

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: KZGIE75B Kit expiry date: 14th April 2025

Reagent Lot Numbers:

3 Screen Coated Wells: <u>ZGIE42</u>	Expiry date: <u>26 May 2025</u>
3 Screen-Biotin: <u>ZGIB29a</u>	Expiry date: <u>14 Apr 2025</u>
Recon. Buffer for 3 Screen-Biotin: <u>3BB27</u>	Expiry date: <u>17 Jul 2025</u>
Streptavidin Peroxidase: <u>GEP603</u>	Expiry date: <u>17 Jun 2025</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>CW360</u>	Expiry date: <u>22 Dec 2025</u>
Reference Preparation: <u>ZGIR43</u>	Expiry date: <u>03 Jul 2025</u>
Calibrators: <u>ZGIC43</u>	Expiry date: <u>03 Jul 2025</u>
Negative Control: <u>ZGIN43</u>	Expiry date: <u>03 Jul 2025</u>
GAD Ab Positive Control: <u>3SGP43</u>	Expiry date: <u>03 Jul 2025</u>
IA-2 Ab Positive Control: <u>3SIP43</u>	Expiry date: <u>03 Jul 2025</u>
ZnT8 Ab Positive Control: <u>3SZP43</u>	Expiry date: <u>03 Jul 2025</u>

Curve and Controls: Incubation temp: 20 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.071	0.020
Calibrator 15 units per mL	0.132	0.038
Calibrator 100 units per mL	0.512	0.149
Calibrator 400 units per mL	2.145	0.621
Calibrator 2000 units per mL	>4	2.104
Reference Preparation	0.527	0.153
Negative Control	0.033	0.008
GAD Ab Positive Control	1.098	0.318
IA-2 Ab Positive Control	0.531	0.154
ZnT8 Ab Positive Control	0.272	0.078

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	209.1	209.9	210±80	208.3	207.8	210±80
IA-2 Ab Positive	103.7	103.3	120±50	100.8	100.7	120±50
ZnT8 Ab Positive	52.6	50.8	55±22	51.6	51.0	58±23

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: 08th March 2024

Authorised by: *DR G Flood*
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 22nd MAR 2024