

**PRODUCT INFORMATION**

IAS3119

1856EC

Please note that values for Plasma Renin Activity are not available for  
Immunoassay Speciality II Level 3 lot 1856EC.

CCS5875

## IMMUNOASSAY SPECIALITY II - LEVEL 3 (IA SPECIALITY II LEV 3)

**CAT. NO.** IAS 3119

**LOT NO.** 1856EC

**SIZE:** 5 x 1 ml

**EXPIRY:** 2020-10-28

**GTIN:** 05055273207347

### 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°C to +8°C). In reconstituted serum Renin is stable for 5 days, Procalcitonin is stable for 1 day, Gastrin and Calcitonin are stable for 8 hours at +2°C to +8°C if kept capped in original container and free from contamination. The control is stable if frozen once for 28 days at -20°C, except for the Siemens Advia Centaur® CALCT and Siemens Atellica® CALCT assays (Calcitonin) which is stable for 14 days at -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°C to +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.

- Carefully reconstitute each vial of lyophilised serum with exactly 1 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 II - Level 3 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 Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

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Range					
Analyte	unit	Target	low	high	methods
Calcitonin	pmol/l	87.7	65.8	110	Siemens Immulite 2000/2500
	pg/ml	299	224	374	
	pmol/l	137	103	171	Roche Elecsys/Cobas/Modular
	pg/ml	467	351	583	
	pmol/l	129	96.9	161	Siemens ADVIA Centaur® CALCT Assay
	pg/ml	440	330	551	
Gastrin	pmol/l	190	143	238	Siemens Immulite 2000/2500
	pg/ml	396	298	494	
Procalcitonin	µg/l	29.4	22.1	36.8	BioMerieux Vidas
	µg/l	21.3	16.0	26.6	Roche Elecsys/Cobas/Modular
	µg/l	28.6	21.5	35.8	Siemens Centaur XP/XPT/Classic
	µg/l	36.9	27.7	46.1	Diazyme PCT
Renin	mIU/l	172	129	215	Diasorin Liason direct Renin
	pg/ml	101	75.9	126	