

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

CAT. NO. IAS3114 **LOT NO.** 2065EC
SIZE: 5 x 2 ml **EXPIRY:** 2023-03-28
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 Prolactin 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.

- 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 2 5 x 2 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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.

EC	REP
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Size 5 x 2ml Expiry 2023-03-28

Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	221	155	287	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	64.5	48.4	80.6	Roche Vitamin D Total
	nmol/l	79.3	59.5	99.0	Diasorin Liaison
	nmol/l	66.7	50.0	83.4	Abbott Architect (3L52)
	nmol/l	101	75.8	126	Siemens Centaur XP/XPT/Classic
	nmol/l	74.4	55.8	93.0	BioMerieux Vidas
	nmol/l	64.9	48.7	81.1	Beckman Dxl 600/800
	nmol/l	66.8	50.1	83.5	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	80.4	60.3	101	Diasorin Liaison XL
	nmol/l	71.8	53.9	89.8	Roche Vitamin D Total II
	nmol/l	98.3	73.7	123	Siemens Atellica IM
	nmol/l	68.1	51.1	85.1	Roche Vitamin D Total II e801
Anti TG	kU/l	126	94.5	158	Siemens Immulite 2000/2500
	kU/l	180	135	225	Abbott Architect / Alinity
	kU/l	611	458	764	Roche Cobas 4000/E411
	kU/l	675	506	844	Roche Cobas e601/602
	kU/l	230	173	288	Beckman Dxl 600/800
	kU/l	276	207	345	Siemens Centaur XP/XPT/Classic
	kU/l	226	170	283	BioMerieux Vidas
	kU/l	254	191	318	Siemens Atellica IM
	kU/l	647	485	809	Roche Cobas e801
	kU/l	214	161	268	Siemens Atellica IM aTgII
	kU/l	207	155	259	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	95.4	71.6	119	Abbott Architect / Alinity
	kU/l	116	87.0	145	Siemens Immulite 2000/2500
	kU/l	61.3	46.0	76.6	Roche Cobas 4000/E411
	kU/l	60.5	45.4	75.6	Roche Cobas c501/502 e601/602
	kU/l	67.2	50.4	84.0	Beckman Dxl 600/800
	kU/l	345	259	431	Siemens Centaur XP/XPT/Classic
	kU/l	71.0	53.3	88.8	BioMerieux Vidas
	kU/l	78.8	59.1	98.5	Roche Cobas e801
	kU/l	334	251	418	Siemens Atellica IM
C-Peptide	nmol/l	0.918	0.689	1.150	Siemens Centaur XP/XPT/Classic
	ng/ml	2.77	2.08	3.46	
	nmol/l	1.370	1.030	1.710	Roche Cobas e601/602
	ng/ml	4.14	3.11	5.17	
	nmol/l	1.220	0.915	1.530	Abbott Architect / Alinity
	ng/ml	3.68	2.76	4.60	
	nmol/l	1.230	0.923	1.540	Siemens Immulite 2000/2500
	ng/ml	3.71	2.79	4.63	
	nmol/l	1.380	1.040	1.730	Roche Cobas 4000/E411
	ng/ml	4.17	3.14	5.20	

