

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

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

Kit lot number: KZGIE72D Kit expiry date: 11th December 2024

Reagent Lot Numbers:

3 Screen Coated Wells: <u>ZGIE41</u>	Expiry date: <u>11 Dec 2024</u>
3 Screen-Biotin: <u>ZGIB27d</u>	Expiry date: <u>17 Dec 2024</u>
Recon. Buffer for 3 Screen-Biotin: <u>3BB25</u>	Expiry date: <u>13 Mar 2025</u>
Streptavidin Peroxidase: <u>GEP567</u>	Expiry date: <u>25 Dec 2024</u>
Diluent for SA-POD: <u>PB175</u>	Expiry date: <u>30 May 2025</u>
Peroxidase Substrate: <u>PTS183P</u>	Expiry date: <u>24 Oct 2026</u>
Stop Solution: <u>HESP125</u>	Expiry date: <u>31 May 2025</u>
Concentrated Wash Solution: <u>CW343</u>	Expiry date: <u>05 Jul 2025</u>
Reference Preparation: <u>ZGIR42</u>	Expiry date: <u>17 Jan 2025</u>
Calibrators: <u>ZGIC42</u>	Expiry date: <u>17 Jan 2025</u>
Negative Control: <u>ZGIN42</u>	Expiry date: <u>17 Jan 2025</u>
GAD Ab Positive Control: <u>3SGP42</u>	Expiry date: <u>17 Jan 2025</u>
IA-2 Ab Positive Control: <u>3SIP42</u>	Expiry date: <u>17 Jan 2025</u>
ZnT8 Ab Positive Control: <u>3SZP42</u>	Expiry date: <u>17 Jan 2025</u>

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: 14th DEC 2023