

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

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Page **1 of 1**

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

Kit lot number: K21E37A Expiry date: 01 September 2025

**Reagent Lot Numbers:**

Coated Wells: <u>21E37</u>	Expiry date: <u>29 January 2026</u>
21-OH-Biotin: <u>21EB27</u>	Expiry date: <u>01 September 2025</u>
Recon. Buffer for 21-OH-Biotin: <u>21ER29</u>	Expiry date: <u>28 February 2026</u>
SA-POD: <u>GEP657A</u>	Expiry date: <u>12 February 2026</u>
Diluent for SA-POD: <u>2RPD83</u>	Expiry date: <u>10 October 2026</u>
Reaction Enhancer: <u>IES128</u>	Expiry date: <u>08 April 2026</u>
Peroxidase Substrate: <u>PTS138</u>	Expiry date: <u>17 October 2026</u>
Stop Solution: <u>HESP135</u>	Expiry date: <u>23 September 2026</u>
Concentrated Wash: <u>CW414</u>	Expiry date: <u>14 April 2027</u>
Calibrators: <u>21C37a</u>	Expiry date: <u>01 September 2025</u>
Reference Preparation: <u>21ERP37a</u>	Expiry date: <u>01 September 2025</u>
Negative Control: <u>21NC37a</u>	Expiry date: <u>01 September 2025</u>
Positive Controls: <u>21PCa/b37a</u>	Expiry date: <u>01 September 2025</u>

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

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.232	0.072
1 units per mL	0.633	0.189
10 units per mL	1.993	0.590
100 units per mL	4.297 (derived from Abs at 405nm)	1.264
Reference Preparation	0.663	0.197
Negative Control	0.033	0.014
Positive Control I	0.765	0.228
Positive Control II	1.854	0.550

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	1.36	1.36	0.8 – 1.9	115.4	115.7	75 – 165
Positive II	8.45	8.45	6 - 13	279.6	279.2	165 - 385

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  
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Position: Senior Scientist  
Date: 30 October 2024

Authorised by: DR G Flood  
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Position: HEAD OF QC  
Date: 2<sup>ND</sup> DEC 2024