

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: **K21E35B** Expiry date: **16 March 2025**

Reagent Lot Numbers:

Coated Wells: 21E35	Expiry date: 16 April 2025
21-OH-Biotin: 21EB25c	Expiry date: 16 March 2025
Recon. Buffer for 21-OH-Biotin: 21ER28	Expiry date: 01 July 2025
SA-POD: GEP609	Expiry date: 15 July 2025
Diluent for SA-POD: 2RPD81	Expiry date: 03 April 2026
Reaction Enhancer: IES128	Expiry date: 08 April 2026
Peroxidase Substrate: PTS136	Expiry date: 12 June 2026
Stop Solution: HESP128	Expiry date: 02 November 2025
Concentrated Wash: CW371	Expiry date: 23 March 2026
Calibrators: 21C35b	Expiry date: 16 March 2025
Reference Preparation: 21ERP35b	Expiry date: 16 March 2025
Negative Control: 21NC35b	Expiry date: 16 March 2025
Positive Controls: 21PCa/b35b	Expiry date: 16 March 2025

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**
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Position: **Senior Scientist**
Date: **15 May 2024**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **23RD MAY 2024**