

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: K21E35A Expiry date: 21 January 2025

Reagent Lot Numbers:

Coated Wells: <u>21E35</u>	Expiry date: <u>16 April 2025</u>
21-OH-Biotin: <u>21EB25b</u>	Expiry date: <u>21 January 2025</u>
Recon. Buffer for 21-OH-Biotin: <u>21ER28</u>	Expiry date: <u>01 July 2025</u>
SA-POD: <u>GEP609</u>	Expiry date: <u>15 July 2025</u>
Diluent for SA-POD: <u>2RPD81</u>	Expiry date: <u>03 April 2026</u>
Reaction Enhancer: <u>IES120</u>	Expiry date: <u>13 March 2025</u>
Peroxidase Substrate: <u>PTS134</u>	Expiry date: <u>19 December 2025</u>
Stop Solution: <u>HESP125</u>	Expiry date: <u>31 May 2025</u>
Concentrated Wash: <u>CW359</u>	Expiry date: <u>27 December 2025</u>
Calibrators: <u>21C35a</u>	Expiry date: <u>21 January 2025</u>
Reference Preparation: <u>21ERP35a</u>	Expiry date: <u>21 January 2025</u>
Negative Control: <u>21NC35a</u>	Expiry date: <u>21 January 2025</u>
Positive Controls: <u>21PCa/b35a</u>	Expiry date: <u>21 January 2025</u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.214	0.062
1 units per mL	0.561	0.165
10 units per mL	1.588	0.469
100 units per mL	3.707 (derived from Abs at 405nm)	1.090
Reference Preparation	0.570	0.165
Negative Control	0.038	0.010
Positive Control I	0.667	0.194
Positive Control II	1.569	0.463

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	1.39	1.36	0.8 – 1.9	117.0	117.6	70 - 160
Positive II	9.74	9.68	6 - 13	275.3	280.6	160 - 370

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: 20 March 2024

Authorised by: DR G Flood
Signature: [Signature]
Position: HEAD OF QC
Date: 2nd APR 2024