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

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Approved by: F Ryrie

Kit lot number: KZGIE72 Kit expiry date: 03rd September 2024

Reagent Lot Numbers:

3 Screen Coated Wells:	ZGIE41	Expiry date:	11 Dec 2024
3 Screen-Biotin:	ZGIB27	Expiry date:	03 Sep 2024
Recon. Buffer for 3 Screen-Biotin:	3BB24	Expiry date:	20 Dec 2024
Streptavidin Peroxidase:	GEP567	Expiry date:	25 Dec 2024
Diluent for SA-POD:	PB173	Expiry date:	09 Nov 2024
Peroxidase Substrate:	PTS181P	Expiry date:	21 Apr 2026
Stop Solution:	HESP122	Expiry date:	14 Dec 2024
Concentrated Wash Solution:	CW343	Expiry date:	05 Jul 2025
Reference Preparation:	ZGIR42	Expiry date:	17 Jan 2025
Calibrators:	ZGIC42	Expiry date:	17 Jan 2025
Negative Control:	ZGIN42	Expiry date:	17 Jan 2025
GAD Ab Positive Control:	3SGP42	Expiry date:	17 Jan 2025
IA-2 Ab Positive Control:	3SIP42	Expiry date:	17 Jan 2025
ZnT8 Ab Positive Control:	3SZP42	Expiry date:	17 Jan 2025

Curve and Controls: Incubation temp: 22 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.087	0.027
Calibrator 15 units per mL	0.160	0.051
Calibrator 100 units per mL	0.591	0.187
Calibrator 400 units per mL	2.344	0.750
Calibrator 2000 units per mL	>4	2.309
Reference Preparation	0.603	0.191
Negative Control	0.044	0.014
GAD Ab Positive Control	1.174	0.371
IA-2 Ab Positive Control	0.575	0.182
ZnT8 Ab Positive Control	0.332	0.106

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	202.2	194.2	200±80	194.7	194.2	200±80
IA-2 Ab Positive	97.0	97.2	100±40	95.4	95.3	100±40
ZnT8 Ab Positive	52.8	56.4	53±21	55.1	55.5	56±22

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: 25th July 2023

Authorised by : DR G FLOOD
Signature:
Position: HEAD OF QC
Date: 29TH AUG 2023