

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

Document: **wi/qcrs/40**
 Revision: **2**
 Date: **10.10.18**
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Prepared by: G. Flood
 Approved by: W. Dowler

Kit lot number: K21E35B **Expiry date:** 16 March 2025

Reagent Lot Numbers:

Coated Wells: <u> 21E35 </u>	Expiry date: <u> 16 April 2025 </u>
21-OH-Biotin: <u> 21EB25c </u>	Expiry date: <u> 16 March 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> IES128 </u>	Expiry date: <u> 08 April 2026 </u>
Peroxidase Substrate: <u> PTS136 </u>	Expiry date: <u> 12 June 2026 </u>
Stop Solution: <u> HESP128 </u>	Expiry date: <u> 02 November 2025 </u>
Concentrated Wash: <u> CW371 </u>	Expiry date: <u> 23 March 2026 </u>
Calibrators: <u> 21C35b </u>	Expiry date: <u> 16 March 2025 </u>
Reference Preparation: <u> 21ERP35b </u>	Expiry date: <u> 16 March 2025 </u>
Negative Control: <u> 21NC35b </u>	Expiry date: <u> 16 March 2025 </u>
Positive Controls: <u> 21PCa/b35b </u>	Expiry date: <u> 16 March 2025 </u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.252	0.075
1 units per mL	0.715	0.211
10 units per mL	1.886	0.559
100 units per mL	4.211 (derived from Abs at 405nm)	1.239
Reference Preparation	0.715	0.211
Negative Control	0.044	0.013
Positive Control I	0.857	0.253
Positive Control II	1.807	0.535

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	1.42	1.41	0.8 – 1.9	119.9	119.9	70 - 160
Positive II	8.99	8.99	6 - 13	252.7	253.6	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
 Signature: *H Sanyaolu*
 Position: Senior Scientist
 Date: 15 May 2024

Authorised by: DR G Flood
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 22ND MAY 2024