



Invoice Date & Tax Point <b>05 February 2024</b>		Invoice No. <b>37495-24</b>		<b>RSR Limited</b> Parc Ty Glas Llanishen Cardiff, CF14 5DU UK Tel: +44(29)2068 9299 Fax: +44(29)2075 7770 Email: orders@rsrltd.com VAT Registration No: GB 736 8339 02 EORI NO: GB 736 8339 02 000			
Date Requested <b>12, 19 &amp; 29 January 2024</b>		Customer Purchase No. <b>PO00037211, PO00037244 &amp; PO00037271</b>					
Bill to:-  Abacus dx Pty Limited PO Box 446 Waterford 4133 Queensland AUSTRALIA		Deliver to:-  Abacus dx Pty Limited Southgate Corporate Park 34 Corporate Drive Cannon Hill 4170 Queensland AUSTRALIA Please notify: DSV (+61 7 3268 8600)					
-		CCN 3822 1900			Incoterm: EXW		
Qty	Order Code	Description	Lot No.	Expiry Date	Unit Price GBP	Total Amount	
6	FKIE/96	ElisaRSR™ Fast IA-2 Ab 96W	FKIE150	2024.10.15	175.00	1,050.00	
5	FKIE/96	ElisaRSR™ Fast IA-2 Ab 96W	FKIE154	2025.01.21	175.00	875.00	
15	IAA/100	RiaRSR™ IAA 100T	3INK340	2024.03.22	140.00	2,100.00	
12	LEM/25	RiaRSR™ VGCC Ab 25T	LK246	2024.04.12	FOC	-	
Total MBq of 125-I = 1.488							
"I the undersigned do hereby certify that the goods mentioned on the invoice are wholly of United Kingdom origin and that the particulars covered are true and correct." For and on behalf of RSR Limited. (Authorised Signatory) 			On arrival, keep refrigerated 2-8°C		Subtotal		4,025.00
					Shipping and Handling		579.00
					Invoice Total		GBP 4,604.00
-							
Shipping Date 05 February 2024							
-							
Our bankers:		HSBC Bank Plc GB89HBUK40100841201379 HBUKGB4136P		Account Name: RSR Limited Sort Code: 40-10-08 Account No.: 41201379			
Shipper's Checker (Intl) GM		Shipping Details		Weight: Net: 23 Kg			
GM		Courier: Alexian		Gross: 27 Kg			
Shipper's Signature YE		AWB: 618-6617 2131		Dimensions (cm): (Qty) SBNo			
		Flight: SQ 319 06/02/24		48 x 42 x 42 (x 2) 8			
		SQ 255 08/02/24		36 x 23 x 25 (x 1) 4			
3 pieces							

618-66172131

Original 3 (for Shipper)

618-66172131



# RSR LIMITED

PARC TY GLAS  
LLANISHEN  
CARDIFF  
CF14 5DU  
UNITED KINGDOM  
TELEPHONE: +44 (0)29 20 68 9299  
FACSIMILE: +44 (0)29 20 75 7770  
EMAIL: info@rsrltd.com  
WEBSITE: www.rsrltd.com

## Manufacturer's Declaration

Manufacturer: RSR Limited  
Parc Ty Glas  
Llanishen  
Cardiff  
CF14 5DU, UK

Importer: Abacus dx Pty Ltd  
Southgate Corporate Park  
34 Corporate Drive  
CANNON HILL  
Queensland 4170  
AUSTRALIA

Invoice Number	37495-24
Date	05 <sup>th</sup> February 2024

I, the authorised representative RSR Limited declare this consignment contains: *Diagnostic test kits excluding those testing for Listed Human Diseases and zoonotic diseases*

Order Codes: FKIE/96 IAA/100 LEM/25

- The goods are diagnostic test kits (or individual components specifically designed for use with kits eligible for import under these conditions) testing human conditions only.
- All components derived from disease agents are incapable of replicating.
- The goods do not test for Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 2).
- The goods do not contain Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 2) (live, live or inactivated) or their derivatives (e.g. antigens).
- The goods do not contain any components raised against Listed Human Diseases (as published on the Department of Health's website) or zoonotic diseases of biosecurity concern (Appendix 2) (e.g. antibodies).
- All animal derived material contained in these diagnostic test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit. Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

X 

Yuuki Evans  
Administrator

**RSR LIMITED**

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WEBSITE: [www.rsrltd.com](http://www.rsrltd.com)

Date: 05/02/24

To whom it may concern,

In relation to consignment: Invoice number: 37495-24

The ELISA products do not contain live or whole inactivated viruses, or bacteria or any other microorganisms.

