

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

CAT NO. IAS3113 **LOT NO.** 2529EC
SIZE: 5 x 2 ml **EXPIRY:** 2027-02-28
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

Unopened: Unreconstituted control is stable up to the expiry date shown on the side of each individual bottle.

Opened: Once reconstituted, the components of the control are stable for 5 days at +2°C to +8°C and 28 days at -20°C when frozen once. Except:

Analyte	+2°C to +8°C	Aliquoted and frozen once at -20°C
Anti-TG	3 days	-
C-Peptide	1 day	-
IGF-I	8 hours	-
Osteocalcin	4 hours	-
Parathyroid Hormone (PTH)	4 hours	14 days
Procalcitonin	1 day	-

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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 I 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.

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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Lot. No: 2529EC Cat. No: IAS3113 Expiry: 2027/02/28							
Size: 5 x 2 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
1-25-(OH)2 Vitamin D	pmol/l	143	100	186	21.5	43.0	DiaSorin Liaison XL
25-OH-Vitamin D	nmol/l	27.1	20.3	33.9	3.40	6.80	Abbott Alinity i
	nmol/l	28.5	21.4	35.6	3.55	7.10	Abbott Architect (3L52)
	nmol/l	26.8	20.1	33.5	3.35	6.70	Abbott Architect (5P02)
	nmol/l	38.3	28.7	47.9	4.80	9.60	Beckman Dxl 600/800
	nmol/l	38.9	29.2	48.6	4.85	9.70	bioMerieux Vidas/mini Vidas/Vidas 3
	nmol/l	50.0	37.5	62.5	6.25	12.5	DiaSorin Liaison
	nmol/l	45.0	33.8	56.2	5.60	11.2	DiaSorin Liaison XL
	nmol/l	11.0	8.25	13.8	1.40	2.80	Roche Vitamin D Total II
	nmol/l	45.2	33.9	56.5	5.65	11.3	Siemens Atellica IM
Anti-TG	kU/l	52.8	39.6	66.0	6.60	13.2	Abbott Architect/ Alinity
	kU/l	82.8	62.1	104	10.6	21.2	Beckman Access/LXi725
	kU/l	75.3	56.5	94.1	9.40	18.8	Beckman Dxl 600/800
	kU/l	64.8	48.6	81.0	8.10	16.2	BioMerieux VIDAS
	kU/l	68.3	51.2	85.4	8.55	17.1	DiaSorin Liaison XL
	kU/l	43.2	32.4	54.0	5.40	10.8	Mindray CL 8000i/6000i/2000i/1200i/1000i
	kU/l	99.1	74.3	124	12.5	24.9	Roche Cobas 4000/e411
	kU/l	95.9	71.9	120	12.1	24.1	Roche Cobas e402/e801
	kU/l	98.6	74.0	123	12.2	24.4	Roche Cobas e601/602
	kU/l	103	77.3	129	13.0	26.0	Roche Elecsys
	kU/l	51.2	38.4	64.0	6.40	12.8	Siemens Atellica IM
	kU/l	54.3	40.7	67.9	6.80	13.6	Siemens Atellica IM aTgII
	kU/l	54.9	41.2	68.6	6.85	13.7	Siemens Centaur aTgII
	kU/l	40.7	30.5	50.9	5.10	10.2	Siemens/DPC Immulite 2000/2500
Anti-TPO	kU/l	39.2	29.4	49.0	4.90	9.80	Abbott Architect/ Alinity
	kU/l	22.9	17.2	28.6	2.85	5.70	Beckman Access/LXi725
	kU/l	20.8	15.6	26.0	2.60	5.20	Beckman Dxl 600/800
	kU/l	34.3	25.7	42.9	4.30	8.60	BioMerieux VIDAS
	kU/l	49.3	37.0	61.6	6.15	12.3	DiaSorin Liaison XL
	kU/l	25.5	19.1	31.9	3.20	6.40	Mindray CL 8000i/6000i/2000i/1200i/1000i
	kU/l	19.2	14.4	24.0	2.40	4.80	Roche Cobas e402/e801
	kU/l	36.3	27.2	45.4	4.55	9.10	Siemens/DPC Immulite 2000/2500
C-Peptide	ng/ml	1.42	1.07	1.77	0.175	0.350	Abbott Architect/ Alinity
	nmol/l	0.471	0.353	0.589	0.059	0.118	
	ng/ml	1.84	1.38	2.30	0.230	0.460	DiaSorin Liaison XL
	nmol/l	0.608	0.456	0.760	0.076	0.152	
	ng/ml	1.76	1.32	2.20	0.220	0.440	Roche Cobas 4000/e411
	nmol/l	0.582	0.437	0.727	0.073	0.145	