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			low	high	
C-Peptide	nmol/l	1.340	1.010	1.680	Roche Cobas e801
	ng/ml	4.05	3.05	5.05	
	nmol/l	0.904	0.678	1.130	Siemens Atellica IM
	ng/ml	2.73	2.05	3.41	
	nmol/l	1.317	0.988	1.646	Ortho Vitros ECI
	ng/ml	3.98	2.98	4.97	
IGF 1	µg/l	254	191	318	Siemens Immulite 2000/2500
	µg/l	129	96.8	161	Diasorin Liaison
	µg/l	85.4	64.1	107	Roche Cobas 4000/E411
	µg/l	82.5	61.9	103	Roche Cobas 6000/8000
Insulin	mU/l	9.53	7.15	11.9	Abbott Architect
	µU/ml	9.53	7.15	11.9	
	mU/l	11.8	8.85	14.8	Roche Cobas 6000/8000
	µU/ml	11.8	8.85	14.8	
	mU/l	10.7	8.03	13.4	Siemens Centaur XP/XPT/Classic
	µU/ml	10.7	8.03	13.4	
	mU/l	3.93	2.95	4.91	Siemens Immulite 2000
	µU/ml	3.93	2.95	4.91	
	mU/l	8.98	6.74	11.2	Beckman Dxl 600/800
	µU/ml	8.98	6.74	11.2	
	mU/l	11.8	8.85	14.8	Roche Cobas 4000/E411
	µU/ml	11.8	8.85	14.8	
	mU/l	10.9	8.18	13.6	Siemens Atellica IM
	µU/ml	10.9	8.18	13.6	
	mU/l	9.56	6.06	13.1	Ortho Vitros ECI
	µU/ml	9.56	6.06	13.1	
Osteocalcin	µg/l	48.3	36.2	60.4	Siemens Immulite 2000/2500
	µg/l	84.8	63.6	106	Roche Elecsys
	µg/l	88.8	66.6	111	Roche Cobas 6000/8000
	µg/l	84.5	63.4	106	Roche Cobas 4000/E411
	µg/l	90.1	67.6	113	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	47.6	35.7	59.5	Abbott Architect / Alinity
	pg/ml	452	339	565	
	pmol/l	33.2	24.9	41.5	Beckman Dxl 600/800
	pg/ml	315	236	394	
	pmol/l	56.0	42.0	70.0	Siemens Immulite 2000/2500
	pg/ml	532	399	665	
	pmol/l	29.1	21.8	36.4	Roche Cobas e601/602 PTH
	pg/ml	276	207	345	
	pmol/l	32.2	24.2	40.3	Roche Cobas 4000/e411 PTH/PTH STAT
	pg/ml	306	230	382	
	pmol/l	41.2	30.9	51.5	Siemens Centaur XP/XPT/Classic
	pg/ml	391	293	489	
	pmol/l	28.6	21.5	35.8	Roche Cobas e601/602 PTH (1-84)
pg/ml	272	204	340		
pmol/l	31.6	23.7	39.5	Roche Cobas 4000/E411 PTH (1-84)	
pg/ml	300	225	375		

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			low	high	
Parathyroid Hormone (PTH)	pmol/l	40.4	30.3	50.5	Siemens Atellica IM
	pg/ml	384	288	480	
	pmol/l	29.7	22.3	37.1	Roche Cobas e801 PTH
	pg/ml	282	212	352	
	pmol/l	28.7	21.5	35.9	Roche Cobas e801 PTH (1-84)
	pg/ml	273	204	342	
	pmol/l	29.1	21.8	36.4	Roche Cobas e801 PTH STAT
	pg/ml	276	207	345	
	pmol/l	27.6	20.7	34.5	Roche Cobas e601/602 PTH STAT
	pg/ml	262	197	327	
Procalcitonin	µg/l	1.94	1.46	2.43	Brahms Kryptor
	µg/l	3.40	2.55	4.25	BioMerieux Vidas
	µg/l	2.29	1.72	2.86	Roche Elecsys/Cobas/Modular
	µg/l	4.52	3.39	5.65	Diasorin IRMA
	µg/l	2.79	2.09	3.49	Siemens Centaur XP/XPT/Classic
	µg/l	2.89	2.17	3.61	Siemens Centaur CP 10378883
	µg/l	4.82	3.86	5.79	Diazyme PCT
	µg/l	2.49	1.87	3.11	Abbott Architect / Alinity Brahms PCT
	µg/l	2.24	1.68	2.80	Roche Cobas e801
	µg/l	2.91	2.18	3.64	Siemens Atellica IM 10995651
	µg/l	3.26	2.45	4.08	Beckman Access PCT
	µg/l	2.78	2.09	3.48	Siemens Centaur XP/XPT 11202697
	µg/l	2.99	2.24	3.74	Siemens Centaur CP 11202697
	µg/l	2.87	2.15	3.59	Siemens Atellica IM 11202699
	µg/l	2.37	1.86	2.88	Ortho Vitros ECI
	µg/l	8.50	4.68	12.3	Nexus IB10