

Title: **Quality Control Record Sheet  
21-OH Ab ELISA Kit QC Data**

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Prepared by: G. Flood  
Approved by: W. Dowler

**Kit lot number:**                     K21E26A                     **Expiry date:**                     31 October 2021                    

**Reagent Lot Numbers:**

|   |   |
|---|---|
| Coated Wells: <u>                    21E26                    </u>                    | Expiry date: <u>                    27 March 2022                    </u>     |
| 21-OH-Biotin: <u>                    21EB18b                    </u>                  | Expiry date: <u>                    31 October 2021                    </u>   |
| Recon. Buffer for 21-OH-Biotin: <u>                    21ER23                    </u> | Expiry date: <u>                    20 January 2022                    </u>   |
| SA-POD: <u>                    GEP379                    </u>                         | Expiry date: <u>                    06 January 2022                    </u>   |
| Diluent for SA-POD: <u>                    2RPD75                    </u>             | Expiry date: <u>                    17 November 2022                    </u>  |
| Reaction Enhancer: <u>                    IES106                    </u>              | Expiry date: <u>                    02 February 2022                    </u>  |
| Peroxidase Substrate: <u>                    PTS124                    </u>           | Expiry date: <u>                    03 September 2023                    </u> |
| Stop Solution: <u>                    HESP107                    </u>                 | Expiry date: <u>                    15 September 2022                    </u> |
| Concentrated Wash: <u>                    CW259                    </u>               | Expiry date: <u>                    07 March 2023                    </u>     |
| Calibrators: <u>                    21C26a                    </u>                    | Expiry date: <u>                    31 October 2021                    </u>   |
| Reference Preparation: <u>                    21ERP26a                    </u>        | Expiry date: <u>                    31 October 2021                    </u>   |
| Negative Control: <u>                    21NC26a                    </u>              | Expiry date: <u>                    31 October 2021                    </u>   |
| Positive Controls: <u>                    21PCa/b26a                    </u>          | Expiry date: <u>                    31 October 2021                    </u>   |

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

|                              | Absorbance at 450 nm        | Absorbance at 405 nm |
|------------------------------|-----------------------------|----------------------|
| <b>0.3 units per mL</b>      | 0.208                       | 0.062                |
| <b>1 units per mL</b>        | 0.625                       | 0.184                |
| <b>10 units per mL</b>       | 2.500                       | 0.741                |
| <b>100 units per mL</b>      | 4.604                       | 1.354                |
|                              | (derived from Abs at 405nm) |                      |
| <b>Reference Preparation</b> | 0.649                       | 0.192                |
| <b>Negative Control</b>      | 0.026                       | 0.009                |
| <b>Positive Control I</b>    | 0.792                       | 0.234                |
| <b>Positive Control II</b>   | 2.354                       | 0.698                |

| 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    | <0.3                                   | <0.3                                   | <0.3                 | <45                   | <45                   | <45                 |
| Positive I  | 1.33                                   | 1.33                                   | 0.8 – 1.8            | 122.0                 | 121.9                 | 70 - 170            |
| Positive II | 8.61                                   | 8.60                                   | 5 - 13               | 362.7                 | 363.5                 | 230 - 470           |

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:                     Hannah Sanyaolu                      
Signature:                     Hanyaolu                      
Position:                     Scientist                      
Date:                     07 January 2021                    

Authorised by:                     DR G Flood                      
Signature:                     G Flood                      
Position:                     HEAD OF QC                      
Date:                     19<sup>th</sup> JAN 2021