

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

**CAT. NO.** IAS3114      **LOT NO.** 2013EC  
**SIZE:** 5 x 2 ml      **EXPIRY:** 2022-11-28  
**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 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.

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  $\pm 2$  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](mailto:Technical.Services@randox.com).

EC	REP
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26 Mar '21 me

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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) <sub>2</sub> Vitamin D	pmol/l	245	172	319	Diasorin Liaison XL
25-OH Vitamin D	nmol/l	71.6	53.7	89.5	Roche Vitamin D Total
	nmol/l	90.5	67.9	113	Diasorin Liaison
	nmol/l	78.1	58.6	97.6	Abbott Architect (3L52)
	nmol/l	105	78.8	131	Siemens Centaur XP/XPT/Classic
	nmol/l	79.7	59.8	100	BioMerieux Vidas
	nmol/l	80.8	60.6	101	Beckman Dxl 600/800
	nmol/l	80.5	60.4	101	Beckman Access 25 OH Vitamin D Total
	nmol/l	77.9	58.4	97.4	Abbott Architect (5P02)/ Alinity (8P45)
	nmol/l	88.8	66.6	111	Diasorin Liaison XL
	nmol/l	78.8	59.1	98.5	Roche Vitamin D Total II
	nmol/l	111	83.3	139	Siemens Atellica IM
	nmol/l	82.7	62.0	103	Roche Vitamin D Total II e801
Anti TG	kU/l	114	85.5	143	Siemens Immulite 2000/2500
	kU/l	190	143	238	Abbott Architect / Alinity
	kU/l	547	410	684	Roche Cobas 4000/E411
	kU/l	572	429	715	Roche Cobas e601/602
	kU/l	213	160	266	Beckman Dxl 600/800
	kU/l	292	219	365	Siemens Centaur XP/XPT/Classic
	kU/l	218	164	273	Beckman Access/LXi725
	kU/l	236	177	295	BioMerieux Vidas
	kU/l	270	203	338	Siemens Atellica IM
	kU/l	591	443	739	Roche Cobas e801
	kU/l	222	167	278	Siemens Atellica IM aTgII
	kU/l	218	164	273	Siemens Centaur XP/XPT aTgII
Anti TPO	kU/l	104	78.0	130	Abbott Architect / Alinity
	kU/l	128	96.0	160	Siemens Immulite 2000/2500
	kU/l	67.0	50.3	83.8	Roche Cobas 4000/E411
	kU/l	68.3	51.2	85.4	Roche Cobas c501/502 e601/602
	kU/l	76.3	57.2	95.4	Beckman Dxl 600/800
	kU/l	356	267	445	Siemens Centaur XP/XPT/Classic
	kU/l	78.8	59.1	98.5	BioMerieux Vidas
	kU/l	91.1	68.3	114	Roche Cobas e801
	kU/l	347	260	434	Siemens Atellica IM
C-Peptide	nmol/l	1.030	0.773	1.290	Siemens Centaur XP/XPT/Classic
	ng/ml	3.11	2.33	3.89	
	nmol/l	1.310	0.983	1.640	Roche Cobas e601/602
	ng/ml	3.95	2.97	4.93	
	nmol/l	1.150	0.863	1.440	Abbott Architect / Alinity
	ng/ml	3.47	2.61	4.33	
	nmol/l	1.160	0.870	1.450	Siemens Immulite 2000/2500
	ng/ml	3.50	2.63	4.37	

