

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

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Page **1 of 1**

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

Kit lot number: **KZGIE88A** Kit expiry date: **11th May 2026**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE50	Expiry date: 02 Aug 2026
3 Screen-Biotin: ZGIB32d	Expiry date: 11 May 2026
Recon. Buffer for 3 Screen-Biotin: 3BB32	Expiry date: 10 Sep 2026
Streptavidin Peroxidase: GEP683	Expiry date: 05 Jul 2026
Diluent for SA-POD: PB184	Expiry date: 26 Nov 2026
Peroxidase Substrate: PTS189L	Expiry date: 09 May 2028
Stop Solution: HESP137	Expiry date: 27 Nov 2026
Concentrated Wash Solution: CW420	Expiry date: 21 May 2027
Reference Preparation: ZGIR47	Expiry date: 05 Jul 2026
Calibrators: ZGIC47	Expiry date: 05 Jul 2026
Negative Control: ZGIN47	Expiry date: 05 Jul 2026
GAD Ab Positive Control: 3SGP47	Expiry date: 05 Jul 2026
IA-2 Ab Positive Control: 3SIP47	Expiry date: 05 Jul 2026
ZnT8 Ab Positive Control: 3SZP47	Expiry date: 05 Jul 2026

Curve and Controls: Incubation temp: **20 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.081	0.022
Calibrator 15 units per mL	0.141	0.039
Calibrator 100 units per mL	0.514	0.147
Calibrator 400 units per mL	2.296	0.664
Calibrator 2000 units per mL	>4	2.237
Reference Preparation	0.553	0.159
Negative Control	0.043	0.011
GAD Ab Positive Control	1.143	0.330
IA-2 Ab Positive Control	0.462	0.134
ZnT8 Ab Positive Control	0.257	0.072

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	206.2	207.4	195±75	206.7	207.5	205±80
IA-2 Ab Positive	90.8	91.6	85±30	83.5	84.3	85±30
ZnT8 Ab Positive	51.6	50.6	45±18	46.5	45.3	47±17

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: **F Ryrie**
Position: **Scientist**
Date: **17/18 March 2025**

Authorised by: **DR G Flood**
Signature: **G Flood**
Position: **HEAD OF QC**
Date: **25th APR 2025**