

【英文名称】: IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)

【中文名称】: 免疫分析专用质控品 (水平 3)

【货号】 (CAT. NUMBER): IAS3115

【批号】 (LOT NUMBER): 2556EC

【包装规格】 (SIZE): 5 x 2ml

【到期】 (EXPIRY): 2026-10-28

本产品的准备和使用详见试剂盒内说明书。

Full instructions for the use and preparation of this product are included with the kit.

质控品靶值和范围如下所示。

Target values and ranges are listed below.

ZH: 16 Jan '25 me

Method 所有仪器均值		IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3) 免疫分析专用质控品 (水平3)							
批号 (Lot. No): 2556EC 货号 (Cat. No): IAS3115 到期 (Expiry): 2026-10-28									
包装规格 (Size): 5 x 2ml		Range		范围					
Analyte	分析项目	Unit 单位	Target 靶值	Low 低值	High 高值	ISD	2SD	方法	Method
I-25-(OH)2-Vitamin D	I-25-二羟维生素D	pmol/l	409	286	532	61.5	123	Diasorin Liaison XL	DiaSorin Liaison XL
25-OH Vitamin D	25-羟维生素D	nmol/l	106	79.5	133	13.5	27.0	Abbott Architect (3L52)	Abbott Architect (3L52)
		nmol/l	104	78.0	130	13.0	26.0	Abbott Architect (5P02)	Abbott Architect (5P02)
		nmol/l	80.5	60.4	101	10.3	20.5	AutoBio CLIA	AutoBio CLIA
		nmol/l	141	106	176	17.5	35.0	Beckman Dxl 600/800	Beckman Dxl 600/800
		nmol/l	96.7	72.5	121	12.2	24.3	bioMerieux Vidas/mini Vidas/Vidas 3	bioMerieux Vidas/mini Vidas/Vidas 3
		nmol/l	99.6	74.7	125	12.7	25.4	Diasorin Liaison XL	DiaSorin Liaison XL
		nmol/l	109	81.8	136	13.5	27.0	Diasorin Liaison	DiaSorin Liaison
		nmol/l	96.4	72.3	121	12.3	24.6	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		nmol/l	97.1	72.8	121	12.0	23.9	Roche 维生素D总量 II	Roche Vitamin D Total II
		nmol/l	97.3	73.0	122	12.4	24.7	Roche 维生素D总量 II e801	Roche Vitamin D Total II e801
		nmol/l	95.1	71.3	119	12.0	23.9	Roche 维生素D总量 III	Roche Vitamin D total III
		nmol/l	95.5	71.6	119	11.8	23.5	Roche 维生素D总量 III e402/e801	Roche Vitamin D Total III e402/e801
		nmol/l	133	99.8	166	16.5	33.0	Siemens Atellica IM	Siemens Atellica IM
		nmol/l	123	92.3	154	15.5	31.0	Siemens Centaur XP/Classic	Siemens Centaur XP/Classic
		nmol/l	151	113	189	19.0	38.0	SNIBE Maglumi 分析仪	SNIBE Maglumi Analyser
Anti-TG	抗甲状腺球蛋白抗体	kU/l	221	166	276	27.5	55.0	Abbott Architect / Alinity	Abbott Architect / Alinity
		kU/l	156	117	195	19.5	39.0	AutoBio CLIA	AutoBio CLIA
		kU/l	360	270	450	45.0	90.0	Beckman Dxl 600/800	Beckman Dxl 600/800
		kU/l	317	238	396	39.5	79.0	bioMerieux VIDAS	bioMerieux VIDAS
		kU/l	279	209	349	35.0	70.0	Diasorin Liaison XL	DiaSorin Liaison XL
		kU/l	1260	945	1575	158	315	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		kU/l	1213	910	1516	152	303	Roche Cobas e402/e801	Roche Cobas e402/e801
		kU/l	1373	1030	1716	172	343	Roche Cobas e601/602	Roche Cobas e601/602
		kU/l	248	186	310	31.0	62.0	Siemens Atellica IM	Siemens Atellica IM
		kU/l	243	182	304	30.5	61.0	Siemens Atellica IM aTgII	Siemens Atellica IM aTgII
		kU/l	238	179	297	29.5	59.0	Siemens Centaur XP/XPT	Siemens Centaur XP/XPT
		kU/l	239	179	299	30.0	60.0	Siemens Centaur XP/XPT aTgII	Siemens Centaur XP/XPT aTgII
		kU/l	223	167	279	28.0	56.0	Siemens/DPC Immulite 2000/2500	Siemens/DPC Immulite 2000/2500
		kU/l	875	656	1094	110	219	SNIBE Maglumi 分析仪	SNIBE Maglumi analysers

