BGT BioGenTechnologies GmbH
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-o-trol IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)

CE

Chargen-B.: 901EC **Artikel-Nr.: KG3115**
Inhalt: 5 x 2ml **Verwendbar bis: 2012-02**

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 - 8°C). Reconstituted serum is stable for 5 days at 2 - 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 - 8°C. C-Peptide is stable for 1 day at 2 - 8ºC. Parathyroid hormone (PTH) should be tested within 4 hours of reconstitution when stored at 2 - 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 - 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 2ml of distilled water at +20 to 25°C. Close 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 3 5 x 2ml

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 BGT BioGenTechnologies GmbH, Tel: 02551/4090 or email info@biogentechnologies.de.

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			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
1-25 OH Vitamin D	pmol/l	111	88.8	133	IDS RIA
25-OH Vitamin D	nmol/l	130	97.5	163	Roche Modular E170
	nmol/l	164	123	205	Roche Elecsys
	nmol/l	152	114	190	Roche Cobas E411
	nmol/l	127	95.3	159	Diasorin Liaison
	nmol/l	132	99.0	165	IDS RIA
	nmol/l	125	93.8	156	IDS ELISA
	nmol/l	168	126	210	HPLC
Anti TG	kU/l	195	146	244	Siemens Immulite 2000/2500
	kU/l	635	476	794	Roche Modular E170
	kU/l	86.1	64.6	108	Abbott Architect
	kU/l	309	232	386	Abbott AXSYM
	kU/l	682	512	853	Roche Cobas E411
	kU/l	626	470	783	Roche Cobas 6000
Anti TPO	kU/l	161	121	201	Roche Modular E170
	kU/l	148	111	185	Abbott Architect
	kU/l	155	116	194	Siemens Immulite 2000/2500
	kU/l	158	119	198	Roche Cobas E411
	kU/l	168	126	210	Roche Cobas 6000
	kU/l	177	133	221	Roche Elecsys
	kU/l	123	92.3	154	Beckman Dxl 600/800
	kU/l	425	319	531	Siemens Advia Centaur
	kU/l	418	314	523	Brahms RIA
C-Peptide	nmol/l	1.780	1.340	2.230	Siemens Advia Centaur
	ng/ml	5.37	4.05	6.69	
	nmol/l	1.990	1.490	2.490	Roche Cobas 6000
	ng/ml	6.01	4.50	7.52	
	nmol/l	2.050	1.540	2.560	Roche Elecsys
	ng/ml	6.19	4.65	7.73	
	nmol/l	1.910	1.430	2.390	Siemens Immulite 1000
	ng/ml	5.77	4.32	7.22	
	nmol/l	1.920	1.440	2.400	Siemens Immulite 2000/2500
	ng/ml	5.80	4.35	7.25	
	nmol/l	2.020	1.520	2.530	Roche Modular E170
	ng/ml	6.10	4.59	7.61	
	nmol/l	1.980	1.490	2.480	Roche Cobas E411
	ng/ml	5.98	4.50	7.46	
IGF 1	µg/l	589	442	736	Siemens Immulite 2000/2500
	µg/l	581	436	726	Siemens Immulite 1000
Osteocalcin	µg/l	295	221	369	Roche Modular E170
	µg/l	289	217	361	Roche Elecsys
Parathyroid Hormone (PTH)	pmol/l	57.3	45.8	68.8	Roche Modular E170
	pg/ml	544	435	653	

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Parathyroid Hormone (PTH)	pmol/l	104	83.2	125	Abbott Architect
	pg/ml	988	790	1186	
	pmol/l	120	96.0	144	Siemens Immulite 1000
	pg/ml	1140	912	1368	
	pmol/l	123	98.4	148	Siemens Immulite 2000/2500
	pg/ml	1168	935	1401	
	pmol/l	58.5	46.8	70.2	Roche Cobas 6000
	pg/ml	556	444	668	
	pmol/l	118	94.4	142	Siemens Advia Centaur
	pg/ml	1121	897	1345	
Procalcitonin	µg/l	7.27	5.45	9.09	Brahms Kryptor
	µg/l	19.4	14.6	24.3	bioMerieux Vidas
	µg/l	12.4	9.30	15.5	Roche Cobas E411
	µg/l	12.3	9.23	15.4	Roche Elecsys
	µg/l	12.4	9.30	15.5	Roche Cobas 6000

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