

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

**CAT. NO.** IAS3114  
**SIZE:** 5 x 2 ml

**LOT NO.** 1852EC  
**EXPIRY:** 2020-10-28

**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  $\pm 2$  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](mailto:Technical.Services@randox.com).

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Size: 5 x 2 ml Expiry: 2020-10-28

Analyte	unit	Target	Range		methods
			low	high	
1-25(OH) vitamin D	pmol/L	272	190	354	Diasorin Liaison
25-OH Vitamin D	nmol/l	95.4	71.6	119	Roche Vitamin D Total
	nmol/l	116	87.0	145	Diasorin Liaison
	nmol/l	108	81.0	135	Abbott Architect
	nmol/l	148	111	185	Siemens Centaur XP/XPT/Classic
	nmol/l	92.5	69.4	116	BioMerieux Vidas
	nmol/l	102	76.5	128	Beckman Dxl 600/800
	nmol/l	114	85.5	143	Diasorin Liaison XL
	nmol/l	110	82.5	138	Roche Vitamin D Total II
Anti-TG	kU/l	158	119	198	Abbott Architect
	kU/l	1011	758	1264	Roche Cobas E411
	kU/l	884	663	1105	Roche Cobas 6000/8000
	kU/l	517	388	646	Beckman Dxl 600/800
	kU/l	1006	755	1258	Siemens Centaur XP/XPT/Classic
	kU/l	600	450	750	BioMerieux Vidas
Anti-TPO	kU/l	94.3	70.7	118	Abbott Architect
	kU/l	106	79.5	133	Siemens Immulite 2000/2500
	kU/l	62.1	46.6	77.6	Roche Cobas E411
	kU/l	65.7	49.3	82.1	Roche Cobas 6000/8000
	kU/l	75.0	56.3	93.8	Beckman Dxl 600/800
	kU/l	307	230	384	Siemens Centaur XP/XPT/Classic
	kU/l	93.3	70.0	117	BioMerieux Vidas
C-Peptide	nmol/l	1.100	0.825	1.380	Siemens Centaur XP/XPT/Classic
	ng/ml	3.32	2.49	4.15	
	nmol/l	1.520	1.140	1.900	Roche Cobas 6000/8000
	ng/ml	4.59	3.44	5.74	
	nmol/l	1.680	1.260	2.100	Diasorin Liaison
	ng/ml	5.07	3.80	6.34	
	nmol/l	1.310	0.983	1.640	Abbott Architect
	ng/ml	3.95	2.97	4.93	
	nmol/l	1.380	1.040	1.730	Siemens Immulite 2000/2500
	ng/ml	4.17	3.14	5.20	
IGF-1	nmol/l	1.530	1.150	1.910	Roche Cobas E411
	ng/ml	4.62	3.47	5.77	
	µg/l	225	169	281	Siemens Immulite 2000/2500
IGF-1	µg/l	203	152	254	Diasorin Liaison
	µg/l	121	90.8	151	Roche Cobas 6000/8000
	Insulin	mU/l	13.7	10.3	17.1
µU/ml		13.7	10.3	17.1	
mU/l		17.2	12.9	21.5	Roche Cobas 6000/8000
µU/ml		17.2	12.9	21.5	
mU/l		16.1	12.1	20.1	Siemens Centaur XP/XPT/Classic
µU/ml		16.1	12.1	20.1	

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Analyte	unit	Target	Range		methods
			low	high	
Insulin	mU/l	4.98	3.74	6.23	Siemens Immulite 2000
	µU/ml	4.98	3.74	6.22	
	mU/l	14.2	10.7	17.8	Beckman Dxl 600/800
	µU/ml	14.2	10.7	17.7	
	mU/l	18.0	13.5	22.5	Roche Cobas E411
	µU/ml	18.0	13.5	22.5	
Osteocalcin	µg/l	52.3	39.2	65.4	Siemens Immulite 2000/2500
	µg/l	84.8	63.6	106	Roche Cobas 6000/8000
	µg/l	83.6	62.7	105	Roche Cobas E411
	µg/l	96.3	72.2	120	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	41.1	30.8	51.4	Abbott Architect
	pg/ml	390	293	487	
	pmol/l	31.2	23.4	39.0	Beckman Dxl 600/800
	pg/ml	296	222	370	
	pmol/l	52.5	39.4	65.6	Siemens Immulite 2000/2500
	pg/ml	499	374	624	
	pmol/l	28.5	21.4	35.6	Roche Cobas 6000/8000
	pg/ml	271	203	339	
	pmol/l	29.3	22.0	36.6	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	278	209	347	
	pmol/l	38.2	28.7	47.8	Siemens Centaur XP/XPT/Classic
	pg/ml	363	273	453	
Procalcitonin	µg/l	1.99	1.49	2.49	Brahms Kryptor
	µg/l	5.11	3.83	6.39	BioMerieux Vidas
	µg/l	3.02	2.27	3.78	Roche Elecsys/Cobas/Modular
	µg/l	4.72	3.54	5.90	Siemens Centaur XP/XPT/Classic
	µg/l	6.67	4.67	8.67	SNIBE Maglumi Analysers
	µg/l	5.10	3.83	6.38	Siemens Centaur CP
	µg/l	4.53	3.40	5.66	Fujirebio Lumipulse G Series
	µg/l	4.55	3.41	5.69	Diazyme PCT