

PRODUCT INFORMATION

IAS3118

2471EC

Please note that for Immunoassay Speciality II Level 2, lot 2471EC,
Renin is stable for **1 day** at +2°C to +8°C.

CCS INC1598

PRODUCT INFORMATION

Catalogue Number IAS3118

Lot number 2471EC

Please note Immunoassay Speciality II – Level 2 IAS3118 lot 2471EC the concentration of analytes listed below are lower compared to previous lots:

Renin, approximate concentration 36.34 μ IU/ml

Gastrin, approximate concentration 88.9ng/l

For any queries, please contact Technical Services at technical.services@radox.com.

CCS INC1452

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

CAT. NO. IAS 3118 **LOT NO.** 2471EC
SIZE 5 x 1 ml **EXPIRY:** 2027-01-28
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

Unopened: Unreconstituted control is stable up to the expiry date shown on the side of each individual bottle.

Opened: Stability claims once reconstituted are listed below.

Analyte	+2°C to +8°C	Aliquoted and frozen once at -20°C
Gastrin	8 hours	28 days
Calcitonin	8 hours	28 days
Siemens ADVIA Centaur CALCT Assay (Calcitonin)	8 hours	14 days
Procalcitonin	1 day	28 days
Renin	1 day	28 days

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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 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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Table of Content

Method

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Method		Immunoassay Speciality II - Level 2 (IA SPECIALITY II LEV 2)					
Lot. No: 2471EC Cat. No: IAS3118 Expiry: 2027/01/28							
Size: 5 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Calcitonin	pg/ml	140	105	175	17.5	35.0	DiaSorin Liaison XL
	pmol/l	41.0	30.8	51.2	5.10	10.2	
	pg/ml	133	99.8	166	16.5	33.0	Roche Cobas e402/e801
	pmol/l	39.1	29.3	48.9	4.90	9.80	
	pg/ml	140	105	175	17.5	35.0	Roche Elecsys/Cobas/Modular
	pmol/l	41.2	30.9	51.5	5.15	10.3	
	pg/ml	125	93.8	156	15.5	31.0	Siemens Atellica IM
	pmol/l	36.6	27.5	45.7	4.55	9.10	
	pg/ml	126	94.5	158	16.0	32.0	Siemens Immulite 2000/2500
	pmol/l	37.0	27.8	46.2	4.60	9.20	
Gastrin	pg/ml	90.2	67.7	113	11.4	22.8	Siemens Immulite 2000/2500
	pmol/l	43.3	32.5	54.1	5.40	10.8	
Procalcitonin	µg/l	2.12	1.59	2.65	0.265	0.530	Abbott Alinity i
	µg/l	2.26	1.70	2.82	0.280	0.560	Abbott Architect
	µg/l	3.00	2.25	3.75	0.375	0.750	Beckman Access PCT
	µg/l	2.98	2.24	3.72	0.370	0.740	BioMerieux VIDAS
	µg/l	1.84	1.38	2.30	0.230	0.460	Brahms Kryptor
	µg/l	2.07	1.55	2.59	0.260	0.520	Roche Cobas e402/e801
	µg/l	2.05	1.54	2.56	0.255	0.510	Roche Elecsys/Cobas/Modular
Renin	pg/ml	23.5	17.6	29.4	2.95	5.90	DiaSorin Liaison XL, direct Renin
	mIU/l	40.0	30.0	50.0	5.00	10.0	
	pg/ml	24.9	18.7	31.1	3.10	6.20	Diasorin Liaison, direct Renin
	mIU/l	42.3	31.7	52.9	5.30	10.6	
	pg/ml	39.6	29.7	49.5	4.95	9.90	IDS iSYS
	mIU/l	67.3	50.5	84.1	8.40	16.8	