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

CAT. NO. IAS 3118 **LOT NO.** 2173EC
SIZE: 5 x 1 ml **EXPIRY:** 2024-03-28
GTIN: 05055273207330

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, Procalcitionin 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 assay (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.
1. 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.
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
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Calcitonin	pmol/l	34.4	25.8	43.0	Siemens Immulite 2000/2500
	pg/ml	117	88.0	146	
	pmol/l	38.7	29.0	48.4	Roche Elecsys/Cobas/Modular
	pg/ml	132	98.9	165	
	pmol/l	32.5	24.4	40.6	Diasorin Liaison XL
	pg/ml	111	83.2	139	
	pmol/l	40.0	30.0	50.0	Roche Cobas e402/e801
	pg/ml	136	102	170	
Gastrin	pmol/l	37.5	28.1	46.9	Siemens Immulite 2000/2500
	pg/ml	78.1	58.5	97.7	
Procalcitonin	µg/l	3.77	2.83	4.71	BioMerieux Vidas
	µg/l	2.45	1.84	3.06	Roche Elecsys/Cobas/Modular
	µg/l	2.56	1.92	3.20	Abbott Architect / Alinity Brahms PCT
	µg/l	2.44	1.83	3.05	Roche Cobas e402/e801
	µg/l	3.38	2.54	4.23	Beckman Access PCT
	µg/l	2.12	1.59	2.65	Shanghai I-Reader
	µg/l	3.06	2.30	3.83	Siemens Atellica IM 11202699
Renin	mIU/l	77.4	58.1	96.8	Diasorin Liaison direct Renin
	pg/ml	45.5	34.2	56.8	
	mIU/l	78.6	59.0	98.3	Diasorin Liaison XL direct Renin
	pg/ml	46.2	34.7	57.7	

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