

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

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 Revision: **3**
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Prepared by: **G Flood**
 Approved by: **F Rylie**

Kit lot number: KZGIE53A Kit expiry date: 03rd July 2021

Reagent Lot Numbers:

3 Screen Coated Wells: <u>ZGIE32</u>	Expiry date: <u>01 Dec 2021</u>
3 Screen-Biotin: <u>ZGIB19g</u>	Expiry date: <u>03 Jan 2022</u>
Recon. Buffer for 3 Screen-Biotin: <u>3BB15</u>	Expiry date: <u>27 Jan 2022</u>
Streptavidin Peroxidase: <u>GEP356</u>	Expiry date: <u>17 Aug 2021</u>
Diluent for SA-POD: <u>PB158</u>	Expiry date: <u>05 May 2022</u>
Peroxidase Substrate: <u>PTS171C</u>	Expiry date: <u>27 Feb 2022</u>
Stop Solution: <u>HESP107</u>	Expiry date: <u>15 Sep 2022</u>
Concentrated Wash Solution: <u>CW247</u>	Expiry date: <u>24 Sep 2022</u>
Reference Preparation: <u>ZGIR33B</u>	Expiry date: <u>03 Nov 2021</u>
Calibrators: <u>ZGIC33B</u>	Expiry date: <u>03 Nov 2021</u>
Negative Control: <u>ZGIN33B</u>	Expiry date: <u>03 Nov 2021</u>
GAD Ab Positive Control: <u>3SGP33B</u>	Expiry date: <u>03 Nov 2021</u>
IA-2 Ab Positive Control: <u>3SIP33B</u>	Expiry date: <u>03 Nov 2021</u>
ZnT8 Ab Positive Control: <u>3SZP33B</u>	Expiry date: <u>03 Nov 2021</u>

Curve and Controls: Incubation temp: 20 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.073	0.022
Calibrator 15 units per mL	0.132	0.041
Calibrator 100 units per mL	0.514	0.162
Calibrator 400 units per mL	1.999	0.629
Calibrator 2000 units per mL	>4	2.080
Reference Preparation	0.534	0.169
Negative Control	0.045	0.014
GAD Ab Positive Control	1.129	0.355
IA-2 Ab Positive Control	0.599	0.188
ZnT8 Ab Positive Control	0.374	0.119

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	231.5	225.1	230±80	211.4	210.1	220±70
IA-2 Ab Positive	119.5	117.7	115 110±40	112.2	111.2	110±40
ZnT8 Ab Positive	69.0	72.1	65±22	70.0	70.4	68±24

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:	<u>Fiona Rylie</u>	Authorised by:	<u>DR G Flood</u>
Signature:	<u>Fiona Rylie</u>	Signature:	<u>G Flood</u>
Position:	<u>Scientific Assistant</u>	Position:	<u>HEAD OF QC</u>
Date:	<u>01st December 2020</u>	Date:	<u>15th DEC 2020</u>