

Title: **Quality Control Record Sheet**
3 Screen ICA ELISA Kit QC Data

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Prepared by: **G Flood**
Approved by: **F Ryrie**

Kit lot number: **KZGIE63B** Kit expiry date: **15th May 2023**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE37	Expiry date: 28 May 2023
3 Screen-Biotin: ZGIB23c	Expiry date: 15 May 2023
Recon. Buffer for 3 Screen-Biotin: 3BB19	Expiry date: 21 Aug 2023
Streptavidin Peroxidase: GEP467	Expiry date: 25 Jul 2023
Diluent for SA-POD: PB167	Expiry date: 28 Jun 2023
Peroxidase Substrate: PTS177L	Expiry date: 03 May 2024
Stop Solution: HESP112	Expiry date: 22 Jun 2023
Concentrated Wash Solution: CW294	Expiry date: 09 Feb 2024
Reference Preparation: ZGIR38	Expiry date: 09 Aug 2023
Calibrators: ZGIC38	Expiry date: 09 Aug 2023
Negative Control: ZGIN38	Expiry date: 09 Aug 2023
GAD Ab Positive Control: 3SGP38	Expiry date: 09 Aug 2023
IA-2 Ab Positive Control: 3SIP38	Expiry date: 09 Aug 2023
ZnT8 Ab Positive Control: 3SZP38	Expiry date: 09 Aug 2023

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

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.069	0.021
Calibrator 15 units per mL	0.132	0.041
Calibrator 100 units per mL	0.556	0.176
Calibrator 400 units per mL	2.371	0.757
Calibrator 2000 units per mL	>4	2.312
Reference Preparation	0.562	0.178
Negative Control	0.033	0.011
GAD Ab Positive Control	1.279	0.404
IA-2 Ab Positive Control	0.473	0.150
ZnT8 Ab Positive Control	0.254	0.081

Control	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)	Index Value at 450 nm	Index Value at 405 nm	Range (index value)
Negative	<5	<5	<5	<30	<30	<30
GAD Ab Positive	219.8	211.8	220±90	227.6	227.0	220±90
IA-2 Ab Positive	85.7	86.9	90±35	84.2	84.3	90±35
ZnT8 Ab Positive	46.2	50.3	46±18	45.2	45.5	52±21

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: **22nd March 2022**

Authorised by: **DR G Flood**
Signature: **G Flood**
Position: **HEAD OF QC**
Date: **3rd Mar 2022**