Method		Immunoassay Speciality I - Level 1 (IA SPECIALITY I LEV 1)					
Lot. No: 2529EC Cat. No: IAS3113 Expiry: 2027/02/28							
Size: 5 x 2 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
C-Peptide	ng/ml	1.57	1.18	1.96	0.195	0.390	Roche Cobas e402/e801
	nmol/l	0.520	0.390	0.650	0.065	0.130	
	ng/ml	1.63	1.22	2.04	0.205	0.410	Roche Cobas e601/ 602
	nmol/l	0.541	0.406	0.676	0.068	0.135	
	ng/ml	1.35	1.01	1.69	0.170	0.340	Siem Atel IM (Rgt lot 207&cal lot 09&up)
	nmol/l	0.447	0.335	0.559	0.056	0.112	
	ng/ml	1.25	0.938	1.56	0.155	0.310	Siemens Atellica IM
	nmol/l	0.414	0.311	0.517	0.052	0.103	
IGF-1	ng/ml	1.17	0.878	1.46	0.145	0.290	Siemens/DPC Immulite 2000/2500
	nmol/l	0.388	0.291	0.485	0.049	0.097	
	µg/l	24.0	18.0	30.0	3.00	6.00	DiaSorin Liaison XL
	µg/l	21.7	16.3	27.1	2.70	5.40	IDS, CLIA
	µg/l	15.7	11.8	19.6	1.95	3.90	Roche Cobas 4000/e411
	µg/l	15.3	11.5	19.1	1.90	3.80	Roche Cobas 6000/8000
	µg/l	15.5	11.6	19.4	1.95	3.90	Roche Elecsys
	µg/l	48.1	36.1	60.1	6.00	12.0	Siemens/DPC Immulite 2000/2500
Insulin	µg/l	49.2	36.9	61.5	6.15	12.3	Siemens/DPC Immulite 2000/2500 Re-std
	mU/l	2.57	1.93	3.21	0.320	0.640	Abbott Alinity i
	µU/ml	2.57	1.93	3.21	0.320	0.640	
	mU/l	2.73	2.05	3.41	0.340	0.680	Abbott Architect
	µU/ml	2.73	2.05	3.41	0.340	0.680	
	mU/l	2.58	1.94	3.22	0.320	0.640	Beckman Dxl 600/800
	µU/ml	2.58	1.94	3.22	0.320	0.640	
	mU/l	3.14	2.36	3.92	0.390	0.780	Roche Cobas 4000/e411
µU/ml	3.14	2.36	3.92	0.390	0.780		
Osteocalcin	mU/l	3.11	2.33	3.89	0.390	0.780	Roche Cobas 6000/8000
	µU/ml	3.11	2.33	3.89	0.390	0.780	
	mU/l	2.97	2.23	3.71	0.370	0.740	Roche Elecsys
	µU/ml	2.97	2.23	3.71	0.370	0.740	
	mU/l	3.00	2.25	3.75	0.375	0.750	Siemens Atellica IM
	µU/ml	3.00	2.25	3.75	0.375	0.750	
	µg/l	50.3	37.7	62.9	6.30	12.6	DiaSorin Liaison XL
	µg/l	45.1	33.8	56.4	5.65	11.3	Roche Cobas 4000/e411
Procalcitonin	µg/l	45.7	34.3	57.1	5.70	11.4	Roche Cobas 6000/8000
	µg/l	45.9	34.4	57.4	5.75	11.5	Roche Elecsys
	µg/l	23.4	17.6	29.2	2.90	5.80	Siemens/DPC Immulite 2000/2500
Procalcitonin	µg/l	1.04	0.780	1.30	0.130	0.260	Abbott Alinity i
	µg/l	1.12	0.840	1.40	0.140	0.280	Abbott Architect
	µg/l	1.43	1.07	1.79	0.180	0.360	Beckman Access PCT

