

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

CAT NO.	IAS3115	LOT NO.	1945EC
SIZE:	5 x 2 ml	EXPIRY:	2021-11-28
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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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) vitamin D	pmol/L	393	275	511	Diasorin Liaison
25-OH Vitamin D	nmol/l	108	81.0	135	Roche Vitamin D Total
	nmol/l	117	87.8	146	Diasorin Liaison
	nmol/l	123	92.3	154	Abbott Architect
	nmol/l	157	118	196	Siemens Centaur XP/XPT/Classic
	nmol/l	92.6	69.5	116	BioMerieux Vidas
	nmol/l	126	94.5	158	Beckman Dxl 600/800
	nmol/l	113	84.8	141	Beckman Access 25 OH Vitamin D Total
	nmol/l	122	91.5	153	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	122	91.5	153	Diasorin Liaison XL
	nmol/l	126	94.5	158	Roche Vitamin D Total II
	nmol/l	166	125	208	Siemens Atellica IM
Anti TG	kU/l	454	341	568	Siemens Immulite 2000/2500
	kU/l	246	185	308	Abbott Architect
	kU/l	989	742	1236	Roche Cobas E411
	kU/l	914	686	1143	Roche Cobas 6000/8000
	kU/l	824	618	1030	Beckman Dxl 600/800
	kU/l	1617	1213	2021	Siemens Centaur XP/XPT/Classic
	kU/l	731	548	914	Beckman Access/LXi725
	kU/l	997	748	1246	BioMerieux Vidas
	kU/l	1803	1352	2254	Siemens Atellica IM
Anti TPO	kU/l	163	122	204	Abbott Architect
	kU/l	174	131	218	Siemens Immulite 2000/2500
	kU/l	117	87.8	146	Roche Cobas E411
	kU/l	123	92.3	154	Roche Cobas 6000/8000
	kU/l	125	93.8	156	Beckman Dxl 600/800
	kU/l	518	389	648	Siemens Centaur XP/XPT/Classic
	kU/l	118	88.5	148	Beckman Access/LXi725
	kU/l	159	119	199	BioMerieux Vidas
	kU/l	504	378	630	Siemens Atellica IM
C-Peptide	nmol/l	1.760	1.320	2.200	Siemens Centaur XP/XPT/Classic
	ng/ml	5.31	3.99	6.63	
	nmol/l	2.290	1.720	2.860	Roche Cobas 6000/8000
	ng/ml	6.91	5.19	8.63	
	nmol/l	2.550	1.910	3.190	Diasorin Liaison
	ng/ml	7.70	5.77	9.63	
	nmol/l	2.020	1.520	2.530	Abbott Architect
	ng/ml	6.10	4.59	7.61	
	nmol/l	2.270	1.700	2.840	Siemens Immulite 2000/2500
	ng/ml	6.85	5.13	8.57	
nmol/l	2.340	1.760	2.930	Roche Cobas E411	
ng/ml	7.06	5.31	8.81		

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Analyte	unit	Target	Range		methods	
			low	high		
C-Peptide	nmol/l	1.700	1.280	2.130	Siemens Atellica IM	
	ng/ml	5.13	3.86	6.40		
	nmol/l	2.210	1.620	2.800	Ortho Vitros ECI	
	ng/ml	6.67	4.89	8.45		
IGF 1	µg/l	420	315	525	Siemens Immulite 2000/2500	
	µg/l	338	254	423	Diasorin Liaison	
	µg/l	219	164	274	Roche Cobas 6000/8000	
Insulin	mU/l	28.1	21.1	35.1	Abbott Architect	
	µU/ml	28.1	21.1	35.1		
	mU/l	40.0	30.0	50.0	Roche Cobas 6000/8000	
	µU/ml	40.0	30.0	50.0		
	mU/l	25.2	18.9	31.5	Siemens Centaur XP/XPT/Classic	
	µU/ml	25.2	18.9	31.5		
	mU/l	13.2	9.90	16.5	Siemens Immulite 2000	
	µU/ml	13.2	9.90	16.5		
	mU/l	29.9	22.4	37.4	Beckman Dxl 600/800	
	µU/ml	29.9	22.4	37.4		
	mU/l	40.2	30.2	50.3	Roche Cobas E411	
	µU/ml	40.2	30.2	50.2		
Osteocalcin	µg/l	94.5	70.9	118	Siemens Immulite 2000/2500	
	µg/l	146	110	183	Roche Cobas 6000/8000	
	µg/l	149	112	186	Roche Cobas E411	
	µg/l	197	148	246	Diasorin Liaison	
	Parathyroid Hormone (PTH)	pmol/l	133	100	166	Abbott Architect
		pg/ml	1263	950	1576	
		pmol/l	92.0	69.0	115	Beckman Dxl 600/800
		pg/ml	874	655	1093	
pmol/l		159	119	199	Siemens Immulite 2000/2500	
pg/ml		1510	1130	1890		
pmol/l		86.3	64.7	108	Roche Cobas 6000/8000	
pg/ml		820	614	1026		
pmol/l		89.3	67.0	112	Roche Cobas 4000/e411 PTH/PTH STAT	
pg/ml		848	636	1060		
pmol/l		126	94.5	158	Siemens Centaur XP/XPT/Classic	
pg/ml		1197	897	1497		
Procalcitonin	pmol/l	122	91.5	153	Siemens Atellica IM	
	pg/ml	1159	869	1449		
	µg/l	12.3	9.23	15.4	Brahms Kryptor	
	µg/l	20.2	15.2	25.3	BioMerieux Vidas	
	µg/l	16.3	12.2	20.4	Roche Elecsys/Cobas/Modular	
	µg/l	19.5	14.6	24.4	Siemens Centaur XP/XPT/Classic	
	µg/l	18.9	14.2	23.6	Siemens Centaur CP	
µg/l	25.3	19.0	31.6	Fujirebio Lumipulse G Series		
µg/l	15.2	11.9	18.5	Ortho Vitros Brahms PCT		