

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

Document: **wilqcrs/0.43**

Revision: **3**

Date: **07/09/18**

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Prepared by: **G Flood**

Approved by: **F Ryrie**

Kit lot number: **KZGIE92**

Kit expiry date: **23rd November 2026**

Reagent Lot Numbers:

3 Screen Coated Wells: **ZGIE53**

Expiry date: **13 Jan 2027**

3 Screen-Biotin: **ZGIB33e**

Expiry date: **23 Nov 2026**

Recon. Buffer for 3 Screen-Biotin: **3BB34**

Expiry date: **16 Apr 2027**

Streptavidin Peroxidase: **GEP747**

Expiry date: **13 Apr 2027**

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: **ZGIR49**

Expiry date: **13 Apr 2027**

Calibrators: **ZGIC49**

Expiry date: **13 Apr 2027**

Negative Control: **ZGIN49**

Expiry date: **13 Apr 2027**

GAD Ab Positive Control: **3SGP49**

Expiry date: **13 Apr 2027**

IA-2 Ab Positive Control: **3SIP49**

Expiry date: **13 Apr 2027**

ZnT8 Ab Positive Control: **3SZP49**

Expiry date: **13 Apr 2027**

Curve and Controls:

Incubation temp: **21 °C**

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.095	0.029
Calibrator 15 units per mL	0.168	0.050
Calibrator 100 units per mL	0.657	0.192
Calibrator 400 units per mL	2.513	0.732
Calibrator 2000 units per mL	>4	2.241
Reference Preparation	0.671	0.195
Negative Control	0.046	0.015
GAD Ab Positive Control	1.342	0.389
IA-2 Ab Positive Control	0.641	0.186
ZnT8 Ab Positive Control	0.518	0.152

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	205.6	205.5	200±100	200.0	199.5	200±100
IA-2 Ab Positive	97.6	97.1	105±50	95.5	95.4	105±50
ZnT8 Ab Positive	78.7	78.9	67±33	77.2	77.9	66±32

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: **28/29 October 2025**

Authorised by: **DR G Flood**

Signature: **G Flood**

Position: **HEAD OF QC**

Date: **19th Nov 2025**