The RIA (radioimmunoassay) products contain Protein A as a component, which contains heat killed, formalin fixed *Staphylococcus aureus* (a bacteria) which is not considered hazardous.

Signature:

X



Yuuki Evans  
Administrator

Title: **Quality Control Record Sheet**  
**Fast IA-2 Ab ELISA Kit QC Data**

Document: **wi/qcrs/0.28b**

Revision: **0**

Date: **20 September 2022**

Page **1 of 1**

Prepared by: **G FLOOD**

Approved by: **L CARR**

Kit lot number: **FKIE150**

Kit expiry date: **15 October 2024**

Kit manufacture date: **16 October 2023**

**Reagent Lot Numbers:**

IA-2 Coated Wells:	<b>IE223</b>	Expiry date:	<b>06 FEB 2025</b>
IA-2-Biotin:	<b>IEB151</b>	Expiry date:	<b>25 NOV 2024</b>
Recon. Buffer for IA-2-Biotin:	<b>IBB182</b>	Expiry date:	<b>20 FEB 2025</b>
Streptavidin Peroxidase:	<b>GEP589</b>	Expiry date:	<b>28 MAR 2025</b>
Diluent for SA-POD:	<b>PB174</b>	Expiry date:	<b>12 FEB 2025</b>
Reaction Enhancer:	<b>IES124</b>	Expiry date:	<b>16 AUG 2025</b>
Peroxidase Substrate:	<b>PTS183F</b>	Expiry date:	<b>24 OCT 2026</b>
Stop Solution:	<b>HESP123</b>	Expiry date:	<b>12 JAN 2025</b>
Concentrated Wash Solution:	<b>CW353</b>	Expiry date:	<b>01 NOV 2025</b>
Calibrators:	<b>IC150</b>	Expiry date:	<b>15 OCT 2024</b>
Controls:	<b>INC150/IPC150</b>	Expiry date:	<b>15 OCT 2024</b>

**Curve and Controls:** Incubation temp: **+21 °C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.069	0.015
7.5	0.170	0.047
35	0.397	0.120
120	1.831	0.571
350	>4	1.554
4000	>4	2.738

Control	Absorbance at 450 nm	Absorbance at 405 nm	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)
Positive I	1.800	0.567	118.5	119.3	115 ± 40

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by: **Fiona Ryrie**

Signature: **Fiona Ryrie**

Position: **Scientist**

Date: **05 October 2023**

Authorised by: **J. Bradbury**

Signature: **J. Bradbury**

Position: **pp Head of Quality Control**

Date: **17 October 2023**



Title:

# Quality Control Record Sheet

## Fast IA-2 Ab ELISA Kit QC Data

Document: **wi/qcrs/0.28b**Revision: **0**Date: **20 September 2022**Page **1 of 1**Prepared by: **G FLOOD**Approved by: **L CARR**Kit lot number: **FKIE154**Kit expiry date: **21 January 2025**Kit manufacture date: **22 January 2024****Reagent Lot Numbers:**IA-2 Coated Wells: **IE225**Expiry date: **22 APR 2025**IA-2-Biotin: **IEB156**Expiry date: **30 APR 2025**Recon. Buffer for IA-2-Biotin: **IBB182**Expiry date: **20 FEB 2025**Streptavidin Peroxidase: **GEP599**Expiry date: **20 MAY 2025**Diluent for SA-POD: **PB177**Expiry date: **10 AUG 2025**Reaction Enhancer: **IES124**Expiry date: **16 AUG 2025**Peroxidase Substrate: **PTS185Ga**Expiry date: **27 JUL 2027**Stop Solution: **HESP127**Expiry date: **20 SEP 2025**Concentrated Wash Solution: **CW371**Expiry date: **24 MAR 2026**Calibrators: **IC154A**Expiry date: **21 JAN 2025**Controls: **INC154A/IPC154A**Expiry date: **21 JAN 2025****Curve and Controls:** Incubation temp: **+21 °C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.069	0.020
7.5	0.182	0.053
35	0.442	0.127
120	1.878	0.540
350	>4	1.679
4000	>4	2.892

Control	Absorbance at 450 nm	Absorbance at 405 nm	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)
Positive I	1.987	0.572	124.8	124.8	125 ± 40

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by: **Rebecca Coles**Authorised by: **SARAH NUTE**Signature: **R. Coles**Signature: **SRNUTE**Position: **Senior Scientist**Position: **Head of Quality Control**Date: **08 January 2024**Date: **23 JAN 2024**

