

IMMUNOASSAY SPECIALITY I - LEVEL 2 (IA SPECIALITY I LEV 2)

CAT. NO. IAS3114

LOT NO. 1944EC

SIZE: 5 x 2 ml

EXPIRY: 2021-11-28

GTIN: 05055273207309

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 2 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.

03 Mar '20 bm

IMMUNOASSAY GD97-5 @HM=!'@J9 @&'f15 'GD97-5 @HM=!'@J'&L

Cat. No. IAS3114 Lot. No. 1944EC Size 5 x 2ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
1-25 (OH) ₂ Vitamin D	pmol/l	237	166	308	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	70.2	52.7	87.8	Roche Vitamin D Total
	nmol/l	80.3	60.2	100	Diasorin Liaison
	nmol/l	78.5	58.9	98.1	Abbott Architect
	nmol/l	105	78.8	131	Siemens Centaur XP/XPT/Classic
	nmol/l	69.3	52.0	86.6	BioMerieux Vidas
	nmol/l	71.4	53.6	89.3	Beckman Dxl 600/800
	nmol/l	75.8	56.9	94.8	Beckman Access 25 OH Vitamin D Total
	nmol/l	84.7	63.5	106	Diasorin Liaison XL
	nmol/l	80.4	60.3	101	Roche Vitamin D Total II
	nmol/l	108	81.0	135	Siemens Atellica IM
	nmol/l	79.4	59.6	99.3	Abbott Alinity i
Anti TG	kU/l	261	196	326	Siemens Immulite 2000/2500
	kU/l	160	120	200	Abbott Architect
	kU/l	1002	752	1253	Roche Cobas E411
	kU/l	794	596	993	Roche Cobas 6000/8000
	kU/l	532	399	665	Beckman Dxl 600/800
	kU/l	961	721	1201	Siemens Centaur XP/XPT/Classic
	kU/l	500	375	625	Beckman Access/LXi725
	kU/l	674	506	843	BioMerieux Vidas
	kU/l	165	124	206	Abbott Alinity i
Anti TPO	kU/l	114	85.5	143	Abbott Architect
	kU/l	132	99.0	165	Siemens Immulite 2000/2500
	kU/l	80.6	60.5	101	Roche Cobas E411
	kU/l	81.9	61.4	102	Roche Cobas 6000/8000
	kU/l	89.4	67.1	112	Beckman Dxl 600/800
	kU/l	379	284	474	Siemens Centaur XP/XPT/Classic
	kU/l	110	82.5	138	BioMerieux Vidas
	kU/l	113	84.8	141	Abbott Alinity i
	kU/l	379	284	474	Siemens Atellica IM
C-Peptide	nmol/l	0.920	0.690	1.150	Siemens Centaur XP/XPT/Classic
	ng/ml	2.78	2.08	3.48	
	nmol/l	1.190	0.893	1.490	Roche Cobas 6000/8000
	ng/ml	3.59	2.70	4.48	
	nmol/l	1.020	0.765	1.280	Abbott Architect
	ng/ml	3.08	2.31	3.85	
	nmol/l	1.040	0.780	1.300	Siemens Immulite 2000/2500
	ng/ml	3.14	2.35	3.93	
	nmol/l	1.230	0.923	1.540	Roche Cobas E411
	ng/ml	3.71	2.79	4.63	
nmol/l	1.000	0.750	1.250	Abbott Alinity i	
ng/ml	3.02	2.26	3.77		

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Analyte	unit	Target	Range		methods
			low	high	
C-Peptide	nmol/l	0.793	0.595	0.991	Siemens Atellica IM
	ng/ml	2.39	1.80	2.99	
IGF 1	µg/l	276	207	345	Siemens Immulite 2000/2500
	µg/l	251	188	314	Diasorin Liaison
	µg/l	153	115	191	Roche Cobas 6000/8000
Insulin	mU/l	13.1	9.83	16.4	Abbott Architect
	µU/ml	13.1	9.83	16.4	
	mU/l	16.3	12.2	20.4	Roche Cobas 6000/8000
	µU/ml	16.3	12.2	20.4	
	mU/l	15.5	11.6	19.4	Siemens Centaur XP/XPT/Classic
	µU/ml	15.5	11.6	19.4	
	mU/l	5.83	4.37	7.29	Siemens Immulite 2000
	µU/ml	5.83	4.37	7.29	
	mU/l	13.0	9.75	16.3	Beckman Dxl 600/800
	µU/ml	13.0	9.75	16.3	
	mU/l	16.8	12.6	21.0	Roche Elecsys
	µU/ml	16.8	12.6	21.0	
	mU/l	16.4	12.3	20.5	Roche Cobas E411
	µU/ml	16.4	12.3	20.5	
	mU/l	14.3	10.7	17.9	Siemens Atellica IM
	µU/ml	14.3	10.7	17.9	
mU/l	12.1	9.08	15.1	Abbott Alinity i	
µU/ml	12.1	9.08	15.1		
Osteocalcin	µg/l	54.2	40.7	67.8	Siemens Immulite 2000/2500
	µg/l	77.9	58.4	97.4	Roche Cobas 6000/8000
	µg/l	78.0	58.5	97.5	Roche Cobas E411
	µg/l	88.6	66.5	111	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	39.4	29.6	49.3	Abbott Architect
	pg/ml	374	281	467	
	pmol/l	28.2	21.2	35.3	Beckman Dxl 600/800
	pg/ml	268	201	335	
	pmol/l	46.0	34.5	57.5	Siemens Immulite 2000/2500
	pg/ml	437	328	546	
	pmol/l	25.5	19.1	31.9	Roche Cobas 6000/8000
	pg/ml	242	181	303	
	pmol/l	27.7	20.8	34.6	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	263	198	328	
	pmol/l	36.1	27.1	45.1	Siemens Centaur XP/XPT/Classic
	pg/ml	343	257	429	
pmol/l	37.8	28.4	47.3	Abbott Alinity i	
pg/ml	359	270	449		
pmol/l	34.9	26.2	43.6	Siemens Atellica IM	
pg/ml	331	249	414		
Procalcitonin	µg/l	1.73	1.30	2.16	Brahms Kryptor
	µg/l	2.92	2.19	3.65	BioMerieux Vidas
	µg/l	2.09	1.57	2.61	Roche Elecsys/Cobas/Modular

RANDOX

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Range

Analyte	unit	Target	low	high	methods
Procalcitonin	µg/l	2.42	1.82	3.03	Siemens Centaur XP/XPT/Classic
	µg/l	2.46	1.85	3.08	Siemens Centaur CP
	µg/l	4.78	3.82	5.74	Diazyme PCT
	µg/l	2.10	1.58	2.63	Abbott Alinity i
	µg/l	2.65	1.99	3.31	Siemens Atellica IM