

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: K21E28A Expiry date: 12 June 2022

Reagent Lot Numbers:

Coated Wells: <u> 21E28 </u>	Expiry date: <u> 15 September 2022 </u>
21-OH-Biotin: <u> 21EB20a </u>	Expiry date: <u> 12 June 2022 </u>
Recon. Buffer for 21-OH-Biotin: <u> 21ER24 </u>	Expiry date: <u> 11 November 2022 </u>
SA-POD: <u> GEP419 </u>	Expiry date: <u> 07 October 2022 </u>
Diluent for SA-POD: <u> 2RPD77 </u>	Expiry date: <u> 29 April 2023 </u>
Reaction Enhancer: <u> IES106A </u>	Expiry date: <u> 03 November 2022 </u>
Peroxidase Substrate: <u> PTS124 </u>	Expiry date: <u> 03 September 2023 </u>
Stop Solution: <u> HESP109 </u>	Expiry date: <u> 10 January 2023 </u>
Concentrated Wash: <u> CW275 </u>	Expiry date: <u> 21 September 2023 </u>
Calibrators: <u> 21C28a </u>	Expiry date: <u> 12 June 2022 </u>
Reference Preparation: <u> 21ERP28a </u>	Expiry date: <u> 12 June 2022 </u>
Negative Control: <u> 21NC28a </u>	Expiry date: <u> 12 June 2022 </u>
Positive Controls: <u> 21PCa/b28a </u>	Expiry date: <u> 12 June 2022 </u>

Curve and Controls: Incubation temp: 22°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.228	0.067
1 units per mL	0.691	0.205
10 units per mL	2.139	0.634
100 units per mL	4.512	1.327
	(derived from Abs at 405nm)	
Reference Preparation	0.684	0.203
Negative Control	0.044	0.014
Positive Control I	0.906	0.269
Positive Control II	2.170	0.645

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	1.56	1.55	0.9 – 2.0	132.5	132.5	80 - 170
Positive II	10.43	10.50	6 - 14	317.3	317.7	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
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Date: 24 June 2021

Authorised by: DR G Flood
Signature: G Flood
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Date: 19th AUG 2021