

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

**CAT NO.** IAS3115

**LOT NO.** 1853EC

**SIZE:** 5 x 2 ml

**EXPIRY:** 2020-10-28

**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, IGF-I and Procalcitonin are stable for 1 day 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.

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 3 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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Analyte	unit	Target	Range		methods
			low	high	
1-25(OH) vitamin D	pmol/L	444	311	577	Diasorin Liaison
25-OH Vitamin D	nmol/l	135	101	169	Roche Vitamin D Total
	nmol/l	153	115	191	Diasorin Liaison
	nmol/l	152	114	190	Abbott Architect
	nmol/l	208	156	260	Siemens Centaur XP/XPT/Classic
	nmol/l	116	87.0	145	BioMerieux Vidas
	nmol/l	154	116	193	Beckman Dxl 600/800
	nmol/l	151	113	189	Diasorin Liaison XL
	nmol/l	156	117	195	Roche Vitamin D Total II
Anti-TG	kU/l	494	371	618	Siemens Immulite 2000/2500
	kU/l	246	185	308	Abbott Architect
	kU/l	1292	969	1615	Roche Cobas E411
	kU/l	1103	827	1379	Roche Cobas 6000/8000
	kU/l	814	611	1018	Beckman Dxl 600/800
	kU/l	1896	1422	2370	Siemens Centaur XP/XPT/Classic
	kU/l	989	742	1236	BioMerieux Vidas
Anti-TPO	kU/l	143	107	179	Abbott Architect
	kU/l	169	127	211	Siemens Immulite 2000/2500
	kU/l	107	80.3	134	Roche Cobas E411
	kU/l	106	79.5	133	Roche Cobas 6000/8000
	kU/l	116	87.0	145	Beckman Dxl 600/800
	kU/l	438	329	548	Siemens Centaur XP/XPT/Classic
	kU/l	150	113	188	BioMerieux Vidas
C-Peptide	nmol/l	2.370	1.780	2.960	Siemens Centaur XP/XPT/Classic
	ng/ml	7.16	5.37	8.95	
	nmol/l	2.810	2.110	3.510	Roche Cobas 6000/8000
	ng/ml	8.48	6.37	10.6	
	nmol/l	3.030	2.270	3.790	Diasorin Liaison
	ng/ml	9.15	6.85	11.5	
	nmol/l	2.610	1.960	3.260	Abbott Architect
	ng/ml	7.88	5.92	9.84	
	nmol/l	2.940	2.210	3.680	Siemens Immulite 2000/2500
	ng/ml	8.88	6.67	11.1	
IGF-1	nmol/l	2.810	2.110	3.510	Roche Cobas E411
	ng/ml	8.48	6.37	10.6	
	µg/l	362	272	453	Siemens Immulite 2000/2500
Insulin	µg/l	300	225	375	Diasorin Liaison
	µg/l	189	142	236	Roche Cobas 6000/8000
	mU/l	26.2	19.7	32.8	Abbott Architect
	µU/ml	26.2	19.7	32.7	
Insulin	mU/l	37.6	28.2	47.0	Roche Cobas 6000/8000
	µU/ml	37.6	28.2	47.0	

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Analyte	unit	Target	Range		methods	
			low	high		
Insulin	mU/l	27.6	20.7	34.5	Siemens Centaur XP/XPT/Classic	
	µU/ml	27.6	20.7	34.5		
	mU/l	11.4	8.55	14.3	Siemens Immulite 2000	
	µU/ml	11.4	8.55	14.3		
	mU/l	27.8	20.9	34.8	Beckman Dxl 600/800	
	µU/ml	27.8	20.9	34.7		
	mU/l	37.2	27.9	46.5	Roche Cobas E411	
	µU/ml	37.2	27.9	46.5		
	Osteocalcin	µg/l	86.3	64.7	108	Siemens Immulite 2000/2500
		µg/l	171	128	214	Roche Cobas 6000/8000
		µg/l	164	123	205	Roche Cobas E411
		µg/l	228	171	285	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	103	77.3	129	Roche Modular E170 PTH/PTH STAT	
	pg/ml	978	734	1222		
	pmol/l	144	108	180	Abbott Architect	
	pg/ml	1368	1026	1710		
	pmol/l	109	81.8	136	Beckman Dxl 600/800	
	pg/ml	1035	777	1293		
	pmol/l	187	140	234	Siemens Immulite 2000/2500	
	pg/ml	1776	1330	2222		
	pmol/l	100	75.0	125	Roche Elecsys PTH/PTH STAT	
	pg/ml	950	712	1188		
	pmol/l	99.8	74.9	125	Roche Cobas 6000/8000	
	pg/ml	948	711	1185		
	pmol/l	106	79.5	133	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	1007	755	1259		
Procalcitonin	pmol/l	135	101	169	Siemens Centaur XP/XPT/Classic	
	pg/ml	1282	959	1605		
	pmol/l	86.4	64.8	108	Diasorin Liaison XL 1-84 PTH	
	pg/ml	821	615	1026		
	µg/l	14.2	10.7	17.8	Brahms Kryptor	
	µg/l	30.2	22.7	37.8	BioMerieux Vidas	
	µg/l	23.2	17.4	29.0	Roche Elecsys/Cobas/Modular	
	µg/l	31.5	23.6	39.4	Siemens Centaur XP/XPT/Classic	
	µg/l	31.1	23.3	38.9	Siemens Centaur CP	
	µg/l	38.7	29.0	48.4	Diazyme PCT	
µg/l	52.7	36.9	68.5	SNIBE Maglumi Analysers		