

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

CAT NO. IAS3113

LOT NO. 1851EC

SIZE: 5 x 2 ml

EXPIRY: 2020-10-28

GTIN: 05055273207293

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 I 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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IMMUNOASSAY SPECIALITY I - LEVEL 1 (IA SPECIALITY I LEV 1)

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Analyte	unit	Target	Range		methods
			low	high	
1-25(OH) vitamin D	pmol/L	160	112	208	Diasorin Liaison
	pmol/L	41.9	29.3	54.5	IDS iSYS
25-OH Vitamin D	nmol/l	65.2	48.9	81.5	Diasorin Liaison
	nmol/l	38.0	28.5	47.5	Abbott Architect
	nmol/l	78.7	59.0	98.4	Siemens Centaur XP/XPT/Classic
	nmol/l	45.4	34.1	56.8	BioMerieux Vidas
	nmol/l	46.0	34.5	57.5	Beckman Dxl 600/800
	nmol/l	63.5	47.6	79.4	Diasorin Liaison XL
	nmol/l	40.7	30.5	50.9	Roche Vitamin D Total II
Anti-TG	kU/l	101	75.8	126	Siemens Immulite 2000/2500
	kU/l	65.2	48.9	81.5	Abbott Architect
	kU/l	549	412	686	Roche Cobas E411
	kU/l	518	389	648	Roche Cobas 6000/8000
	kU/l	215	161	269	Beckman Dxl 600/800
	kU/l	436	327	545	Siemens Centaur XP/XPT/Classic
	kU/l	246	185	308	BioMerieux Vidas
Anti-TPO	kU/l	33.8	25.4	42.3	Abbott Architect
	kU/l	40.6	30.5	50.8	Siemens Immulite 2000/2500
	kU/l	27.6	20.7	34.5	Beckman Dxl 600/800
	kU/l	126	94.5	158	Siemens Centaur XP/XPT/Classic
	kU/l	39.6	29.7	49.5	BioMerieux Vidas
C-Peptide	nmol/l	0.388	0.291	0.485	Siemens Centaur XP/XPT/Classic
	ng/ml	1.17	0.879	1.46	
	nmol/l	0.598	0.449	0.748	Roche Cobas 6000/8000
	ng/ml	1.81	1.36	2.26	
	nmol/l	0.491	0.368	0.614	Abbott Architect
	ng/ml	1.48	1.11	1.85	
	nmol/l	0.441	0.331	0.551	Siemens Immulite 2000/2500
	ng/ml	1.33	0.999	1.66	
nmol/l	0.601	0.451	0.751	Roche Cobas E411	
ng/ml	1.81	1.36	2.26		
IGF-1	µg/l	64.2	48.2	80.3	Siemens Immulite 2000/2500
	µg/l	66.3	49.7	82.9	Diasorin Liaison
	µg/l	38.0	28.5	47.5	Roche Cobas 6000/8000
Insulin	mU/l	5.70	4.28	7.13	Abbott Architect
	µU/ml	5.70	4.28	7.12	
	mU/l	6.52	4.89	8.15	Roche Cobas 6000/8000
	µU/ml	6.52	4.89	8.15	
	mU/l	5.93	4.45	7.41	Siemens Centaur XP/XPT/Classic
	µU/ml	5.93	4.45	7.41	
	mU/l	5.04	3.78	6.30	Beckman Dxl 600/800
µU/ml	5.04	3.78	6.30		

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Analyte	unit	Target	Range		methods
			low	high	
Insulin	mU/l	6.28	4.71	7.85	Roche Cobas E411
	µU/ml	6.28	4.71	7.85	
Osteocalcin	µg/l	12.2	9.15	15.3	Siemens Immulite 2000/2500
	µg/l	22.4	16.8	28.0	Roche Cobas 6000/8000
	µg/l	22.3	16.7	27.9	Roche Cobas E411
	µg/l	23.1	17.3	28.9	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	5.75	4.31	7.19	Abbott Architect
	pg/ml	54.6	40.9	68.3	
	pmol/l	4.17	3.13	5.21	Beckman Dxl 600/800
	pg/ml	39.6	29.7	49.5	
	pmol/l	6.26	4.70	7.83	Siemens Immulite 2000/2500
	pg/ml	59.5	44.6	74.4	
	pmol/l	4.87	3.65	6.09	Roche Cobas 6000/8000
	pg/ml	46.3	34.7	57.9	
	pmol/l	4.95	3.71	6.19	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	47.0	35.2	58.8	
Procalcitonin	pmol/l	5.25	3.94	6.56	Siemens Centaur XP/XPT/Classic
	pg/ml	49.9	37.4	62.4	
	µg/l	0.903	0.677	1.13	Brahms Kryptor
	µg/l	2.52	1.89	3.15	BioMerieux Vidas
	µg/l	1.18	0.885	1.48	Roche Elecsys/Cobas/Modular
	µg/l	2.13	1.60	2.66	Siemens Centaur XP/XPT/Classic
	µg/l	2.25	1.69	2.81	Siemens Centaur CP
	µg/l	2.52	1.76	3.28	SNIBE Maglumi Analysers