

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

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Revision: **2**
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Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: K21E24A Expiry date: 04 May 2021

Reagent Lot Numbers:

| | |
|---|---|
| Coated Wells: <u> 21E24 </u> | Expiry date: <u> 04 May 2021 </u> |
| 21-OH-Biotin: <u> 21EB17d </u> | Expiry date: <u> 04 May 2021 </u> |
| Recon. Buffer for 21-OH-Biotin: <u> 21ER22 </u> | Expiry date: <u> 01 June 2021 </u> |
| SA-POD: <u> GEP346 </u> | Expiry date: <u> 19 June 2021 </u> |
| Diluent for SA-POD: <u> 2RPD73 </u> | Expiry date: <u> 31 October 2021 </u> |
| Reaction Enhancer: <u> IES99 </u> | Expiry date: <u> 22 October 2021 </u> |
| Peroxidase Substrate: <u> PTS118 </u> | Expiry date: <u> 21 July 2022 </u> |
| Stop Solution: <u> HESP102 </u> | Expiry date: <u> 31 October 2021 </u> |
| Concentrated Wash: <u> CW234 </u> | Expiry date: <u> 06 May 2022 </u> |
| Calibrators: <u> 21C24a </u> | Expiry date: <u> 04 May 2021 </u> |
| Reference Preparation: <u> 21ERP24a </u> | Expiry date: <u> 04 May 2021 </u> |
| Negative Control: <u> 21NC24a </u> | Expiry date: <u> 04 May 2021 </u> |
| Positive Controls: <u> 21PCa/b24a </u> | Expiry date: <u> 04 May 2021 </u> |

Curve and Controls: Incubation temp: 21°C

| | Absorbance at 450 nm | Absorbance at 405 nm |
|-----------------------|-----------------------------|----------------------|
| 0.3 units per mL | 0.204 | 0.064 |
| 1 units per mL | 0.634 | 0.192 |
| 10 units per mL | 2.425 | 0.723 |
| 100 units per mL | 4.495 | 1.322 |
| | (derived from Abs at 405nm) | |
| Reference Preparation | 0.564 | 0.166 |
| Negative Control | 0.046 | 0.033 |
| Positive Control I | 0.792 | 0.234 |
| Positive Control II | 2.197 | 0.650 |

| 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 | 1.32 | 1.28 | 0.8 – 1.8 | 140.4 | 141.0 | 70 - 170 |
| Positive II | 7.77 | 7.61 | 5 - 12 | 389.5 | 391.6 | 210 – 450 |

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: Morwen Williams
Signature: *Morwen Williams*
Position: Scientist
Date: 18 June 2020

Authorised by: DR G Flood
Signature: *G Flood*
Position: HEAD OF QC
Date: 14TH AUG 2020