

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

Document: **wi/qcrs/0.43**
 Revision: **3**
 Date: **07/09/18**
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Prepared by: G Flood
 Approved by: F Ryrie

Kit lot number: KZGIE72C

Kit expiry date: 26th November 2024

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE41

Expiry date: 11 Dec 2024

3 Screen-Biotin: ZGIB27c

Expiry date: 26 Nov 2024

Recon. Buffer for 3 Screen-Biotin: 3BB25

Expiry date: 13 Mar 2025

Streptavidin Peroxidase: GEP567

Expiry date: 25 Dec 2024

Diluent for SA-POD: PB175

Expiry date: 30 May 2025

Peroxidase Substrate: PTS183P

Expiry date: 24 Oct 2026

Stop Solution: HESP125

Expiry date: 31 May 2025

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: 21 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.071	0.022
Calibrator 15 units per mL	0.134	0.042
Calibrator 100 units per mL	0.510	0.162
Calibrator 400 units per mL	2.125	0.676
Calibrator 2000 units per mL	>4	2.209
Reference Preparation	0.530	0.167
Negative Control	0.032	0.009
GAD Ab Positive Control	1.011	0.320
IA-2 Ab Positive Control	0.489	0.155
ZnT8 Ab Positive Control	0.283	0.090

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	199.4	192.2	200±80	190.8	191.6	200±80
IA-2 Ab Positive	95.6	96.0	100±40	92.3	92.8	100±40
ZnT8 Ab Positive	52.4	55.5	53±21	53.4	53.9	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: 27th October 2023

Authorised by: DR G Flood
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 24th NOV 2023