

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: **K21E34** Expiry date: **05 August 2024**

Reagent Lot Numbers:

Coated Wells: 21E34	Expiry date: 25 December 2024
21-OH-Biotin: 21EB24c	Expiry date: 05 August 2024
Recon. Buffer for 21-OH-Biotin: 21ER27	Expiry date: 25 October 2024
SA-POD: GEP591	Expiry date: 02 April 2024⁵
Diluent for SA-POD: 2RPD80	Expiry date: 18 May 2024⁵
Reaction Enhancer: IES120	Expiry date: 13 March 2025
Peroxidase Substrate: PTS134	Expiry date: 19 December 2025
Stop Solution: HESP125	Expiry date: 31 May 2025
Concentrated Wash: CW359	Expiry date: 27 December 2025
Calibrators: 21C34	Expiry date: 05 August 2024
Reference Preparation: 21ERP34	Expiry date: 05 August 2024
Negative Control: 21NC34	Expiry date: 05 August 2024
Positive Controls: 21PCa/b34	Expiry date: 05 August 2024

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.220	0.063
1 units per mL	0.635	0.187
10 units per mL	1.944	0.574
100 units per mL	4.415	1.299
	(derived from Abs at 405nm)	
Reference Preparation	0.622	0.180
Negative Control	0.032	0.006
Positive Control I	0.725	0.211
Positive Control II	1.780	0.525

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	1.25	1.22	0.8 – 1.9	116.6	117.2	70 - 160
Positive II	8.15	8.09	5 - 12	286.2	291.7	170 - 400

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: **04 October 2023**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **24TH OCT 2023**