

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: KZGIE61A Kit expiry date: 28th May 2022

Reagent Lot Numbers:

3 Screen Coated Wells: <u> ZGIE36 </u>	Expiry date: <u> 15 Feb 2023 </u>
3 Screen-Biotin: <u> ZGIB22f </u>	Expiry date: <u> 28 Nov 2022 </u>
Recon. Buffer for 3 Screen-Biotin: <u> 3BB17 </u>	Expiry date: <u> 10 Nov 2022 </u>
Streptavidin Peroxidase: <u> GEP425 </u>	Expiry date: <u> 09 Nov 2022 </u>
Diluent for SA-POD: <u> PB167 </u>	Expiry date: <u> 28 Jun 2023 </u>
Peroxidase Substrate: <u> PTS175Q </u>	Expiry date: <u> 13 Apr 2023 </u>
Stop Solution: <u> HESP112 </u>	Expiry date: <u> 22 Jun 2023 </u>
Concentrated Wash Solution: <u> CW294 </u>	Expiry date: <u> 09 Feb 2024 </u>
Reference Preparation: <u> ZGIR37A </u>	Expiry date: <u> 28 Feb 2023 </u>
Calibrators: <u> ZGIC37A </u>	Expiry date: <u> 28 Feb 2023 </u>
Negative Control: <u> ZGIN37A </u>	Expiry date: <u> 28 Feb 2023 </u>
GAD Ab Positive Control: <u> 3SGP37A </u>	Expiry date: <u> 28 Feb 2023 </u>
IA-2 Ab Positive Control: <u> 3SIP37A </u>	Expiry date: <u> 28 Feb 2023 </u>
ZnT8 Ab Positive Control: <u> 3SZP37A </u>	Expiry date: <u> 28 Feb 2023 </u>

Curve and Controls: Incubation temp: 21 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.076	0.023
Calibrator 15 units per mL	0.134	0.042
Calibrator 100 units per mL	0.467	0.147
Calibrator 400 units per mL	2.222	0.708
Calibrator 2000 units per mL	>4	2.202
Reference Preparation	0.466	0.148
Negative Control	0.054	0.017
GAD Ab Positive Control	1.222	0.386
IA-2 Ab Positive Control	0.473	0.151
ZnT8 Ab Positive Control	0.238	0.076

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	229.5	222.1	220±80	262.2	260.8	260±90
IA-2 Ab Positive	101.1	101.9	105±40	101.5	102.0	110±40
ZnT8 Ab Positive	54.7	59.4	54±19	51.1	51.4	51±18

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: 05th November 2021

Authorised by: DR G Flood
 Signature: G Flood
 Position: HEAD OF QC
 Date: 24th Nov 2021