

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: **KZGIE68A** Kit expiry date: **01st January 2024**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE39	Expiry date: 30 Apr 2024
3 Screen-Biotin: ZGIB25c	Expiry date: 01 Jan 2024
Recon. Buffer for 3 Screen-Biotin: 3BB22	Expiry date: 26 Apr 2024
Streptavidin Peroxidase: GEP502	Expiry date: 11 Jan 2024
Diluent for SA-POD: PB171	Expiry date: 16 May 2023⁴ AW
Peroxidase Substrate: PTS181J	Expiry date: 21 Apr 2026
Stop Solution: HESP119	Expiry date: 05 Jul 2024
Concentrated Wash Solution: CW310	Expiry date: 13 Aug 2024
Reference Preparation: ZGIR40	Expiry date: 14 May 2024
Calibrators: ZGIC40	Expiry date: 14 May 2024
Negative Control: ZGIN40	Expiry date: 14 May 2024
GAD Ab Positive Control: 3SGP40	Expiry date: 14 May 2024
IA-2 Ab Positive Control: 3SIP40	Expiry date: 14 May 2024
ZnT8 Ab Positive Control: 3SZP40	Expiry date: 14 May 2024

Curve and Controls: Incubation temp: **19 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.079	0.024
Calibrator 15 units per mL	0.135	0.041
Calibrator 100 units per mL	0.511	0.161
Calibrator 400 units per mL	2.192	0.702
Calibrator 2000 units per mL	>4	2.187
Reference Preparation	0.537	0.170
Negative Control	0.046	0.014
GAD Ab Positive Control	1.155	0.365
IA-2 Ab Positive Control	0.592	0.188
ZnT8 Ab Positive Control	0.314	0.098

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	217.2	208.8	230±90	215.1	214.7	230±90
IA-2 Ab Positive	115.4	114.5	120±50	110.2	110.6	120±50
ZnT8 Ab Positive	61.6	65.0	60±24	58.5	57.6	61±24

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: **30th November 2022**

Authorised by: **DR G Flood**
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **4th JAN 2023**