

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: **KZGIE65** Kit expiry date: **04th September 2023**

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE38	Expiry date: 22 Nov 2023
3 Screen-Biotin: ZGIB23g	Expiry date: 04 Sep 2023
Recon. Buffer for 3 Screen-Biotin: 3BB21	Expiry date: 07 Feb 2024
Streptavidin Peroxidase: GEP502	Expiry date: 11 Jan 2024
Diluent for SA-POD: PB169	Expiry date: 19 Oct 2023
Peroxidase Substrate: PTS179L	Expiry date: 30 Sep 2024
Stop Solution: HESP115	Expiry date: 18 Oct 2023
Concentrated Wash Solution: CW277	Expiry date: 08 Oct 2023
Reference Preparation: ZGIR39	Expiry date: 24 Jan 2024
Calibrators: ZGIC39	Expiry date: 24 Jan 2024
Negative Control: ZGIN39	Expiry date: 24 Jan 2024
GAD Ab Positive Control: 3SGP39	Expiry date: 24 Jan 2024
IA-2 Ab Positive Control: 3SIP39	Expiry date: 24 Jan 2024
ZnT8 Ab Positive Control: 3SZP39	Expiry date: 24 Jan 2024

Curve and Controls: Incubation temp: **22 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.103	0.032
Calibrator 15 units per mL	0.168	0.053
Calibrator 100 units per mL	0.610	0.192
Calibrator 400 units per mL	2.495	0.799
Calibrator 2000 units per mL	>4	2.358
Reference Preparation	0.629	0.199
Negative Control	0.056	0.017
GAD Ab Positive Control	1.371	0.434
IA-2 Ab Positive Control	0.618	0.195
ZnT8 Ab Positive Control	0.312	0.099

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	219.7	211.2	220±90	218.0	218.1	220±90
IA-2 Ab Positive	101.3	101.2	95±35	98.3	98.0	95±35
ZnT8 Ab Positive	50.2	54.1	51±20	49.6	49.7	53±21

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: **16th August 2022**

Authorised by: **Jill Clark**
Signature: **Jill Clark**
Position: **pp-HEAD OF QUALITY CONTROL**
Date: **5th SEPTEMBER 2022**