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			low	high		
C-Peptide	nmol/l	1.290	0.968	1.610	Roche Cobas 4000/E411	
	ng/ml	3.89	2.92	4.86		
	nmol/l	1.280	0.960	1.600	Roche Cobas e801	
	ng/ml	3.86	2.90	4.82		
	nmol/l	0.958	0.719	1.200	Siemens Atellica IM	
	ng/ml	2.89	2.17	3.61		
	IGF 1	µg/l	249	187	311	Siemens Immulite 2000/2500
		µg/l	119	89.3	149	Diasorin Liaison
µg/l		90.3	67.7	113	Roche Cobas 4000/E411	
µg/l		83.8	62.9	105	Roche Cobas 6000/8000	
Insulin	mU/l	9.03	6.77	11.3	Abbott Architect	
	µU/ml	9.03	6.77	11.3		
	mU/l	11.4	8.55	14.3	Roche Cobas 6000/8000	
	µU/ml	11.4	8.55	14.3		
	mU/l	10.3	7.73	12.9	Siemens Centaur XP/XPT/Classic	
	µU/ml	10.3	7.73	12.9		
	mU/l	3.57	2.68	4.46	Siemens Immulite 2000	
	µU/ml	3.57	2.68	4.46		
	mU/l	8.40	6.30	10.5	Beckman Dxl 600/800	
	µU/ml	8.40	6.30	10.5		
	mU/l	11.0	8.25	13.8	Roche Cobas 4000/E411	
	µU/ml	11.0	8.25	13.8		
Osteocalcin	mU/l	10.1	7.58	12.6	Siemens Atellica IM	
	µU/ml	10.1	7.58	12.6		
	µg/l	35.3	26.5	44.1	Siemens Immulite 2000/2500	
	µg/l	64.4	48.3	80.5	Roche Elecsys	
	µg/l	69.3	52.0	86.6	Roche Cobas 6000/8000	
Parathyroid Hormone (PTH)	µg/l	67.1	50.3	83.9	Roche Cobas 4000/E411	
	µg/l	75.9	56.9	94.9	Diasorin Liaison	
	pmol/l	44.1	33.1	55.1	Abbott Architect / Alinity	
	pg/ml	419	314	524		
	pmol/l	30.9	23.2	38.6	Beckman Dxl 600/800	
	pg/ml	293	220	366		
	pmol/l	51.3	38.5	64.1	Siemens Immulite 2000/2500	
	pg/ml	487	366	608		
	pmol/l	28.7	21.5	35.9	Roche Cobas e601/602 PTH	
	pg/ml	273	204	342		
	pmol/l	30.4	22.8	38.0	Roche Cobas 4000/e411 PTH/PTH STAT	
	pg/ml	289	217	361		
	pmol/l	36.9	27.7	46.1	Siemens Centaur XP/XPT/Classic	
	pg/ml	350	263	437		
	pmol/l	27.0	20.3	33.8	Roche Cobas e601/602 PTH (1-84)	
pg/ml	256	193	319			
pmol/l	29.2	21.9	36.5	Roche Cobas 4000/E411 PTH (1-84)		
pg/ml	277	208	346			
pmol/l	37.8	28.4	47.3	Siemens Atellica IM		
pg/ml	359	270	448			

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Analyte	unit	Target	Range		methods
			low	high	
Parathyroid Hormone (PTH)	pmol/l	27.3	20.5	34.1	Roche Cobas e801 PTH
	pg/ml	259	195	323	
	pmol/l	27.3	20.5	34.1	Roche Cobas e801 PTH (1-84)
	pg/ml	259	195	323	
	pmol/l	26.7	20.0	33.4	Roche Cobas e801 PTH STAT
	pg/ml	254	190	318	
Procalcitonin	pmol/l	28.0	21.0	35.0	Roche Cobas e601/602 PTH STAT
	pg/ml	266	199	333	
	µg/l	2.14	1.61	2.68	Brahms Kryptor
	µg/l	3.85	2.89	4.81	BioMerieux Vidas
	µg/l	2.45	1.84	3.06	Roche Elecsys/Cobas/Modular
	µg/l	3.09	2.32	3.86	Siemens Centaur XP/XPT/Classic
	µg/l	3.19	2.39	3.99	Siemens Centaur CP 10378883
	µg/l	5.31	4.25	6.37	Diazyme PCT
	µg/l	2.68	2.01	3.35	Abbott Architect / Alinity Brahms PCT
	µg/l	2.45	1.84	3.06	Roche Cobas e801
	µg/l	3.03	2.27	3.79	Siemens Atellica IM 10995651
	µg/l	3.47	2.60	4.34	Beckman Access PCT
	µg/l	3.03	2.27	3.79	Siemens Centaur XP/XPT 11202697
	µg/l	3.37	2.53	4.21	Siemens Centaur CP 11202697
	µg/l	3.11	2.33	3.89	Siemens Atellica IM 11202699
µg/l	2.00	1.54	2.46	Hipro HP Series (HP-083/4 / HP-AFS/1 / HP-AFS/3 / HP-AFS/1 Pro)	
µg/l	7.05	3.88	10.2	Nexus IB10	