

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

Cat. No: IAS3114
Size: 5 x 2 ml

Lot No. 1522EC
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 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.

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Range					
Analyte	unit	Target	low	high	methods
1-25 (OH) ₂ Vitamin D	pmol/l	237	166	308	Diasorin RIA
25-OH Vitamin D	nmol/l	60.9	45.7	76.1	Roche Vitamin D Total
	nmol/l	71.8	53.9	89.8	Diasorin Liaison
	nmol/l	51.5	38.6	64.4	IDS iSYS
	nmol/l	61.0	45.8	76.3	Abbott Architect
	nmol/l	102	76.5	128	Siemens Centaur XP/XPT/Classic
	nmol/l	71.5	53.6	89.4	BioMerieux Vidas
	nmol/l	60.2	45.2	75.3	Beckman Dxl 600/800
Anti TG	kU/l	198	149	248	Siemens Immulite 2000/2500
	kU/l	455	341	569	Roche Modular E170
	kU/l	90.4	67.8	113	Abbott Architect
	kU/l	516	387	645	Roche Cobas E411
	kU/l	476	357	595	Roche Elecsys
	kU/l	454	341	568	Roche Cobas 6000/8000
	kU/l	370	278	463	Diasorin Liaison
	kU/l	452	339	565	Beckman Dxl 600/800
	kU/l	856	642	1070	Siemens Centaur XP/XPT/Classic
	kU/l	440	330	550	Beckman Access/LXi725
Anti TPO	kU/l	98.2	73.7	123	Roche Modular E170
	kU/l	88.1	66.1	110	Abbott Architect
	kU/l	93.7	70.3	117	Siemens Immulite 2000/2500
	kU/l	103	77.3	129	Roche Cobas E411
	kU/l	101	75.8	126	Roche Cobas 6000/8000
	kU/l	104	78.0	130	Roche Elecsys
	kU/l	109	81.8	136	Diasorin Liaison
	kU/l	76.0	57.0	95.0	Beckman Dxl 600/800
	kU/l	292	219	365	Siemens Centaur XP/XPT/Classic
	kU/l	269	202	336	Brahms RIA
	kU/l	75.2	56.4	94.0	Tosoh AIA360
	kU/l	79.1	59.3	98.9	Beckman Access/LXi725
C-Peptide	nmol/l	0.960	0.720	1.200	Siemens Centaur XP/XPT/Classic
	ng/ml	2.90	2.17	3.63	
	nmol/l	1.150	0.863	1.440	Roche Cobas 6000/8000
	ng/ml	3.47	2.61	4.33	
	nmol/l	1.140	0.855	1.430	Roche Elecsys
	ng/ml	3.44	2.58	4.30	
	nmol/l	1.450	1.090	1.810	Diasorin Liaison
	ng/ml	4.38	3.29	5.47	
	nmol/l	0.966	0.725	1.210	Siemens Immulite 1000
	ng/ml	2.92	2.19	3.65	
	nmol/l	0.821	0.616	1.030	Abbott Architect
	ng/ml	2.48	1.86	3.10	

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Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	0.952	0.714	1.190	Siemens Immulite 2000/2500
	ng/ml	2.87	2.16	3.58	
	nmol/l	1.170	0.878	1.460	Roche Cobas E411
	ng/ml	3.53	2.65	4.41	
IGF 1	µg/l	421	316	526	Siemens Immulite 2000/2500
	µg/l	260	195	325	Diasorin Liaison
	µg/l	462	347	578	Siemens Immulite 1000
Insulin	mU/l	8.22	6.17	10.3	Abbott Architect
	mU/l	8.17	6.13	10.2	Roche Cobas 6000/8000
	mU/l	11.3	8.48	14.1	Siemens Centaur XP/XPT/Classic
	mU/l	2.89	2.17	3.61	Siemens Immulite 2000
	mU/l	8.04	6.03	10.1	Beckman Dxl 600/800
	mU/l	10.1	7.58	12.6	Diasorin Liaison
	mU/l	8.14	6.11	10.2	Roche Cobas E411
	mU/l	8.21	6.16	10.3	Roche Modular E170
Osteocalcin	µg/l	94.9	71.2	119	Roche Modular E170
	µg/l	41.1	30.8	51.4	Siemens Immulite 2000/2500
	µg/l	97.5	73.1	122	Roche Elecsys
	µg/l	90.5	67.9	113	Roche Cobas 6000/8000
	µg/l	86.8	65.1	109	Roche Cobas E411
	µg/l	126	94.5	158	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	15.5	11.6	19.4	Roche Modular E170 PTH/PTH STAT
	pg/ml	147	110	184	
	pmol/l	30.1	22.6	37.6	Abbott Architect
	pg/ml	286	215	357	
	pmol/l	26.0	19.5	32.5	Siemens Immulite 1000
	pg/ml	247	185	309	
	pmol/l	20.5	15.4	25.6	Beckman Dxl 600/800
	pg/ml	195	146	244	
	pmol/l	27.8	20.9	34.8	Siemens Immulite 2000/2500
	pg/ml	264	198	330	
	pmol/l	17.3	13.0	21.6	Roche Elecsys PTH/PTH STAT
	pg/ml	164	123	205	
	pmol/l	16.5	12.4	20.6	Roche Cobas 6000/8000
	pg/ml	157	118	196	
	pmol/l	17.6	13.2	22.0	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	167	125	209	
	pmol/l	26.4	19.8	33.0	Siemens Centaur XP/XPT/Classic
	pg/ml	251	188	314	
	pmol/l	14.0	10.5	17.5	Diasorin Liaison
	pg/ml	133	100	166	
	pmol/l	23.6	17.7	29.5	Tosoh AIA360
	pg/ml	224	168	280	
Procalcitonin	µg/l	0.573	0.430	0.716	Brahms Kryptor
	µg/l	2.05	1.54	2.56	BioMerieux Vidas
	µg/l	0.985	0.739	1.23	Roche Elecsys/Cobas/Modular

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

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Range					
Analyte	unit	Target	low	high	methods
Procalcitonin	µg/l	1.71	1.28	2.14	Diasorin IRMA
	µg/l	2.60	1.95	3.25	Siemens Centaur XP/XPT/Classic
	µg/l	0.980	0.735	1.23	Boditech Med Inc i-CHROMA
	µg/l	2.79	2.09	3.49	Siemens Centaur CP