# IMMUNOASSAY SPECIALITY II - LEVEL 2 (IA SPECIALITY II LEV 2)

**Cat. No.** IAS 3118 **Lot No.** 1527EC
**Size:** 5 x 1ml **Expiry:** 2017-04

## 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. 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.
1. Carefully reconstitute each vial of lyophilised serum with exactly 1ml of distilled water at +20°C 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 1ml

## 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 ±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 Support, Northern Ireland, tel: +44 (0) 28 9442 2413 or email Technical.Support@randox.com

8 Apr 16 bi

RANDOX

# IMMUNOASSAY SPECIALITY II - LEVEL 2 (IA SPECIALITY II LEV 2)

**Cat. No. IAS3118 Lot No. 1527EC Size: 5 x 1 ml Expiry: 2017-04**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Calcitonin | pmol/l | 33.4 | 25.1 | 41.8 | Siemens Immulite 2000/2500 |
| | pg/ml | 114 | 85.6 | 142 | |
| | pmol/l | 24.7 | 18.5 | 30.9 | Diasorin Liaison |
| | pg/ml | 84.2 | 63.1 | 105 | |
| | pmol/l | 35.3 | 26.5 | 44.1 | Roche Elecsys/Cobas/Modular |
| | pg/ml | 120 | 90.4 | 150 | |
| Gastrin | pmol/l | 164 | 123 | 205 | Siemens Immulite 1000 |
| | pg/ml | 342 | 256 | 428 | |
| | pmol/l | 155 | 116 | 194 | Siemens Immulite 2000/2500 |
| | pg/ml | 323 | 242 | 404 | |
| Plasma Renin Activity | µg/l/h | 2.85 | 2.14 | 3.56 | Diasorin/RRENCTK R Angiotensin RIA |
| Procalcitonin | µg/l | 2.36 | 1.77 | 2.95 | BioMerieux Vidas |
| | µg/l | 1.11 | 0.833 | 1.39 | Roche Elecsys/Cobas/Modular |
| | µg/l | 2.98 | 2.24 | 3.73 | Siemens Centaur XP/XPT/Classic |
| Renin | mIU/l | 62.2 | 46.7 | 77.8 | Diasorin Liason direct Renin |
| | pg/ml | 36.6 | 27.5 | 45.7 | |
| | mIU/l | 46.9 | 35.2 | 58.6 | CISBIO RIA |
| | pg/ml | 27.6 | 20.7 | 34.5 | |

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com