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

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Revision: **2**
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Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: K21E33A **Expiry date:** 16 April 2024

Reagent Lot Numbers:

Coated Wells:	21E33	Expiry date:	12 September 2024
21-OH-Biotin:	21EB24a	Expiry date:	16 April 2024
Recon. Buffer for 21-OH-Biotin:	21ER27	Expiry date:	25 October 2024
SA-POD:	GEP561	Expiry date:	18 November 2024
Diluent for SA-POD:	2RPD80	Expiry date:	18 May 2025
Reaction Enhancer:	IES120	Expiry date:	13 March 2025
Peroxidase Substrate:	PTS132	Expiry date:	02 February 2025
Stop Solution:	HESP124	Expiry date:	02 April 2025
Concentrated Wash:	CW352	Expiry date:	05 October 2025
Calibrators:	21C33a	Expiry date:	16 April 2024
Reference Preparation:	21ERP33a	Expiry date:	16 April 2024
Negative Control:	21NC33a	Expiry date:	16 April 2024
Positive Controls:	21PCa/b33a	Expiry date:	16 April 2024

Curve and Controls: **Incubation temp: 21°C**

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.259	0.077
1 units per mL	0.673	0.200
10 units per mL	1.808	0.535
100 units per mL	3.522 (derived from Abs at 405nm)	1.036
Reference Preparation	0.697	0.206
Negative Control	0.027	0.008
Positive Control I	0.793	0.235
Positive Control II	1.792	0.532

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	1.34	1.34	0.8 – 1.8	113.8	114.1	70 - 160
Positive II	9.75	9.84	5 - 13	257.1	258.3	160 - 380

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: Phalisha Valji
Signature: [signature]
Position: Scientific Assistant
Date: 09 June 2023

Authorised by: DR G Flood
Signature: [signature]
Position: HEAD OF QC
Date: 30TH JUN 2023