

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: **K21E30B** Expiry date: **14 May 2023**

Reagent Lot Numbers:

Coated Wells: 21E30	Expiry date: 03 July 2023
21-OH-Biotin: 21EB22b	Expiry date: 14 May 2023
Recon. Buffer for 21-OH-Biotin: 21ER25	Expiry date: 19 July 2023
SA-POD: GEP499	Expiry date: 28 December 2023
Diluent for SA-POD: 2RPD78	Expiry date: 21 April 2024
Reaction Enhancer: IES115	Expiry date: 10 February 2024
Peroxidase Substrate: PTS126	Expiry date: 23 November 2023
Stop Solution: HESP117	Expiry date: 10 March 2024
Concentrated Wash: CW307	Expiry date: 11 July 2024
Calibrators: 21C30b	Expiry date: 14 May 2023
Reference Preparation: 21ERP30b	Expiry date: 14 May 2023
Negative Control: 21NC30b	Expiry date: 14 May 2023
Positive Controls: 21PCa/b30b	Expiry date: 14 May 2023

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.189	0.055
1 units per mL	0.620	0.182
10 units per mL	1.943	0.574
100 units per mL	4.021	1.183
	(derived from Abs at 405nm)	
Reference Preparation	0.548	0.159
Negative Control	0.024	0.007
Positive Control I	0.705	0.206
Positive Control II	1.850	0.546

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	1.21	1.20	0.8 – 1.9	128.6	129.6	70 - 170
Positive II	8.83	8.81	5 - 13	337.6	343.4	190 - 430

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: *Hannah Sanyaolu*
Position: **Senior Scientist**
Date: **12 July 2022**

Authorised by: *OR G Flood*
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **21st JULY 2022**