

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

CAT NO. IAS3115

LOT NO. 2069EC

SIZE: 5 x 2 ml

EXPIRY: 2023-08-28

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 ± 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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Dungloe, Donegal,
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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	446	312	580	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	103	77.3	129	Roche Vitamin D Total
	nmol/l	135	101	169	Diasorin Liaison
	nmol/l	118	88.5	148	Abbott Architect
	nmol/l	174	131	218	Siemens Centaur XP/XPT/Classic
	nmol/l	104	78.0	130	BioMerieux Vidas
	nmol/l	132	99.0	165	Beckman Access 25 OH Vitamin D Total
	nmol/l	124	93.0	155	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	129	96.8	161	Diasorin Liaison XL
	nmol/l	136	102	170	Roche Vitamin D Total II
	nmol/l	182	137	228	Siemens Atellica IM
Anti-TG	kU/l	255	191	319	Siemens Immulite 2000/2500
	kU/l	218	164	273	Abbott Architect
	kU/l	1132	849	1415	Roche Cobas E411
	kU/l	1073	805	1341	Roche Cobas 6000/8000
	kU/l	471	353	589	Beckman Dxl 600/800
	kU/l	839	629	1049	Siemens Centaur XP/XPT/Classic
	kU/l	560	420	700	BioMerieux Vidas
	kU/l	871	653	1089	Siemens Atellica IM
Anti-TPO	kU/l	165	124	206	Abbott Architect
	kU/l	180	135	225	Siemens Immulite 2000/2500
	kU/l	111	83.3	139	Roche Cobas E411
	kU/l	117	87.8	146	Roche Cobas 6000/8000
	kU/l	128	96.0	160	Beckman Dxl 600/800
	kU/l	509	382	636	Siemens Centaur XP/XPT/Classic
	kU/l	495	371	619	Brahms RIA
	kU/l	136	102	170	Beckman Access/LXi725
	kU/l	151	113	189	BioMerieux Vidas
	kU/l	504	378	630	Siemens Atellica IM
C-Peptide	nmol/l	2.030	1.520	2.540	Siemens Centaur XP/XPT/Classic
	ng/ml	6.13	4.59	7.67	
	nmol/l	2.600	1.950	3.250	Roche Cobas 6000/8000
	ng/ml	7.85	5.89	9.81	
	nmol/l	2.940	2.210	3.680	Diasorin Liaison
	ng/ml	8.88	6.67	11.1	
	nmol/l	2.440	1.830	3.050	Abbott Architect
	ng/ml	7.37	5.52	9.22	
	nmol/l	2.630	1.970	3.290	Siemens Immulite 2000/2500
	ng/ml	7.94	5.95	9.93	
	nmol/l	2.670	2.000	3.340	Roche Cobas E411
	ng/ml	8.06	6.04	10.1	
nmol/l	2.090	1.570	2.610	Siemens Atellica IM	
ng/ml	6.31	4.74	7.88		

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Analyte	unit	Target	Range		methods
			low	high	
IGF-1	µg/l	446	335	558	Siemens Immulite 2000/2500
	µg/l	334	251	418	Diasorin Liaison
	µg/l	205	154	256	Roche Cobas 6000/8000
Insulin	mU/l	24.3	18.2	30.4	Abbott Architect
	µU/ml	24.3	18.2	30.4	
	mU/l	33.3	25.0	41.6	Roche Cobas 6000/8000
	µU/ml	33.3	25.0	41.6	
	mU/l	31.0	23.3	38.8	Siemens Centaur XP/XPT/Classic
	µU/ml	31.0	23.3	38.7	
	mU/l	26.6	20.0	33.3	Beckman Dxl 600/800
	µU/ml	26.6	20.0	33.2	
	mU/l	34.3	25.7	42.9	Roche Cobas E411
	µU/ml	34.3	25.7	42.9	
Osteocalcin	mU/l	30.8	23.1	38.5	Siemens Atellica IM
	µU/ml	30.8	23.1	38.5	
	µg/l	75.4	56.6	94.3	Siemens Immulite 2000/2500
	µg/l	141	106	176	Roche Cobas 6000/8000
Parathyroid Hormone (PTH)	µg/l	140	105	175	Roche Cobas E411
	µg/l	174	131	218	Diasorin Liaison
	pmol/l	147	110	184	Abbott Architect
	pg/ml	1396	1045	1747	
	pmol/l	102	76.5	128	Beckman Dxl 600/800
	pg/ml	969	727	1211	
	pmol/l	184	138	230	Siemens Immulite 2000/2500
	pg/ml	1747	1311	2183	
	pmol/l	93.4	70.1	117	Roche Cobas 6000/8000
	pg/ml	887	666	1108	
	pmol/l	99.5	74.6	124	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	945	708	1182	
Procalcitonin	pmol/l	127	95.3	159	Siemens Centaur XP/XPT/Classic
	pg/ml	1206	905	1507	
	pmol/l	121	90.8	151	Siemens Atellica IM
	pg/ml	1149	862	1436	
	µg/l	13.1	9.83	16.4	Brahms Kryptor
	µg/l	20.6	15.5	25.8	BioMerieux Vidas
	µg/l	16.5	12.4	20.6	Roche Elecsys/Cobas/Modular
	µg/l	20.5	15.4	25.6	Siemens Centaur XP/XPT/Classic
µg/l	20.2	15.2	25.3	Siemens Centaur CP	
µg/l	37.1	29.7	44.5	Diazyme PCT	
µg/l	16.3	12.2	20.4	Abbott Architect Brahms PCT	