Title: **Quality Control Record Sheet  
Insulin Ab 3 QC Data**

Prepared by: Geoff Flood  
Approved by: Janet Bradbury

Document: wi/qcrs/0.08b  
Revision: 2  
Date: 09.01.14  
Page 1 of 1

Tracer iodination date: 25 January 2024

Kit lot number: 3INK340

Kit expiry date: 22 March 2024

<sup>125</sup> I - Insulin	Lot No. IT340R	Expiry Date: 22 MAR 2024
Assay Buffer	Lot No. MIAB149	Expiry Date: 05 MAY 2025
Anti-human IgG	Lot No. 187PG	Expiry Date: 28 MAR 2025
Calibrators	Lot No. IMS38B	Expiry Date: 26 FEB 2025
Negative Control	Lot No. IN131	Expiry Date: 06 JUL 2024
Kit Controls	Lot No. IMCa38B/IMCb38B	Expiry Date: 26 FEB 2025

Total cpm in 25 µl <sup>125</sup>I - Insulin 27932

<u>Sample</u>	<u>% <sup>125</sup>I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	1.1		
INS-Ab calibrator:			
0.4 u/mL	2.4		
1 u/mL	4.6		
10 u/mL	16.2		
50 u/mL	54.8		
Control I	4.3	0.86	0.5 – 1.7
Control II	18.5	11.5	8 – 18

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies at the time of testing.

Assay Date: 30 Jan 2024

Performed by: J DAVIES

Signature: 

Position: Senior Scientist

Authorised by: DR G FLOOD

Signature: 

Position: Head of Quality Control

Date: 30<sup>TH</sup> JAN 2024



Title:

# Quality Control Record Sheet VGCC Ab QC Data

Document:

wi/qcrs/0.15

Revision:

8

Date:

15/08/18

Page

1 of 1

Kit Lot Number: LK246Kit Expiry Date: 12 April 2024Kit Manufacture Date: 26 January 2024<sup>125</sup>I-VGCC for total binding lot number: LT246Expiry Date: 12 April 2024<sup>125</sup>I-VGCC for non-specific binding lot number: NS246Expiry Date: 12 April 2024Dilution buffer lot number: 239LBaExpiry Date: 12 April 2024Anti-human IgG lot number: 27LGnExpiry Date: 12 April 2024Wash solution lot number: 169LWExpiry Date: 12 April 2024Negative control lot number: 21LNeExpiry Date: 12 April 2024Positive control lot number: 26LPdExpiry Date: 12 April 2024At Manufacture Date: 6574 dpm = 1 fmoleAt QC Assay Date<sup>1</sup>: 6350 dpm = 1 fmole (conversion factor A)Counter Efficiency: 73.4 % (B)<sup>2</sup> Positive control range: 165 ± 75 pmol/L

	NSB		T			
Sample	Mean cpm - background	fmol/ Pellet (E)	Mean cpm - background	fmol/ pellet (D)	<sup>125</sup> I-conotoxin labelled VGCC bound (pmol/L serum)	pmol/L serum VGCC Ab (after subtraction of negative control)
Total counts	17643	3.786	16862	3.618		
Negative control	358	0.077	317	0.068	-3.5 (G)	-
Positive control	409	0.088	1974	0.424	134.3 (F)	137.8 (H)
Test sample 1	345	0.074	1442	0.309	94.2 (F)	97.7 (H)
Test sample 2b	246	0.053	968	0.208	62.0 (F)	65.5 (H)
Test sample 3c	325	0.070	1515	0.325	102.1 (F)	105.7 (H)
Test sample 4a	212	0.045	1938	0.416	148.1 (F)	151.7 (H)
Test sample 5d	355	0.076	1858	0.399	129.0 (F)	132.5 (H)

Assay date (weeks after QC assay)	Decay factor (C)	Assay date (weeks after QC assay)	Decay factor (C)
Up to 1 week	1.00	+ 6 – 7 weeks	0.61
+ 1 – 2 weeks	0.92	+ 7 – 8 weeks	0.56
+ 2 – 3 weeks	0.85	+ 8 – 9 weeks	0.52
+ 3 – 4 weeks	0.78	+ 9 – 10 weeks	0.48
+ 4 – 5 weeks	0.72	+ 10 – 11 weeks	0.44
+ 5 – 6 weeks	0.66		

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

QC Assay Date<sup>1</sup>: 29 January 2024Performed by: A. HuckleSignature: A. HucklePosition: Senior TechnicianAuthorised by: DR G FloodSignature: G FloodPosition: Head of Quality ControlDate: 31<sup>st</sup> JAN 2024