

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

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Page **1 of 1**

Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: **K21E32B** Expiry date: **21 February 2024**

Reagent Lot Numbers:

Coated Wells: 21E32	Expiry date: ^{14 May} 21 February 2024
21-OH-Biotin: 21EB24	Expiry date: ²¹ 21 February 2024
Recon. Buffer for 21-OH-Biotin: 21ER26	Expiry date: 05 April 2024
SA-POD: GEP529	Expiry date: 01 June 2024
Diluent for SA-POD: 2RPD80	Expiry date: 18 May 2025
Reaction Enhancer: IES120	Expiry date: 13 March 2025
Peroxidase Substrate: PTS128	Expiry date: 10 March 2024
Stop Solution: HESP122	Expiry date: 14 December 2024
Concentrated Wash: CW341	Expiry date: 12 June 2025
Calibrators: 21C32b	Expiry date: 21 February 2024
Reference Preparation: 21ERP32b	Expiry date: 21 February 2024
Negative Control: 21NC32b	Expiry date: 21 February 2024
Positive Controls: 21PCa/b32b	Expiry date: 21 February 2024

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.246	0.075
1 units per mL	0.686	0.204
10 units per mL	1.884	0.560
100 units per mL	3.995 (derived from Abs at 405nm)	1.175
Reference Preparation	0.664	0.196
Negative Control	0.034	0.012
Positive Control I	0.800	0.237
Positive Control II	1.711	0.507

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	1.33	1.32	0.8 – 1.8	120.5	120.9	70 - 160
Positive II	7.84	7.75	5 – 11	257.7	258.7	160 - 360

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: **Morwen Williams**
Signature: *pp w. Williams*
Position: **Scientist**
Date: **19 April 2023**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **3RD MAY 2023**