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: K21E28 **Expiry date:** ~~April~~ 18 May 2022

Reagent Lot Numbers:

Coated Wells:	21E28	Expiry date:	15 September 2022
21-OH-Biotin:	21EB20	Expiry date:	18 April 2022
Recon. Buffer for 21-OH-Biotin:	21ER24	Expiry date:	11 November 2022
SA-POD:	GEP419	Expiry date:	07 October 2022
Diluent for SA-POD:	2RPD75	Expiry date:	17 November 2022
Reaction Enhancer:	IES106A	Expiry date:	03 November 2022
Peroxidase Substrate:	PTS124	Expiry date:	03 September 2023
Stop Solution:	HESP109	Expiry date:	10 January 2023
Concentrated Wash:	CW263	Expiry date:	~~03 September~~ 18 May 2023
Calibrators:	21C28	Expiry date:	18 April 2022
Reference Preparation:	21ERP28	Expiry date:	18 April 2022
Negative Control:	21NC28	Expiry date:	18 April 2022
Positive Controls:	21PCa/b28	Expiry date:	18 April 2022

Curve and Controls: **Incubation temp: 22°C**

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.188	0.055
1 units per mL	0.605	0.177
10 units per mL	2.004	0.593
100 units per mL	4.276 (derived from Abs at 405nm)	1.258
Reference Preparation	0.557	0.159
Negative Control	0.030	0.008
Positive Control I	0.677	0.196
Positive Control II	1.850	0.544

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	1.18	1.15	0.9 – 2.0	121.5	123.3	80 - 170
Positive II	8.27	8.15	6 - 14	332.1	342.1	180 - 420

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: HSanyaolu
Position: Senior Scientist
Date: 10th June 2021

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 22ND JUN 2021