

Title: **Quality Control Record Sheet**
3 Screen ICA ELISA Kit QC Data

Document: **wi/qcrs/0.43**

Revision: **3**

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Prepared by: **G Flood**

Approved by: **F Ryrie**

Kit lot number: KZGIE58 Kit expiry date: 13th December 2021

Reagent Lot Numbers:

3 Screen Coated Wells: ZGIE35 Expiry date: 18 Oct 2022

3 Screen-Biotin: ZGIB22 Expiry date: 13 Jun 2022

Recon. Buffer for 3 Screen-Biotin: 3BB17 Expiry date: 10 Nov 2022

Streptavidin Peroxidase: GEP425 Expiry date: 09 Nov 2022

Diluent for SA-POD: PB163 Expiry date: 27 Jan 2023

Peroxidase Substrate: PTS173Q Expiry date: 19 Nov 2022

Stop Solution: HESP109 Expiry date: 10 Jan 2023

Concentrated Wash Solution: CW268 Expiry date: 14 Jul 2023

Reference Preparation: ZGIR36 Expiry date: 03 Nov 2022

Calibrators: ZGIC36 Expiry date: 03 Nov 2022

Negative Control: ZGIN36 Expiry date: 03 Nov 2022

GAD Ab Positive Control: 3SGP36 Expiry date: 03 Nov 2022

IA-2 Ab Positive Control: 3SIP36 Expiry date: 03 Nov 2022

ZnT8 Ab Positive Control: 3SZP36 Expiry date: 03 Nov 2022

Curve and Controls: Incubation temp: 20 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.075	0.023
Calibrator 15 units per mL	0.137	0.043
Calibrator 100 units per mL	0.580	0.183
Calibrator 400 units per mL	2.266	0.722
Calibrator 2000 units per mL	>4	2.273
Reference Preparation	0.562	0.180
Negative Control	0.036	0.012
GAD Ab Positive Control	1.210	0.381
IA-2 Ab Positive Control	0.485	0.153
ZnT8 Ab Positive Control	0.257	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	216.0	207.1	220±80	215.3	211.7	220±80
IA-2 Ab Positive	82.3	83.7	90±35	86.3	85.0	95±35
ZnT8 Ab Positive	40.1	43.9	44±17	45.7	45.6	47±16

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: 04th June 2021

Authorised by:

Signature:

Position:

Date:

DR G FLOOD
G Flood
HEAD OF QC
9th JUN 2021