

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

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Revision: **3**  
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Approved by: **F Ryrie**

Kit lot number: **KZGIE64A** Kit expiry date: **10<sup>th</sup> July 2023**

**Reagent Lot Numbers:**

|                                                 |                                 |
|-------------------------------------------------|---------------------------------|
| 3 Screen Coated Wells: <b>ZGIE38</b>            | Expiry date: <b>22 Nov 2023</b> |
| 3 Screen-Biotin: <b>ZGIB23e</b>                 | Expiry date: <b>10 Jul 2023</b> |
| Recon. Buffer for 3 Screen-Biotin: <b>3BB19</b> | Expiry date: <b>21 Aug 2023</b> |
| Streptavidin Peroxidase: <b>GEP467</b>          | Expiry date: <b>25 Jul 2023</b> |
| Diluent for SA-POD: <b>PB169</b>                | Expiry date: <b>19 Oct 2023</b> |
| Peroxidase Substrate: <b>PTS177L</b>            | Expiry date: <b>03 May 2024</b> |
| Stop Solution: <b>HESP115</b>                   | Expiry date: <b>18 Oct 2023</b> |
| Concentrated Wash Solution: <b>CW302</b>        | Expiry date: <b>27 Apr 2024</b> |
| Reference Preparation: <b>ZGIR38</b>            | Expiry date: <b>09 Aug 2023</b> |
| Calibrators: <b>ZGIC38</b>                      | Expiry date: <b>09 Aug 2023</b> |
| Negative Control: <b>ZGIN38</b>                 | Expiry date: <b>09 Aug 2023</b> |
| GAD Ab Positive Control: <b>3SGP38</b>          | Expiry date: <b>09 Aug 2023</b> |
| IA-2 Ab Positive Control: <b>3SIP38</b>         | Expiry date: <b>09 Aug 2023</b> |
| ZnT8 Ab Positive Control: <b>3SZP38</b>         | Expiry date: <b>09 Aug 2023</b> |

**Curve and Controls:** Incubation temp: **21** °C

|                              | Absorbance at 450 nm | Absorbance at 405 nm |
|------------------------------|----------------------|----------------------|
| Calibrator 5 units per mL    | 0.071                | 0.021                |
| Calibrator 15 units per mL   | 0.131                | 0.041                |
| Calibrator 100 units per mL  | 0.573                | 0.181                |
| Calibrator 400 units per mL  | 2.334                | 0.743                |
| Calibrator 2000 units per mL | >4                   | 2.299                |
| Reference Preparation        | 0.578                | 0.183                |
| Negative Control             | 0.039                | 0.011                |
| GAD Ab Positive Control      | 1.212                | 0.383                |
| IA-2 Ab Positive Control     | 0.535                | 0.170                |
| ZnT8 Ab Positive Control     | 0.298                | 0.094                |

| 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  | 210.7                                  | 203.5                                  | 220±90               | 209.7                 | 209.3                 | 220±90              |
| IA-2 Ab Positive | 93.2                                   | 94.3                                   | 90±35                | 92.6                  | 92.9                  | 90±35               |
| ZnT8 Ab Positive | 51.1                                   | 54.4                                   | 46±18                | 51.6                  | 51.4                  | 52±21               |

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: **27<sup>th</sup> May 2022**

Authorised by: **DR G Flood**  
Signature: **G Flood**  
Position: **HEAD OF QC**  
Date: **11<sup>th</sup> JULY 2022**