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Analyte	Unit	Target	Low	High	1SD	2SD	Method
Procalcitonin	µg/l	1.46	1.10	1.82	0.180	0.360	Beckman Dxl 600/800
	µg/l	1.53	1.15	1.91	0.190	0.380	Beckman DXI9000
	µg/l	1.64	1.23	2.05	0.205	0.410	BioMerieux VIDAS
	µg/l	1.87	1.40	2.34	0.235	0.470	DiaSorin Liaison XL
	µg/l	1.90	1.43	2.37	0.235	0.470	DiaSorin Liaison XL Brahms PCT II Gen
	µg/l	1.01	0.758	1.26	0.125	0.250	Mindray CL 8000i/6000i/2000i/1200i/1000i
	µg/l	1.03	0.773	1.29	0.130	0.260	Ortho Vitros 3600/5600/ECi/XT 7600
	µg/l	1.30	0.975	1.63	0.165	0.330	Radiometer AQT90 Flex
	µg/l	0.998	0.749	1.25	0.126	0.252	Roche Cobas e402/e801
	µg/l	0.981	0.736	1.23	0.125	0.249	Roche Elecsys/Cobas/Modular
	µg/l	1.48	1.11	1.85	0.185	0.370	Siemens Atellica IM 10995651
	µg/l	1.44	1.08	1.80	0.180	0.360	Siemens Atellica IM 11202699
	µg/l	1.17	0.878	1.46	0.145	0.290	Siemens Centaur 11202697
PTH	pg/ml	41.9	31.4	52.4	5.25	10.5	Abbott Architect/ Alinity
	pmol/l	3.98	2.99	4.97	0.495	0.990	
	pg/ml	34.4	25.8	43.0	4.30	8.60	Beckman Dxl 600/800
	pmol/l	3.26	2.45	4.07	0.405	0.810	
	pg/ml	37.0	27.8	46.2	4.60	9.20	Roche Cobas 4000/e411 PTH
	pmol/l	3.51	2.63	4.39	0.440	0.880	
	pg/ml	35.3	26.5	44.1	4.40	8.80	Roche Cobas 4000/e411 PTH STAT
	pmol/l	3.35	2.51	4.19	0.420	0.840	
	pg/ml	35.2	26.4	44.0	4.40	8.80	Roche Cobas e402/e801
	pmol/l	3.34	2.51	4.17	0.415	0.830	
	pg/ml	32.9	24.7	41.1	4.10	8.20	Roche Cobas e402/e801 PTH STAT
	pmol/l	3.12	2.34	3.90	0.390	0.780	
	pg/ml	34.9	26.2	43.6	4.35	8.70	Roche Cobas e601/602 PTH
	pmol/l	3.31	2.48	4.14	0.415	0.830	
	pg/ml	33.8	25.4	42.2	4.20	8.40	Roche Cobas e601/602 PTH STAT
	pmol/l	3.21	2.41	4.01	0.400	0.800	
	pg/ml	33.9	25.4	42.4	4.25	8.50	Roche Elecsys PTH
	pmol/l	3.22	2.42	4.02	0.400	0.800	
	pg/ml	39.3	29.5	49.1	4.90	9.80	Siemens Atellica IM
	pmol/l	3.73	2.80	4.66	0.465	0.930	