

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: K21E25B Expiry date: 06 September 2021

Reagent Lot Numbers:

Coated Wells: <u> 21E25 </u>	Expiry date: <u> 08 December 2021 </u>
21-OH-Biotin: <u> 21EB18a </u>	Expiry date: <u> 06 September 2021 </u>
Recon. Buffer for 21-OH-Biotin: <u> 21ER23 </u>	Expiry date: <u> 20 January 2022 </u>
SA-POD: <u> GEP379 </u>	Expiry date: <u> 06 January 2022 </u>
Diluent for SA-POD: <u> 2RPD73 </u>	Expiry date: <u> 31 October 2021 </u>
Reaction Enhancer: <u> IES99 </u>	Expiry date: <u> 22 October 2021 </u>
Peroxidase Substrate: <u> PTS118 </u>	Expiry date: <u> 21 July 2022 </u>
Stop Solution: <u> HESP102 </u>	Expiry date: <u> 31 October 2021 </u>
Concentrated Wash: <u> CW234 </u>	Expiry date: <u> 06 May 2022 </u>
Calibrators: <u> 21C25a </u>	Expiry date: <u> 06 September 2021 </u>
Reference Preparation: <u> 21ERP25a </u>	Expiry date: <u> 06 September 2021 </u>
Negative Control: <u> 21NC25a </u>	Expiry date: <u> 06 September 2021 </u>
Positive Controls: <u> 21PCa/b25a </u>	Expiry date: <u> 06 September 2021 </u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.260	0.077
1 units per mL	0.660	0.195
10 units per mL	2.397	0.710
100 units per mL	4.540	1.335
	(derived from Abs at 405nm)	
Reference Preparation	0.694	0.204
Negative Control	0.025	0.008
Positive Control I	0.908	0.267
Positive Control II	2.277	0.674

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	130.8	130.9	80 - 180
Positive II	8.76	8.72	5 - 12	328.1	330.4	210 - 450

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: Morwen Williams
Signature: Morwen Williams
Position: Scientist
Date: 15 September 2020

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 24th Nov 2020