

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

Cat. No: IAS3113
Size: 5 x 2 ml

Lot No. 1521EC
Expiry: 2017-04

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 I 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.

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Range					
Analyte	unit	Target	low	high	methods
1-25 (OH)2 Vitamin D	pmol/l	95.6	66.9	124	Diasorin RIA
25-OH Vitamin D	nmol/l	34.0	25.5	42.5	Diasorin Liaison
	nmol/l	24.1	18.1	30.1	Abbott Architect
	nmol/l	52.5	39.4	65.6	Siemens Centaur XP/XPT/Classic
	nmol/l	32.1	24.1	40.1	BioMerieux Vidas
	nmol/l	23.3	17.5	29.1	Beckman Dxl 600/800
Anti TG	kU/l	68.5	51.4	85.6	Siemens Immulite 2000/2500
	kU/l	283	212	354	Roche Modular E170
	kU/l	41.5	31.1	51.9	Abbott Architect
	kU/l	67.4	50.6	84.3	Siemens Immulite 1000
	kU/l	302	227	378	Roche Cobas E411
	kU/l	291	218	364	Roche Elecsys
	kU/l	278	209	348	Roche Cobas 6000/8000
	kU/l	174	131	218	Diasorin Liaison
	kU/l	187	140	234	Beckman Dxl 600/800
	kU/l	337	253	421	Siemens Centaur XP/XPT/Classic
	kU/l	118	88.5	148	Tosoh AIA360
	kU/l	185	139	231	Beckman Access/LXi725
Anti TPO	kU/l	17.5	13.1	21.9	Roche Modular E170
	kU/l	34.2	25.7	42.8	Abbott Architect
	kU/l	49.3	37.0	61.6	Siemens Immulite 1000
	kU/l	36.6	27.5	45.8	Siemens Immulite 2000/2500
	kU/l	22.0	16.5	27.5	Roche Cobas E411
	kU/l	17.4	13.1	21.8	Roche Cobas 6000/8000
	kU/l	17.7	13.3	22.1	Roche Elecsys
	kU/l	30.8	23.1	38.5	Beckman Dxl 600/800
	kU/l	129	96.8	161	Siemens Centaur XP/XPT/Classic
	kU/l	27.4	20.6	34.3	Tosoh AIA360
C-Peptide	nmol/l	0.365	0.274	0.456	Siemens Centaur XP/XPT/Classic
	ng/ml	1.10	0.827	1.37	
	nmol/l	0.500	0.375	0.625	Roche Cobas 6000/8000
	ng/ml	1.51	1.13	1.89	
	nmol/l	0.484	0.363	0.605	Roche Elecsys
	ng/ml	1.46	1.10	1.82	
	nmol/l	0.634	0.476	0.793	Diasorin Liaison
	ng/ml	1.91	1.44	2.38	
	nmol/l	0.311	0.233	0.389	Siemens Immulite 1000
	ng/ml	0.939	0.703	1.18	
	nmol/l	0.329	0.247	0.411	Abbott Architect
	ng/ml	0.993	0.746	1.24	
	nmol/l	0.309	0.232	0.386	Siemens Immulite 2000/2500
	ng/ml	0.933	0.700	1.17	

IMMUNOASSAY SPECIALITY I - LEVEL 1 (IA SPECIALITY I LEV 1)

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Range					
Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	0.498	0.374	0.623	Roche Cobas E411
	ng/ml	1.50	1.13	1.87	
IGF 1	µg/l	92.4	69.3	116	Siemens Immulite 2000/2500
	µg/l	71.9	53.9	89.9	Diasorin Liaison
	µg/l	102	76.5	128	Siemens Immulite 1000
Insulin	mU/l	3.45	2.59	4.31	Abbott Architect
	mU/l	2.99	2.24	3.74	Roche Cobas 6000/8000
	mU/l	4.42	3.32	5.53	Siemens Centaur XP/XPT/Classic
	mU/l	2.40	1.80	3.00	Siemens Immulite 2000
	mU/l	3.00	2.25	3.75	Beckman Dxl 600/800
	mU/l	2.60	1.95	3.25	Roche Elecsys
	mU/l	2.92	2.19	3.65	Roche Modular E170
Osteocalcin	µg/l	43.7	32.8	54.6	Roche Modular E170
	µg/l	21.7	16.3	27.1	Siemens Immulite 2000/2500
	µg/l	45.9	34.4	57.4	Roche Elecsys
	µg/l	41.5	31.1	51.9	Roche Cobas 6000/8000
	µg/l	39.8	29.9	49.8	Roche Cobas E411
	µg/l	45.7	34.3	57.1	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	2.70	2.03	3.38	Roche Modular E170 PTH/PTH STAT
	pg/ml	25.6	19.3	31.9	
	pmol/l	3.32	2.49	4.15	Abbott Architect
	pg/ml	31.5	23.6	39.4	
	pmol/l	3.36	2.52	4.20	Siemens Immulite 1000
	pg/ml	31.9	23.9	39.9	
	pmol/l	2.24	1.68	2.80	Beckman Dxl 600/800
	pg/ml	21.3	16.0	26.6	
	pmol/l	3.46	2.60	4.33	Siemens Immulite 2000/2500
	pg/ml	32.9	24.7	41.1	
	pmol/l	2.83	2.12	3.54	Roche Elecsys PTH/PTH STAT
	pg/ml	26.9	20.1	33.7	
	pmol/l	2.77	2.08	3.46	Roche Cobas 6000/8000
	pg/ml	26.3	19.8	32.8	
	pmol/l	2.93	2.20	3.66	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	27.8	20.9	34.7	
	pmol/l	2.93	2.20	3.66	Siemens Centaur XP/XPT/Classic
	pg/ml	27.8	20.9	34.7	
	pmol/l	1.68	1.26	2.10	Diasorin Liaison
	pg/ml	16.0	12.0	20.0	
	pmol/l	2.99	2.24	3.74	Tosoh AIA360
	pg/ml	28.4	21.3	35.5	
Procalcitonin	µg/l	0.231	0.173	0.289	Brahms Kryptor
	µg/l	0.844	0.633	1.06	BioMerieux Vidas
	µg/l	0.380	0.285	0.475	Roche Elecsys/Cobas/Modular
	µg/l	0.616	0.462	0.770	Diasorin IRMA
	µg/l	1.43	1.07	1.79	Siemens Centaur XP/XPT/Classic

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Range

Analyte	unit	Target	low	high	methods
Procalcitonin	µg/l	0.473	0.355	0.591	Boditech Med Inc i-CHROMA
	µg/l	1.54	1.16	1.93	Siemens Centaur CP