

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

CAT NO. IAS3115

LOT NO. 1797EC

SIZE: 5 x 2 ml

EXPIRY: 2020-04-28

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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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	182	155	209	IDS iSYS
25-OH Vitamin D	nmol/l	135	107	163	Roche Vitamin D Total
	nmol/l	147	114	180	Diasorin Liaison
	nmol/l	145	123	167	Abbott Architect
	nmol/l	180	153	207	Siemens Centaur XP/XPT/Classic
	nmol/l	126	107	145	BioMerieux Vidas
	nmol/l	142	118	166	Beckman Dxl 600/800
	nmol/l	150	128	172	Roche Vitamin D Total II
Anti-TG	kU/l	468	382	554	Siemens Immulite 2000/2500
	kU/l	1115	948	1282	Roche Modular E170
	kU/l	221	188	254	Abbott Architect
	kU/l	1221	1036	1406	Roche Cobas E411
	kU/l	1076	915	1237	Roche Cobas 6000/8000
	kU/l	781	636	926	Beckman Dxl 600/800
	kU/l	2161	1751	2571	Siemens Centaur XP/XPT/Classic
Anti-TPO	kU/l	111	94.4	128	Roche Modular E170
	kU/l	134	114	154	Abbott Architect
	kU/l	148	126	170	Siemens Immulite 2000/2500
	kU/l	110	90.6	129	Roche Cobas E411
	kU/l	110	93.0	127	Roche Cobas 6000/8000
	kU/l	112	90.4	134	Beckman Dxl 600/800
	kU/l	428	364	492	Siemens Centaur XP/XPT/Classic
C-Peptide	nmol/l	2.260	1.600	2.920	Siemens Centaur XP/XPT/Classic
	ng/ml	6.82	4.83	8.81	
	nmol/l	2.780	2.360	3.200	Roche Cobas 6000/8000
	ng/ml	8.39	7.12	9.66	
	nmol/l	3.180	2.660	3.700	Diasorin Liaison
	ng/ml	9.60	8.03	11.2	
	nmol/l	2.550	2.170	2.930	Abbott Architect
	ng/ml	7.70	6.55	8.85	
	nmol/l	2.850	2.420	3.280	Siemens Immulite 2000/2500
	ng/ml	8.60	7.31	9.89	
IGF-1	nmol/l	2.800	2.380	3.220	Roche Cobas E411
	ng/ml	8.45	7.19	9.71	
IGF-1	µg/l	356	303	409	Siemens Immulite 2000/2500
	µg/l	265	207	323	Diasorin Liaison
Insulin	mU/l	27.9	23.7	32.1	Abbott Architect
	µU/ml	27.9	23.7	32.1	
	mU/l	39.0	33.2	44.8	Roche Cobas 6000/8000
	µU/ml	39.0	33.2	44.8	
	mU/l	30.8	25.7	35.9	Siemens Centaur XP/XPT/Classic
	µU/ml	30.8	25.7	35.9	

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Range					
Analyte	unit	Target	low	high	methods
Insulin	mU/l	13.7	11.6	15.8	Siemens Immulite 2000
	µU/ml	13.7	11.6	15.8	
	mU/l	29.3	24.9	33.7	Beckman Dxl 600/800
	µU/ml	29.3	24.9	33.7	
	mU/l	38.7	32.9	44.5	Roche Cobas E411
	µU/ml	38.7	32.9	44.5	
Osteocalcin	µg/l	93.7	79.6	108	Siemens Immulite 2000/2500
	µg/l	182	155	209	Roche Cobas 6000/8000
	µg/l	182	155	209	Roche Cobas E411
	µg/l	233	187	279	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	81.1	68.9	93.3	Roche Modular E170 PTH/PTH STAT
	pg/ml	770	654	886	
	pmol/l	125	102	148	Abbott Architect
	pg/ml	1187	969	1405	
	pmol/l	146	119	173	Siemens Immulite 1000
	pg/ml	1387	1130	1644	
	pmol/l	95.7	81.0	110	Beckman Dxl 600/800
	pg/ml	909	769	1049	
	pmol/l	148	125	171	Siemens Immulite 2000/2500
	pg/ml	1406	1187	1625	
	pmol/l	75.9	64.5	87.3	Roche Elecsys PTH/PTH STAT
	pg/ml	721	613	829	
	pmol/l	82.2	69.9	94.5	Roche Cobas 6000/8000
	pg/ml	781	664	898	
pmol/l	85.3	72.5	98.1	Roche Cobas 4000/e411 PTH/PTH STAT	
pg/ml	810	689	931		
pmol/l	119	97.8	140	Siemens Centaur XP/XPT/Classic	
pg/ml	1130	929	1331		
Procalcitonin	µg/l	11.3	9.61	13.0	Brahms Kryptor
	µg/l	23.3	19.8	26.8	BioMerieux Vidas
	µg/l	17.7	15.0	20.4	Roche Elecsys/Cobas/Modular
	µg/l	24.8	21.1	28.5	Siemens Centaur XP/XPT/Classic
	µg/l	25.8	19.2	32.4	Siemens Centaur CP
	µg/l	21.5	18.3	24.7	Diazyme PCT