

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: **KZGIE90D**

Kit expiry date: **06th October 2026**

Reagent Lot Numbers:

3 Screen Coated Wells: **ZGIE52**

Expiry date: **27 Oct 2026**

3 Screen-Biotin: **ZGIB33d**

Expiry date: **26 Oct 2026**

Recon. Buffer for 3 Screen-Biotin: **3BB33**

Expiry date: **07 Oct 2026**

Streptavidin Peroxidase: **GEP706**

Expiry date: **23 Oct 2026**

Diluent for SA-POD: **PB185**

Expiry date: **17 Feb 2027**

Peroxidase Substrate: **PTS191J**

Expiry date: **11 Nov 2028**

Stop Solution: **HESP140**

Expiry date: **07 Apr 2027**

Concentrated Wash Solution: **CW433**

Expiry date: **25 Sep 2027**

Reference Preparation: **ZGIR48**

Expiry date: **06 Oct 2026**

Calibrators: **ZGIC48**

Expiry date: **06 Oct 2026**

Negative Control: **ZGIN48**

Expiry date: **06 Oct 2026**

GAD Ab Positive Control: **3SGP48**

Expiry date: **06 Oct 2026**

IA-2 Ab Positive Control: **3SIP48**

Expiry date: **06 Oct 2026**

ZnT8 Ab Positive Control: **3SZP48**

Expiry date: **06 Oct 2026**

Curve and Controls:

Incubation temp: **21 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.103	0.030
Calibrator 15 units per mL	0.182	0.053
Calibrator 100 units per mL	0.673	0.195
Calibrator 400 units per mL	2.668	0.773
Calibrator 2000 units per mL	>4	2.333
Reference Preparation	0.681	0.198
Negative Control	0.056	0.017
GAD Ab Positive Control	1.371	0.396
IA-2 Ab Positive Control	0.614	0.178
ZnT8 Ab Positive Control	0.375	0.109

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	198.5	198.7	195±75	201.3	200.0	195±75
IA-2 Ab Positive	91.8	91.5	85±35	90.2	89.9	85±35
ZnT8 Ab Positive	56.5	56.3	52±20	55.1	55.1	52±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: **F Ryrie**

Position: **Scientist**

Date: **15/16 May 2025**

Authorised by :

Signature:

Position:

Date:

DR G Flood

[Signature]

HEAD OF QC

27th OCT 2025