

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

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Revision: **3**  
Date: **07/09/18**  
Page **1 of 1**

Prepared by: **G Flood**

Approved by: **F Ryrie**

Kit lot number:                     KZGIE72                    

Kit expiry date:                     03<sup>rd</sup> September 2024                    

**Reagent Lot Numbers:**

3 Screen Coated Wells:                     ZGIE41                    

Expiry date:                     11 Dec 2024                    

3 Screen-Biotin:                     ZGIB27                    

Expiry date:                     03 Sep 2024                    

Recon. Buffer for 3 Screen-Biotin:                     3BB24                    

Expiry date:                     20 Dec 2024                    

Streptavidin Peroxidase:                     GEP567                    

Expiry date:                     25 Dec 2024                    

Diluent for SA-POD:                     PB173                    

Expiry date:                     09 Nov 2024                    

Peroxidase Substrate:                     PTS181P                    

Expiry date:                     21 Apr 2026                    

Stop Solution:                     HESP122                    

Expiry date:                     14 Dec 2024                    

Concentrated Wash Solution:                     CW343                    

Expiry date:                     05 Jul 2025                    

Reference Preparation:                     ZGIR42                    

Expiry date:                     17 Jan 2025                    

Calibrators:                     ZGIC42                    

Expiry date:                     17 Jan 2025                    

Negative Control:                     ZGIN42                    

Expiry date:                     17 Jan 2025                    

GAD Ab Positive Control:                     3SGP42                    

Expiry date:                     17 Jan 2025                    

IA-2 Ab Positive Control:                     3SIP42                    

Expiry date:                     17 Jan 2025                    

ZnT8 Ab Positive Control:                     3SZP42                    

Expiry date:                     17 Jan 2025                    

**Curve and Controls:** Incubation temp:                     22                     °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.087	0.027
Calibrator 15 units per mL	0.160	0.051
Calibrator 100 units per mL	0.591	0.187
Calibrator 400 units per mL	2.344	0.750
Calibrator 2000 units per mL	>4	2.309
Reference Preparation	0.603	0.191
Negative Control	0.044	0.014
GAD Ab Positive Control	1.174	0.371
IA-2 Ab Positive Control	0.575	0.182
ZnT8 Ab Positive Control	0.332	0.106

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	202.2	194.2	200±80	194.7	194.2	200±80
IA-2 Ab Positive	97.0	97.2	100±40	95.4	95.3	100±40
ZnT8 Ab Positive	52.8	56.4	53±21	55.1	55.5	56±22

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:                     25<sup>th</sup> July 2023                    

Authorised by:                     DR G FLOOD                      
Signature:                     G Flood                      
Position:                     HEAD OF QC                      
Date:                     29<sup>th</sup> AUG 2023