Method 所有仪器均值		IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3) 免疫分析专用质控品 (水平3)							
批号 (Lot. No): 2556EC		货号 (Cat. No): IAS3115		到期 (Expiry): 2026-10-28					
包装规格 (Size): 5 x 2ml		Range		范围					
Analyte	分析项目	Unit 单位	Target 靶值	Low 低值	High 高值	ISD	2SD	方法	Method
Anti-TPO	抗甲状腺过氧化物酶抗体	kU/l	195	146	244	24.5	49.0	Abbott Architect / Alinity	Abbott Architect / Alinity
		kU/l	406	305	507	50.5	101	AutoBio CLIA	AutoBio CLIA
		kU/l	111	83.3	139	14.0	28.0	Beckman Dxl 600/800	Beckman Dxl 600/800
		kU/l	175	131	219	22.0	44.0	bioMerieux VIDAS	bioMerieux VIDAS
		kU/l	241	181	301	30.0	60.0	Diasorin Liaison XL	DiaSorin Liaison XL
		kU/l	145	109	181	18.0	36.0	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		kU/l	186	140	232	23.0	46.0	Roche Cobas e402/e801	Roche Cobas e402/e801
		kU/l	149	112	186	18.5	37.0	Roche Cobas e601/602	Roche Cobas e601/602
		kU/l	701	526	876	87.5	175	Siemens Atellica IM	Siemens Atellica IM
		kU/l	678	509	847	84.5	169	Siemens Centaur XP/XPT	Siemens Centaur XP/XPT
		kU/l	227	170	284	28.5	57.0	Siemens/DPC Immulite 2000/2500	Siemens/DPC Immulite 2000/2500
		kU/l	116	87.0	145	14.5	29.0	SNIBE Maglumi 分析仪	SNIBE Maglumi analysers
C-Peptide	C-肽	nmol/l	1.44	1.08	1.80	0.180	0.360	Abbott Architect / Alinity	Abbott Architect / Alinity
		ng/ml	4.35	3.26	5.44	0.545	1.09		
		nmol/l	1.74	1.31	2.17	0.215	0.430	Diasorin Liaison XL	DiaSorin Liaison XL
		ng/ml	5.25	3.94	6.56	0.655	1.31		
		nmol/l	1.53	1.15	1.91	0.190	0.380	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		ng/ml	4.62	3.47	5.77	0.575	1.15		
		nmol/l	1.50	1.13	1.87	0.185	0.370	Roche Cobas e402/e801	Roche Cobas e402/e801
		ng/ml	4.53	3.40	5.66	0.565	1.13		
		nmol/l	1.53	1.15	1.91	0.190	0.380	Roche Cobas e601/602	Roche Cobas e601/602
		ng/ml	4.62	3.47	5.77	0.575	1.15		
		nmol/l	1.42	1.07	1.77	0.175	0.350	Siem Atel IM (Rgt lot 207&cal lot 09&up)	Siem Atel IM (Rgt lot 207&cal lot 09&up)
		ng/ml	4.29	3.22	5.36	0.535	1.07		
		nmol/l	1.34	1.01	1.67	0.165	0.330	Siemens Atellica IM	Siemens Atellica IM
		ng/ml	4.05	3.04	5.06	0.505	1.01		
		nmol/l	1.39	1.04	1.74	0.175	0.350	Siemens/DPC Immulite 2000/2500	Siemens/DPC Immulite 2000/2500
		ng/ml	4.20	3.15	5.25	0.525	1.05		
		nmol/l	1.77	1.33	2.21	0.220	0.440	SNIBE Maglumi 分析仪	SNIBE Maglumi analysers
		ng/ml	5.34	4.01	6.67	0.665	1.33		

