

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: **KZGIE77** Kit expiry date: **09th June 2025**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE44	Expiry date: 11 Sep 2025
3 Screen-Biotin: ZGIB28c	Expiry date: 09 Jun 2025
Recon. Buffer for 3 Screen-Biotin: 3BB26	Expiry date: 17 Jun 2025
Streptavidin Peroxidase: GEP603	Expiry date: 17 Jun 2025
Diluent for SA-POD: PB179	Expiry date: 13 Nov 2025
Peroxidase Substrate: PTS185R	Expiry date: 27 Apr 2027
Stop Solution: HESP129	Expiry date: 10 Dec 2025
Concentrated Wash Solution: CW360	Expiry date: 22 Dec 2025
Reference Preparation: ZGIR44	Expiry date: 06 Sep 2025
Calibrators: ZGIC44	Expiry date: 06 Sep 2025
Negative Control: ZGIN44	Expiry date: 06 Sep 2025
GAD Ab Positive Control: 3SGP44	Expiry date: 06 Sep 2025
IA-2 Ab Positive Control: 3SIP44	Expiry date: 06 Sep 2025
ZnT8 Ab Positive Control: 3SZP44	Expiry date: 06 Sep 2025

Curve and Controls: Incubation temp: **21 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.062	0.018
Calibrator 15 units per mL	0.109	0.032
Calibrator 100 units per mL	0.451	0.132
Calibrator 400 units per mL	1.823	0.529
Calibrator 2000 units per mL	>4	1.984
Reference Preparation	0.454	0.133
Negative Control	0.028	0.008
GAD Ab Positive Control	1.012	0.294
IA-2 Ab Positive Control	0.456	0.132
ZnT8 Ab Positive Control	0.261	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	233.5	234.2	220±90	222.9	221.1	220±90
IA-2 Ab Positive	101.1	100.4	105±40	100.4	99.2	105±40
ZnT8 Ab Positive	52.8	51.4	53±21	57.5	57.1	54±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: **03rd May 2024**

Authorised by: **DR G Flood**
 Signature: **G Flood**
 Position: **HEAD OF QC**
 Date: **10th JUN 2024**