

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: **KZGIE66**

Kit expiry date: **30th October 2023**

Reagent Lot Numbers:

3 Screen Coated Wells: **ZGIE38**

Expiry date: **22 Nov 2023**

3 Screen-Biotin: **ZGIB25**

Expiry date: **30 Oct 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: **PB171**

Expiry date: **16 May 2024**

Peroxidase Substrate: **PTS179L**

Expiry date: **30 Sep 2024**

Stop Solution: **HESP119**

Expiry date: **05 Jul 2024**

Concentrated Wash Solution: **CW302**

Expiry date: **27 Apr 2024**

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: **3SGP39A**

Expiry date: **24 Jan 2024**

IA-2 Ab Positive Control: **3SIP39A**

Expiry date: **24 Jan 2024**

ZnT8 Ab Positive Control: **3SZP39A**

Expiry date: **24 Jan 2024**

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

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.088	0.027
Calibrator 15 units per mL	0.150	0.047
Calibrator 100 units per mL	0.566	0.178
Calibrator 400 units per mL	2.359	0.759
Calibrator 2000 units per mL	>4	2.294
Reference Preparation	0.601	0.191
Negative Control	0.051	0.016
GAD Ab Positive Control	1.279	0.405
IA-2 Ab Positive Control	0.648	0.205
ZnT8 Ab Positive Control	0.297	0.095

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	210.5	220±80	212.8	212.0	220±90
IA-2 Ab Positive	114.2	112.9	110±45	107.8	107.3	110±45
ZnT8 Ab Positive	51.6	56.7	51±20	49.4	49.7	51±20

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: **18th October 2022**

Authorised by: **DR G FLOOD**

Signature: **G Flood**

Position: **HEAD OF QC**

Date: **1st Nov 2022**