

**Chargen-B.: 903EC**  
**Inhalt: 5 x 1 ml****Artikel.-Nr.: KG3118**  
**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). In reconstituted serum Renin and Procalcitonin are stable for 5 days, Gastrin and Calcitonin are stable for 1 day at +2-8°C if kept capped in original container and free from contamination. 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**

Immunoassay Speciality II is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 1 ml 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 II Level 2 5 x 1 ml

**MATERIAL REQUIRED BUT NOT PROVIDED**

Volumetric Pipette

**VALUE ASSIGNMENT**

Each batch of Immunoassay Speciality II 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 BGT BioGenTechnologies GmbH, Tel: 02551/4090 or email [info@biogentechnologies.de](mailto:info@biogentechnologies.de).

## IMMUNOASSAY SPECIALITY II LEVEL 2

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Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
Calcitonin	pmol/l	23.7	17.8	29.6	Siemens Immulite 1000
	pmol/l	24.4	18.3	30.5	Siemens Immulite 2000/2500
	pmol/l	30.7	23.0	38.4	CIS IRMA
Gastrin	pmol/l	146	110	183	Siemens Immulite 2000/2500
Plasma Renin Activity	µg/l/h	0.340	0.255	0.425	Diasorin/RRENCTK R Angiotensin RIA
Procalcitonin	µg/l	0.630	0.473	0.788	Brahms Kryptor
	µg/l	1.99	1.49	2.49	bioMerieux Vidas
Renin	mIU/l	11.2	8.40	14.0	Diasorin Liason direct Renin
	mIU/l	11.4	8.55	14.3	CIS RIA