

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: KZGIE75

Kit expiry date: 18th February 2025

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE42

Expiry date: 26 May 2025

3 Screen-Biotin: ZGIB28a

Expiry date: 18 Feb 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: PB175

Expiry date: 30 May 2025

Peroxidase Substrate: PTS183P

Expiry date: 24 Oct 2026

Stop Solution: HESP125

Expiry date: 31 May 2025

Concentrated Wash Solution: CW360

Expiry date: 22 Dec 2025

Reference Preparation: ZGIR43

Expiry date: 03 Jul 2025

Calibrators: ZGIC43

Expiry date: 03 Jul 2025

Negative Control: ZGIN43

Expiry date: 03 Jul 2025

GAD Ab Positive Control: 3SGP43

Expiry date: 03 Jul 2025

IA-2 Ab Positive Control: 3SIP43

Expiry date: 03 Jul 2025

ZnT8 Ab Positive Control: 3SZP43

Expiry date: 03 Jul 2025

Curve and Controls: Incubation temp: 20 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.071	0.018
Calibrator 15 units per mL	0.127	0.035
Calibrator 100 units per mL	0.487	0.139
Calibrator 400 units per mL	1.958	0.564
Calibrator 2000 units per mL	>4	2.000
Reference Preparation	0.500	0.143
Negative Control	0.033	0.007
GAD Ab Positive Control	0.996	0.286
IA-2 Ab Positive Control	0.577	0.166
ZnT8 Ab Positive Control	0.287	0.082

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	210.8	210±80	199.2	200.0	210±80
IA-2 Ab Positive	120.3	122.0	120±50	115.4	116.1	120±50
ZnT8 Ab Positive	55.5	55.1	55±22	57.4	57.3	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

Authorised by: DR G Flood

Signature: *Fiona Ryrie*

Signature: *G Flood*

Position: Scientist

Position: HEAD OF QC

Date: 09th January 2024

Date: 14th FEB 2024