

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

CAT. NO. IAS 3117

LOT NO. 1775EC

SIZE: 5 x 1 ml

EXPIRY: 2019-12-28

GTIN: 05055273207323

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 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 I 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 ± 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.

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

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Analyte	unit	Target	Range		methods
			low	high	
Calcitonin	pmol/l	7.26	5.45	9.08	Siemens Immulite 2000/2500
	pg/ml	24.8	18.6	31.0	
	pmol/l	5.57	4.18	6.96	Diasorin Liaison
	pg/ml	19.0	14.3	23.7	
	pmol/l	8.89	6.67	11.1	Roche Elecsys/Cobas/Modular
	pg/ml	30.3	22.7	37.9	
	pmol/l	6.58	4.93	8.23	Siemens ADVIA Centaur® CALCT Assay
	pg/ml	22.5	16.9	28.1	
Gastrin	pmol/l	15.6	11.7	19.5	Siemens Immulite 2000/2500
	pg/ml	32.5	24.4	40.6	
Plasma Renin Activity	µg/l/h	0.801	0.561	1.04	Immunotech Angiotensin I RIA
Procalcitonin	µg/l	1.21	0.908	1.51	BioMerieux Vidas
	µg/l	0.768	0.576	0.960	Roche Elecsys/Cobas/Modular
	µg/l	1.14	0.855	1.43	Siemens Centaur XP/XPT/Classic
	µg/l	1.32	0.990	1.65	Diazyme PCT
	µg/l	0.700	0.530	0.880	Abbott Architect Brahms PCT
	µg/l	0.934	0.700	1.17	Radiometer AQT90 Flex
Renin	mIU/l	16.0	12.0	20.0	Diasorin Liason direct Renin
	pg/ml	9.41	7.06	11.8	
	mIU/l	13.5	10.1	16.9	CISBIO RIA
	pg/ml	7.94	5.94	9.94	
	mIU/l	18.6	14.0	23.3	Beckman Active IRMA
	pg/ml	10.9	8.23	13.7	
	mIU/l	14.4	10.8	18.0	IDS iSYS
	pg/ml	8.47	6.35	10.6	