

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

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Approved by: W. Dowler

Kit lot number: **K21E37B** Expiry date: **26 October 2025**

Reagent Lot Numbers:

Coated Wells: 21E37	Expiry date: 29 January 2026
21-OH-Biotin: 21EB27a	Expiry date: 26 October 2025
Recon. Buffer for 21-OH-Biotin: 21ER29	Expiry date: 28 February 2026
SA-POD: GEP657A	Expiry date: 12 February 2026
Diluent for SA-POD: 2RPD83	Expiry date: 10 October 2026
Reaction Enhancer: IES128	Expiry date: 08 April 2026
Peroxidase Substrate: PTS138	Expiry date: 17 October 2026
Stop Solution: HESP135	Expiry date: 23 September 2026
Concentrated Wash: CW414	Expiry date: 14 April 2027
Calibrators: 21C37b	Expiry date: 26 October 2025
Reference Preparation: 21ERP37b	Expiry date: 26 October 2025
Negative Control: 21NC37b	Expiry date: 26 October 2025
Positive Controls: 21PCa/b37b	Expiry date: 26 October 2025

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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Date: **30 October 2024**

Authorised by: **DR G FLOOD**
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Position: **HEAD OF QC**
Date: **14TH JAN 2025**