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: J Bradbury

Kit lot number: KZGIE106 Kit expiry date: 25th October 2027

Kit manufacture date: 26th October 2026

Reagent Lot Numbers:

3 Screen Coated Wells:	ZGIE60	Expiry date:	10 Nov 2027
3 Screen-Biotin:	ZGIB34g	Expiry date:	25 Oct 2027
Recon. Buffer for 3 Screen-Biotin:	3BB37	Expiry date:	03 Feb 2028
Streptavidin Peroxidase:	GEP824	Expiry date:	06 Mar 2028
Diluent for SA-POD:	PB193	Expiry date:	15 Jul 2028
Peroxidase Substrate:	PTS197G	Expiry date:	13 Oct 2029
Stop Solution:	HESP147	Expiry date:	11 Jan 2028
Concentrated Wash Solution:	CW448	Expiry date:	12 Nov 2027
Reference Preparation:	ZGIR52	Expiry date:	09 Feb 2028
Calibrators:	ZGIC52	Expiry date:	09 Feb 2028
Negative Control:	ZGIN52	Expiry date:	09 Feb 2028
GAD Ab Positive Control:	3SGP52	Expiry date:	09 Feb 2028
IA-2 Ab Positive Control:	3SIP52	Expiry date:	09 Feb 2028
ZnT8 Ab Positive Control:	3SZP52	Expiry date:	09 Feb 2028

Curve and Controls: Incubation temp: 21 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.091	0.028
Calibrator 15 units per mL	0.157	0.046
Calibrator 100 units per mL	0.584	0.170
Calibrator 400 units per mL	2.372	0.686
Calibrator 2000 units per mL	>4	2.211
Reference Preparation	0.599	0.173
Negative Control	0.046	0.014
GAD Ab Positive Control	1.414	0.409
IA-2 Ab Positive Control	0.566	0.164
ZnT8 Ab Positive Control	0.375	0.109

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	236.4	237.5	227±113	236.1	236.4	235±117
IA-2 Ab Positive	96.9	96.8	102±51	94.5	94.8	102±51
ZnT8 Ab Positive	64.4	64.2	66±33	62.6	63.0	64±32

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: 21/22 September 2026

Authorised by : DR G Flood
Signature:
Position: HEAD OF QC
Date: 20TH OCT 2026