

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

Cat. No. IAS3115

Lot No. 1523EC

Size: 5 x 2 ml

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 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 ± 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	363	254	472	Diasorin RIA
25-OH Vitamin D	nmol/l	95.8	71.9	120	Roche Vitamin D Total
	nmol/l	102	76.5	128	Diasorin Liaison
	nmol/l	86.3	64.7	108	Abbott Architect
	nmol/l	141	106	176	Siemens Centaur XP/XPT/Classic
	nmol/l	97.5	73.1	122	BioMerieux Vidas
	nmol/l	94.7	71.0	118	Beckman Dxl 600/800
Anti TG	kU/l	323	242	404	Siemens Immulite 2000/2500
	kU/l	485	364	606	Roche Modular E170
	kU/l	154	116	193	Abbott Architect
	kU/l	268	201	335	Siemens Immulite 1000
	kU/l	513	385	641	Roche Cobas E411
	kU/l	482	362	603	Roche Elecsys
	kU/l	471	353	589	Roche Cobas 6000/8000
	kU/l	606	455	758	Diasorin Liaison
	kU/l	793	595	991	Beckman Dxl 600/800
	kU/l	1458	1094	1823	Siemens Centaur XP/XPT/Classic
	kU/l	739	554	924	Beckman Access/LXi725
Anti TPO	kU/l	183	137	229	Roche Modular E170
	kU/l	141	106	176	Abbott Architect
	kU/l	172	129	215	Siemens Immulite 1000
	kU/l	147	110	184	Siemens Immulite 2000/2500
	kU/l	171	128	214	Roche Cobas E411
	kU/l	180	135	225	Roche Cobas 6000/8000
	kU/l	170	128	213	Roche Elecsys
	kU/l	181	136	226	Diasorin Liaison
	kU/l	125	93.8	156	Beckman Dxl 600/800
	kU/l	410	308	513	Siemens Centaur XP/XPT/Classic
	kU/l	419	314	524	Brahms RIA
	kU/l	114	85.5	143	Tosoh AIA360
	kU/l	137	103	171	Beckman Access/LXi725
C-Peptide	nmol/l	1.740	1.310	2.180	Siemens Centaur XP/XPT/Classic
	ng/ml	5.25	3.95	6.55	
	nmol/l	2.130	1.600	2.660	Roche Cobas 6000/8000
	ng/ml	6.43	4.83	8.03	
	nmol/l	2.050	1.540	2.560	Roche Elecsys
	ng/ml	6.19	4.65	7.73	
	nmol/l	2.500	1.880	3.130	Diasorin Liaison
	ng/ml	7.55	5.68	9.42	
	nmol/l	1.870	1.400	2.340	Siemens Immulite 1000
	ng/ml	5.65	4.23	7.07	
	nmol/l	1.590	1.190	1.990	Abbott Architect
	ng/ml	4.80	3.59	6.01	

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Analyte	unit	Target	low	high	methods
C-Peptide	nmol/l	1.950	1.460	2.440	Siemens Immulite 2000/2500
	ng/ml	5.89	4.41	7.37	
	nmol/l	2.120	1.590	2.650	Roche Cobas E411
	ng/ml	6.40	4.80	8.00	
IGF 1	µg/l	709	532	886	Siemens Immulite 2000/2500
	µg/l	412	309	515	Diasorin Liaison
	µg/l	818	614	1023	Siemens Immulite 1000
Insulin	mU/l	22.9	17.2	28.6	Abbott Architect
	mU/l	28.0	21.0	35.0	Roche Cobas 6000/8000
	mU/l	31.4	23.6	39.3	Siemens Centaur XP/XPT/Classic
	mU/l	9.44	7.08	11.8	Siemens Immulite 2000
	mU/l	23.1	17.3	28.9	Beckman Dxl 600/800
	mU/l	27.8	20.9	34.8	Roche Elecsys
	mU/l	25.2	18.9	31.5	Roche Cobas E411
	mU/l	27.4	20.6	34.3	Roche Modular E170
Osteocalcin	µg/l	81.0	60.8	101	Siemens Immulite 2000/2500
	µg/l	192	144	240	Roche Elecsys
	µg/l	204	153	255	Roche Cobas 6000/8000
	µg/l	187	140	234	Roche Cobas E411
	µg/l	266	200	333	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	51.6	38.7	64.5	Roche Modular E170 PTH/PTH STAT
	pg/ml	490	368	612	
	pmol/l	86.8	65.1	109	Abbott Architect
	pg/ml	824	618	1030	
	pmol/l	89.6	67.2	112	Siemens Immulite 1000
	pg/ml	851	638	1064	
	pmol/l	61.7	46.3	77.1	Beckman Dxl 600/800
	pg/ml	586	440	732	
	pmol/l	83.3	62.5	104	Siemens Immulite 2000/2500
	pg/ml	791	594	988	
	pmol/l	54.0	40.5	67.5	Roche Elecsys PTH/PTH STAT
	pg/ml	513	385	641	
	pmol/l	50.5	37.9	63.1	Roche Cobas 6000/8000
	pg/ml	480	360	600	
	pmol/l	53.2	39.9	66.5	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	505	379	631	
	pmol/l	82.2	61.7	103	Siemens Centaur XP/XPT/Classic
	pg/ml	781	586	976	
	pmol/l	46.4	34.8	58.0	Diasorin Liaison
	pg/ml	441	330	552	
	pmol/l	68.9	51.7	86.1	Tosoh AIA360
	pg/ml	654	491	817	
Procalcitonin	µg/l	5.98	4.49	7.48	Brahms Kryptor
	µg/l	16.3	12.2	20.4	BioMerieux Vidas
	µg/l	10.0	7.50	12.5	Roche Elecsys/Cobas/Modular

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Analyte	unit	Target	low	high	methods
Procalcitonin	µg/l	13.5	10.1	16.9	Diasorin IRMA
	µg/l	14.7	11.0	18.4	Siemens Centaur XP/XPT/Classic
	µg/l	9.29	6.97	11.6	Boditech Med Inc i-CHROMA
	µg/l	15.2	11.4	19.0	Siemens Centaur CP