

PRODUCT INFORMATION

IAS3119

2472EC

Please note that for Immunoassay Speciality II Level 3, lot 2472EC,
Renin is stable for **1 day** at +2°C to +8°C.

CCS INC1598

PRODUCT INFORMATION

Catalogue Number IAS3119

Lot number 2472EC

Please note Immunoassay Speciality II – Level 3 IAS3119 lot 2472EC the concentration of analytes listed below are lower compared to previous lots:

Renin, approximate concentration 96.1 μ IU/ml

Gastrin, approximate concentration 317.9ng/l

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

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

CAT. NO. IAS 3119 **LOT NO.** 2472EC
SIZE 5 x 1 ml **EXPIRY:** 2027-01-28
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

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 3 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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Method		Immunoassay Speciality II - Level 3 (IA SPECIALITY II LEV 3)					
Lot. No: 2472EC Cat. No: IAS3119 Expiry: 2027/01/28							
Size: 5 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Calcitonin	pg/ml	471	353	589	59.0	118	DiaSorin Liaison XL
	pmol/l	138	104	172	17.0	34.0	
	pg/ml	460	345	575	57.5	115	Roche Cobas e402/e801
	pmol/l	135	101	169	17.0	34.0	
	pg/ml	484	363	605	60.5	121	Roche Elecsys/Cobas/Modular
	pmol/l	142	107	177	17.5	35.0	
	pg/ml	436	327	545	54.5	109	Siemens Atellica IM
	pmol/l	128	96.0	160	16.0	32.0	
pg/ml	338	254	422	42.0	84.0	Siemens Immulite 2000/2500	
pmol/l	99.2	74.4	124	12.4	24.8		
Gastrin	pg/ml	312	234	390	39.0	78.0	Siemens Immulite 2000/2500
	pmol/l	150	113	187	18.5	37.0	
Procalcitonin	µg/l	15.3	11.5	19.1	1.90	3.80	Abbott Alinity i
	µg/l	16.3	12.2	20.4	2.05	4.10	Abbott Architect
	µg/l	19.8	14.9	24.7	2.45	4.90	BioMerieux VIDAS
	µg/l	11.4	8.55	14.3	1.45	2.90	Brahms Kryptor
	µg/l	15.5	11.6	19.4	1.95	3.90	Roche Cobas e402/e801
	µg/l	15.5	11.6	19.4	1.95	3.90	Roche Elecsys/Cobas/Modular
Renin	pg/ml	64.1	48.1	80.1	8.00	16.0	DiaSorin Liaison XL, direct Renin
	mIU/l	109	81.8	136	13.5	27.0	
	pg/ml	67.6	50.7	84.5	8.45	16.9	Diasorin Liaison, direct Renin
	mIU/l	115	86.3	144	14.5	29.0	
	pg/ml	95.8	71.9	120	12.1	24.2	IDS iSYS
	mIU/l	163	122	204	20.5	41.0	