

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: **K21E29A** Expiry date: **03 November 2022**

Reagent Lot Numbers:

Coated Wells:	21E29	Expiry date:	02 February 2023
21-OH-Biotin:	21EB21a	Expiry date:	27 November 2022
Recon. Buffer for 21-OH-Biotin:	21ER24	Expiry date:	11 November 2022
SA-POD:	GEP450	Expiry date:	25 April 2023
Diluent for SA-POD:	2RPD78	Expiry date:	21 April 2024
Reaction Enhancer:	IES106A	Expiry date:	03 November 2022
Peroxidase Substrate:	PTS124	Expiry date:	03 September 2023
Stop Solution:	HESP112	Expiry date:	22 June 2023
Concentrated Wash:	CW275	Expiry date:	21 September 2023
Calibrators:	21C29a	Expiry date:	27 November 2022
Reference Preparation:	21ERP29a	Expiry date:	27 November 2022
Negative Control:	21NC29a	Expiry date:	27 November 2022
Positive Controls:	21PCa/b29a	Expiry date:	27 November 2022

Curve and Controls: Incubation temp: 22°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.185	0.055
1 units per mL	0.742	0.218
10 units per mL	2.084	0.615
100 units per mL	4.256	1.252
	(derived from Abs at 405nm)	
Reference Preparation	0.691	0.201
Negative Control	0.035	0.011
Positive Control I	0.828	0.243
Positive Control II	1.915	0.564

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	1.19	1.18	0.8 - 1.8	119.8	120.9	70 - 170
Positive II	7.97	7.93	5 - 11	277.1	280.6	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: **Hannah Sanyaolu**
Signature: *Hannah Sanyaolu*
Position: **Senior Scientist**
Date: **01 December 2021**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **HEAD OF QC**
Date: **9TH FEB 2022**