

Chargen-B.: 899EC
Inhalt: 5 x 2ml**Art. Nr.: KG3113**
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 - 8°C. 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 1 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.

IMMUNOASSAY SPECIALITY I - LEVEL 1 (IA SPECIALITY I LEV 1)

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Inhalt 5 x 2ml Verw. bis: 2012-02

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
1-25 OH Vitamin D	pmol/l	47.2	37.8	56.6	IDS RIA
25-OH Vitamin D	nmol/l	74.8	56.1	93.5	Roche Modular E170
	nmol/l	69.4	52.1	86.8	Roche Elecsys
	nmol/l	85.4	64.1	107	Roche Cobas E411
	nmol/l	34.9	26.2	43.6	Diasorin Liaison
	nmol/l	40.7	30.5	50.9	IDS RIA
	nmol/l	61.4	46.1	76.8	IDS ELISA
	nmol/l	32.4	24.3	40.5	HPLC
Anti TG	kU/l	29.7	22.3	37.1	Siemens Immulite 2000/2500
	kU/l	146	110	183	Roche Modular E170
	kU/l	27.2	20.4	34.0	Abbott Architect
	kU/l	64.0	48.0	80.0	Abbott AXSYM
	kU/l	143	107	179	Roche Cobas E411
	kU/l	138	104	173	Roche Cobas 6000
	kU/l	135	101	169	Siemens Advia Centaur
Anti TPO	kU/l	31.9	23.9	39.9	Abbott Architect
	kU/l	33.9	25.4	42.4	Siemens Immulite 2000/2500
	kU/l	21.1	15.8	26.4	Roche Elecsys
	kU/l	24.5	18.4	30.6	Beckman Dxl 600/800
	kU/l	176	132	220	Siemens Advia Centaur
	kU/l	112	84.0	140	Brahms RIA
C-Peptide	nmol/l	0.430	0.323	0.538	Siemens Advia Centaur
	ng/ml	1.30	0.975	1.63	
	nmol/l	0.560	0.420	0.700	Roche Cobas 6000
	ng/ml	1.69	1.27	2.11	
	nmol/l	0.560	0.420	0.700	Roche Elecsys
	ng/ml	1.69	1.27	2.11	
	nmol/l	0.400	0.300	0.500	Siemens Immulite 1000
	ng/ml	1.21	0.906	1.51	
	nmol/l	0.400	0.300	0.500	Siemens Immulite 2000/2500
	ng/ml	1.21	0.906	1.51	
	nmol/l	0.570	0.428	0.713	Roche Modular E170
	ng/ml	1.72	1.29	2.15	
nmol/l	0.560	0.420	0.700	Roche Cobas E411	
ng/ml	1.69	1.27	2.11		
IGF 1	µg/l	61.0	45.8	76.3	Siemens Immulite 2000/2500
	µg/l	78.2	58.7	97.8	DSL RIA
	µg/l	77.1	57.8	96.4	Siemens Immulite 1000
Osteocalcin	µg/l	40.8	30.6	51.0	Roche Modular E170
	µg/l	43.1	32.3	53.9	Roche Elecsys
Parathyroid Hormone (PTH)	pmol/l	2.02	1.62	2.42	Roche Modular E170
	pg/ml	19.2	15.4	23.0	

IMMUNOASSAY SPECIALITY I - LEVEL 1 (IA SPECIALITY I LEV 1)

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Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
Parathyroid Hormone (PTH)	pmol/l	2.67	2.14	3.20	Abbott Architect
	pg/ml	25.4	20.3	30.5	
	pmol/l	2.66	2.13	3.19	Siemens Immulite 1000
	pg/ml	25.3	20.2	30.4	
	pmol/l	2.61	2.09	3.13	Siemens Immulite 2000/2500
	pg/ml	24.8	19.8	29.8	
	pmol/l	2.23	1.78	2.68	Roche Cobas 6000
	pg/ml	21.2	16.9	25.5	
Procalcitonin	pmol/l	2.75	2.20	3.30	Siemens Advia Centaur
	pg/ml	26.1	20.9	31.3	
	µg/l	0.380	0.285	0.475	bioMerieux Vidas
	µg/l	0.250	0.188	0.313	Roche Cobas E411
	µg/l	0.260	0.195	0.325	Roche Modular E170
	µg/l	0.250	0.188	0.313	Roche Cobas 6000