

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

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 Revision: **3**
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Prepared by: **G Flood**
 Approved by: **F Ryrie**

Kit lot number: KZGIE97 Kit expiry date: 12th April 2027

Reagent Lot Numbers:

3 Screen Coated Wells: <u>ZGIE57</u>	Expiry date: <u>14 Jun 2027</u>
3 Screen-Biotin: <u>ZGIB33p</u>	Expiry date: <u>12 Apr 2027</u>
Recon. Buffer for 3 Screen-Biotin: <u>3BB34</u>	Expiry date: <u>16 Apr 2027</u>
Streptavidin Peroxidase: <u>GEP747</u>	Expiry date: <u>13 Apr 2027</u>
Diluent for SA-POD: <u>PB190</u>	Expiry date: <u>10 Dec 2027</u>
Peroxidase Substrate: <u>PTS191Q</u>	Expiry date: <u>11 Nov 2028</u>
Stop Solution: <u>HESP147</u>	Expiry date: <u>11 Jan 2028</u>
Concentrated Wash Solution: <u>CW433</u>	Expiry date: <u>25 Sep 2027</u>
Reference Preparation: <u>ZGIR50</u>	Expiry date: <u>12 May 2027</u>
Calibrators: <u>ZGIC50</u>	Expiry date: <u>12 May 2027</u>
Negative Control: <u>ZGIN50</u>	Expiry date: <u>12 May 2027</u>
GAD Ab Positive Control: <u>3SGP50A</u>	Expiry date: <u>12 May 2027</u>
IA-2 Ab Positive Control: <u>3SIP50A</u>	Expiry date: <u>12 May 2027</u>
ZnT8 Ab Positive Control: <u>3SZP50A</u>	Expiry date: <u>12 May 2027</u>

Curve and Controls: Incubation temp: 20 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.104	0.031
Calibrator 15 units per mL	0.172	0.050
Calibrator 100 units per mL	0.641	0.187
Calibrator 400 units per mL	2.526	0.734
Calibrator 2000 units per mL	>4	2.305
Reference Preparation	0.650	0.189
Negative Control	0.061	0.018
GAD Ab Positive Control	1.461	0.423
IA-2 Ab Positive Control	0.568	0.165
ZnT8 Ab Positive Control	0.438	0.128

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	226.4	226.4	230±110	224.8	223.8	225±110
IA-2 Ab Positive	88.7	88.1	90±40	87.4	87.3	85±40
ZnT8 Ab Positive	68.2	67.7	69±34	67.4	67.7	68±34

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: F Ryrie
 Position: Scientist
 Date: 05/06 March 2026

Authorised by: DR G Flood
 Signature: [Signature]
 Position: NEAO OF QC
 Date: 13th APR 2026