

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: K21E29B **Expiry date:** 24 January 2023

Reagent Lot Numbers:

Coated Wells: <u> 21E29 </u>	Expiry date: <u> 02 February 2023 </u>
21-OH-Biotin: <u> 21EB21b </u>	Expiry date: <u> 24 January 2023 </u>
Recon. Buffer for 21-OH-Biotin: <u> 21ER25 </u>	Expiry date: <u> 19 July 2023 </u>
SA-POD: <u> GEP478 </u>	Expiry date: <u> 22 September 2023 </u>
Diluent for SA-POD: <u> 2RPD78 </u>	Expiry date: <u> 21 April 2024 </u>
Reaction Enhancer: <u> IES115 </u>	Expiry date: <u> 10 February 2024 </u>
Peroxidase Substrate: <u> PTS126 </u>	Expiry date: <u> 23 November 2023 </u>
Stop Solution: <u> HESP112 </u>	Expiry date: <u> 22 June 2023 </u>
Concentrated Wash: <u> CW307 </u>	Expiry date: <u> 11 July 2024 </u>
Calibrators: <u> 21C29b </u>	Expiry date: <u> 24 January 2023 </u>
Reference Preparation: <u> 21ERP29b </u>	Expiry date: <u> 24 January 2023 </u>
Negative Control: <u> 21NC29b </u>	Expiry date: <u> 24 January 2023 </u>
Positive Controls: <u> 21PCa/b29b </u>	Expiry date: <u> 24 January 2023 </u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.184	0.052
1 units per mL	0.684	0.200
10 units per mL	2.255	0.666
100 units per mL	4.062	1.195
	(derived from Abs at 405nm)	
Reference Preparation	0.726	0.214
Negative Control	0.031	0.005
Positive Control I	0.890	0.260
Positive Control II	2.001	0.588

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	1.45	1.43	0.8 – 1.8	122.6	121.5	70 - 170
Positive II	7.20	7.12	5 - 11	275.6	274.8	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: H Sanyaolu
Position: Senior Scientist
Date: 30 March 2022

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 5TH APR 2022