4.47	3.35	5.59	
	nmol/l	1.240	0.930	1.550	Abbott Architect
	ng/ml	3.74	2.81	4.67	
	nmol/l	1.260	0.945	1.580	Siemens Immulite 2000/2500
	ng/ml	3.80	2.85	4.75	
	nmol/l	1.410	1.060	1.760	Roche Cobas E411
	ng/ml	4.26	3.20	5.32	
	nmol/l	0.967	0.725	1.210	Siemens Atellica IM
ng/ml	2.92	2.19	3.65		

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Range					
Analyte	unit	Target	low	high	methods
IGF-1	µg/l	225	169	281	Siemens Immulite 2000/2500
	µg/l	169	127	211	Diasorin Liaison
	µg/l	106	79.5	133	Roche Cobas 6000/8000
Insulin	mU/l	10.9	8.18	13.6	Abbott Architect
	µU/ml	10.9	8.18	13.6	
	mU/l	12.9	9.68	16.1	Roche Cobas 6000/8000
	µU/ml	12.9	9.68	16.1	
	mU/l	13.8	10.4	17.3	Siemens Centaur XP/XPT/Classic
	µU/ml	13.8	10.4	17.2	
	mU/l	4.92	3.69	6.15	Siemens Immulite 2000
	µU/ml	4.92	3.69	6.15	
	mU/l	11.0	8.25	13.8	Beckman Dxl 600/800
	µU/ml	11.0	8.25	13.8	
	mU/l	12.8	9.60	16.0	Roche Cobas E411
	µU/ml	12.8	9.60	16.0	
	mU/l	14.4	10.8	18.0	Diasorin Liaison XL
µU/ml	14.4	10.8	18.0		
mU/l	12.8	9.60	16.0	Siemens Atellica IM	
µU/ml	12.8	9.60	16.0		
Osteocalcin	µg/l	38.0	28.5	47.5	Siemens Immulite 2000/2500
	µg/l	69.4	52.1	86.8	Roche Elecsys
	µg/l	70.7	53.0	88.4	Roche Cobas 6000/8000
	µg/l	69.0	51.8	86.3	Roche Cobas E411
	µg/l	83.6	62.7	105	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	45.6	34.2	57.0	Abbott Architect
	pg/ml	433	325	541	
	pmol/l	31.4	23.6	39.3	Beckman Dxl 600/800
	pg/ml	298	224	372	
	pmol/l	50.6	38.0	63.3	Siemens Immulite 2000/2500
	pg/ml	481	361	601	
	pmol/l	28.9	21.7	36.1	Roche Cobas 6000/8000
	pg/ml	274	206	342	
	pmol/l	29.7	22.3	37.1	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	282	212	352	
	pmol/l	38.4	28.8	48.0	Siemens Centaur XP/XPT/Classic
pg/ml	365	274	456		
pmol/l	38.2	28.7	47.8	Siemens Atellica IM	
pg/ml	363	273	453		
Procalcitonin	µg/l	2.30	1.73	2.88	Brahms Kryptor
	µg/l	4.10	3.08	5.13	BioMerieux Vidas
	µg/l	2.82	2.12	3.53	Roche Elecsys/Cobas/Modular
	µg/l	3.50	2.63	4.38	Siemens Centaur XP/XPT/Classic
	µg/l	3.57	2.68	4.46	Siemens Centaur CP
	µg/l	5.99	4.79	7.18	Diazyme PCT
µg/l	2.95	2.21	3.69	Abbott Architect Brahms PCT	

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Range

Analyte	unit	Target	low	high	methods
Procalcitonin	µg/l	8.18	6.95	9.41	Nexus IB10

**ADDITIONAL VALUES FOR
IMMUNOASSAY SPECIALITY I - LEVEL 2
(IA SPECIALITY I LEV 2)**

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COMPONENT	UNITS	TARGET	RANGE	METHOD
C-Peptide	nmol/l	0.914	0.686 - 1.14	Beckman Dxl 600/800
	ng/ml	2.76	2.07 - 3.45	

EC REP Randox Teoranta, Meenmore,
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