

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

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Revision: **3**

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Prepared by: **G Flood**

Approved by: **F Ryrie**

Kit lot number: KZGIE80 Kit expiry date: 01st September 2025

Reagent Lot Numbers:

3 Screen Coated Wells: <u>ZGIE46</u>	Expiry date: <u>11 Feb 2026</u>
3 Screen-Biotin: <u>ZGIB30a</u>	Expiry date: <u>01 Sep 2025</u>
Recon. Buffer for 3 Screen-Biotin: <u>3BB30</u>	Expiry date: <u>28 Jan 2026</u>
Streptavidin Peroxidase: <u>GEP658</u>	Expiry date: <u>13 Feb 2026</u>
Diluent for SA-POD: <u>PB182</u>	Expiry date: <u>27 Jun 2026</u>
Peroxidase Substrate: <u>PTS187T</u>	Expiry date: <u>30 Nov 2027</u>
Stop Solution: <u>HESP133</u>	Expiry date: <u>19 Jun 2026</u>
Concentrated Wash Solution: <u>CW404</u>	Expiry date: <u>16 Jan 2027</u>
Reference Preparation: <u>ZGIR46</u>	Expiry date: <u>28 Jan 2026</u>
Calibrators: <u>ZGIC46</u>	Expiry date: <u>28 Jan 2026</u>
Negative Control: <u>ZGIN46</u>	Expiry date: <u>28 Jan 2026</u>
GAD Ab Positive Control: <u>3SGP46</u>	Expiry date: <u>28 Jan 2026</u>
IA-2 Ab Positive Control: <u>3SIP46</u>	Expiry date: <u>28 Jan 2026</u>
ZnT8 Ab Positive Control: <u>3SZP46</u>	Expiry date: <u>28 Jan 2026</u>

Curve and Controls: Incubation temp: 22 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.071	0.022
Calibrator 15 units per mL	0.133	0.039
Calibrator 100 units per mL	0.523	0.152
Calibrator 400 units per mL	2.233	0.647
Calibrator 2000 units per mL	>4	2.211
Reference Preparation	0.537	0.149
Negative Control	0.032	0.009
GAD Ab Positive Control	1.164	0.337
IA-2 Ab Positive Control	0.475	0.138
ZnT8 Ab Positive Control	0.265	0.077

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	214.4	215.1	215±85	216.8	226.2	220±80
IA-2 Ab Positive	91.1	90.9	90±35	88.5	92.6	90±35
ZnT8 Ab Positive	50.3	49.9	53±21	49.3	51.7	54±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

Authorised by: DR G FLOOD

Signature: *Fiona Ryrie*

Signature: *G Flood*

Position: Scientist

Position: HEAD OF QC

Date: 21/22 August 2024

Date: 27th AUG 2024