

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: **KZGIE67** Kit expiry date: **27th November 2023**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE39	Expiry date: 30 Apr 2024
3 Screen-Biotin: ZGIB25a	Expiry date: 27 Nov 2023
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
Peroxidase Substrate: PTS179L	Expiry date: 30 Sep 2024
Stop Solution: HESP119	Expiry date: 05 Jul 2024
Concentrated Wash Solution: CW310	Expiry date: 13 Aug 2024
Reference Preparation: ZGIR39	Expiry date: 24 Jan 2024
Calibrators: ZGIC39	Expiry date: 24 Jan 2024
Negative Control: ZGIN39	Expiry date: 24 Jan 2024
GAD Ab Positive Control: 3SGP39A	Expiry date: 24 Jan 2024
IA-2 Ab Positive Control: 3SIP39A	Expiry date: 24 Jan 2024
ZnT8 Ab Positive Control: 3SZP39A	Expiry date: 24 Jan 2024

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

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.079	0.025
Calibrator 15 units per mL	0.137	0.044
Calibrator 100 units per mL	0.546	0.174
Calibrator 400 units per mL	2.327	0.750
Calibrator 2000 units per mL	>4	2.259
Reference Preparation	0.558	0.177
Negative Control	0.041	0.014
GAD Ab Positive Control	1.291	0.410
IA-2 Ab Positive Control	0.556	0.177
ZnT8 Ab Positive Control	0.291	0.093

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	225.5	216.1	220±80	231.4	231.6	220±90
IA-2 Ab Positive	101.8	101.6	110±45	99.6	100.0	110±45
ZnT8 Ab Positive	54.2	58.3	51±20	52.2	52.5	51±20

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: **08th November 2022**

Authorised by: **DR G Flood**
Signature: **G Flood**
Position: **HEAD OF QC**
Date: **28th Nov 2022**