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Analyte	分析项目	Unit 单位	Target 靶值	Low 低值	High 高值	ISD	2SD	方法	Method
IGF-I	胰岛素样生长因子-I	µg/l	561	421	701	70.0	140	AutoBio CLIA	AutoBio CLIA
		µg/l	263	197	329	33.0	66.0	Diasorin Liaison XL	DiaSorin Liaison XL
		µg/l	208	156	260	26.0	52.0	IDS CLIA	IDS, CLIA
		µg/l	166	125	207	20.5	41.0	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		µg/l	160	120	200	20.0	40.0	Roche Cobas 6000/8000	Roche Cobas 6000/8000
		µg/l	156	117	195	19.5	39.0	Roche Elecsys	Roche Elecsys
		µg/l	380	285	475	47.5	95.0	Siemens/DPC Immulite 2000/2500	Siemens/DPC Immulite 2000/2500
		µg/l	374	281	467	46.5	93.0	Siemens/DPC Immulite 2000/2500 Re-std	Siemens/DPC Immulite 2000/2500 Re-std
Insulin	胰岛素	mU/l	18.6	14.0	23.2	2.30	4.60	Abbott Alinity i	Abbott Alinity i
		µU/ml	18.6	14.0	23.2	2.30	4.60		
		mU/l	20.3	15.2	25.4	2.55	5.10	Abbott Architect	Abbott Architect
		µU/ml	20.3	15.2	25.4	2.55	5.10		
		mU/l	32.1	24.1	40.1	4.00	8.00	AutoBio CLIA	AutoBio CLIA
		µU/ml	32.1	24.1	40.1	4.00	8.00		
		mU/l	21.8	16.4	27.2	2.70	5.40	Beckman Dxl 600/800	Beckman Dxl 600/800
		µU/ml	21.8	16.4	27.2	2.70	5.40		
		mU/l	31.2	23.4	39.0	3.90	7.80	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		µU/ml	31.2	23.4	39.0	3.90	7.80		
		mU/l	30.6	23.0	38.2	3.80	7.60	Roche Cobas 6000/8000	Roche Cobas 6000/8000
		µU/ml	30.6	23.0	38.2	3.80	7.60		
		mU/l	30.1	22.6	37.6	3.75	7.50	Roche Elecsys	Roche Elecsys
		µU/ml	30.1	22.6	37.6	3.75	7.50		
		mU/l	24.3	18.2	30.4	3.05	6.10	Siemens Atellica IM	Siemens Atellica IM
		µU/ml	24.3	18.2	30.4	3.05	6.10		
		mU/l	21.5	16.1	26.9	2.70	5.40	Siemens Centaur XP/XPT	Siemens Centaur XP/XPT
		µU/ml	21.5	16.1	26.9	2.70	5.40		
		mU/l	29.5	22.1	36.9	3.70	7.40	SNIBE Maglumi 分析仪	SNIBE Maglumi analysers
		µU/ml	29.5	22.1	36.9	3.70	7.40		

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Analyte	分析项目	Unit 单位	Target 靶值	Low 低值	High 高值	ISD	2SD	方法	Method
Osteocalcin	骨钙素	µg/l	142	107	177	17.5	35.0	Diasorin Liaison XL	DiaSorin Liaison XL
		µg/l	112	84.0	140	14.0	28.0	Roche Cobas 4000/E411	Roche Cobas 4000/e411
		µg/l	117	87.8	146	14.5	29.0	Roche Cobas 6000/8000	Roche Cobas 6000/8000
		µg/l	58.9	44.2	73.6	7.35	14.7	Siemens/DPC Immulite 2000/2500	Siemens/DPC Immulite 2000/2500
		µg/l	195	146	244	24.5	49.0	SNIBE Maglumi 分析仪	SNIBE Maglumi analysers
Procalcitonin	降钙素原	ug/l	11.9	8.93	14.9	1.50	3.00	Abbott Alinity	Abbott Alinity
		ug/l	12.5	9.38	15.6	1.55	3.10	Abbott Architect	Abbott Architect
		ug/l	11.0	8.25	13.8	1.40	2.80	AutoBio CLIA	AutoBio CLIA
		ug/l	15.7	11.8	19.6	1.95	3.90	Beckman Access PCT	Beckman Access PCT
		ug/l	18.3	13.7	22.9	2.30	4.60	bioMerieux VIDAS	bioMerieux VIDAS
		ug/l	17.1	12.8	21.4	2.15	4.30	Diasorin Liaison XL	DiaSorin Liaison XL
		ug/l	11.2	8.40	14.0	1.40	2.80	Ortho Vitros 3600/5600/ECi/XT 7600	Ortho Vitros 3600/5600/ECi/XT 7600
		ug/l	12.7	9.53	15.9	1.60	3.20	Roche Cobas e402/e801	Roche Cobas e402/e801
		ug/l	13.4	10.1	16.7	1.65	3.30	Roche Elecsys/Cobas/Modular	Roche Elecsys/Cobas/Modular
		ug/l	18.6	14.0	23.2	2.30	4.60	Siemens Atellica IM 10995651	Siemens Atellica IM 10995651
		ug/l	18.3	13.7	22.9	2.30	4.60	Siemens Atellica IM 11202699	Siemens Atellica IM 11202699
		ug/l	17.1	12.8	21.4	2.15	4.30	Siemens Centaur XP/XP 10378883	Siemens Centaur XP/XP 10378883
		ug/l	17.7	13.3	22.1	2.20	4.40	Siemens Centaur XP/XPT 11202697	Siemens Centaur XP/XPT 11202697
		ug/l	12.2	9.15	15.3	1.55	3.10	SNIBE Maglumi	SNIBE Maglumi

Method 所有仪器均值			IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3) 免疫分析专用质控品 (水平3)							
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Analyte	分析项目	Unit	Target	Low	High	ISD	2SD	方法	Method	
		单位	靶值	低值	高值					
PTH	甲状旁腺激素	pmol/l	117	87.8	146	14.5	29.0	Abbott Architect / Alinity	Abbott Architect / Alinity	
		pg/ml	1111	833	1389	139	278			
		pmol/l	73.3	55.0	91.6	9.15	18.3	AutoBio CLIA	AutoBio CLIA	
		pg/ml	696	522	870	87.0	174			
		pmol/l	92.8	69.6	116	11.6	23.2	Beckman Dxl 600/800	Beckman Dxl 600/800	
		pg/ml	881	661	1101	110	220			
		pmol/l	82.2	61.7	103	10.4	20.8	Roche Cobas 4000/e411 PTH	Roche Cobas 4000/e411 PTH	
		pg/ml	781	586	976	97.5	195			
		pmol/l	78.5	58.9	98.1	9.80	19.6	Roche Cobas 4000/e411 PTH (I-84)	Roche Cobas 4000/e411 PTH (I-84)	
		pg/ml	746	560	932	93.0	186			
		pmol/l	80.6	60.5	101	10.2	20.4	Roche Cobas 4000/e411 PTH STAT	Roche Cobas 4000/e411 PTH STAT	
		pg/ml	765	574	956	95.5	191			
		pmol/l	76.3	57.2	95.4	9.55	19.1	Roche Cobas e601/602 PTH	Roche Cobas e601/602 PTH	
		pg/ml	725	544	906	90.5	181			
		pmol/l	74.4	55.8	93.0	9.30	18.6	Roche Cobas e601/602 PTH STAT	Roche Cobas e601/602 PTH STAT	
		pg/ml	707	530	884	88.5	177			
		pmol/l	74.1	55.6	92.6	9.25	18.5	Roche Cobas e601/602 PTH (I-84)	Roche Cobas e601/602 PTH (I-84)	
		pg/ml	704	528	880	88.0	176			
		pmol/l	73.4	55.1	91.7	9.15	18.3	Roche Cobas e801 PTH	Roche Cobas e801 PTH	
		pg/ml	697	523	871	87.0	174			
		pmol/l	67.0	50.3	83.7	8.35	16.7	Roche Cobas e801 PTH (I-84)	Roche Cobas e801 PTH (I-84)	
		pg/ml	636	477	795	79.5	159			
		pmol/l	69.6	52.2	87.0	8.70	17.4	Roche Cobas e801 PTH STAT	Roche Cobas e801 PTH STAT	
		pg/ml	661	496	826	82.5	165			
		pmol/l	111	83.3	139	14.0	28.0	Siemens Atellica IM	Siemens Atellica IM	
		pg/ml	1054	791	1317	132	263			
		pmol/l	112	84.0	140	14.0	28.0	Siemens Atellica IM	Siemens Centaur CP/ XP/XPT	
		pg/ml	1064	798	1330	133	266			
		pmol/l	99.0	74.3	124	12.5	25.0	Siemens Centaur CP/ XP/XPT	SNIBE Maglumi analysers	
		pg/ml	940	705	1175	118	235			