

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: K21E33A Expiry date: 16 April 2024

Reagent Lot Numbers:

Coated Wells: <u>21E33</u>	Expiry date: <u>12 September 2024</u>
21-OH-Biotin: <u>21EB24a</u>	Expiry date: <u>16 April 2024</u>
Recon. Buffer for 21-OH-Biotin: <u>21ER27</u>	Expiry date: <u>25 October 2024</u>
SA-POD: <u>GEP561</u>	Expiry date: <u>18 November 2024</u>
Diluent for SA-POD: <u>2RPD80</u>	Expiry date: <u>18 May 2025</u>
Reaction Enhancer: <u>IES120</u>	Expiry date: <u>13 March 2025</u>
Peroxidase Substrate: <u>PTS132</u>	Expiry date: <u>02 February 2025</u>
Stop Solution: <u>HESP124</u>	Expiry date: <u>02 April 2025</u>
Concentrated Wash: <u>CW352</u>	Expiry date: <u>05 October 2025</u>
Calibrators: <u>21C33a</u>	Expiry date: <u>16 April 2024</u>
Reference Preparation: <u>21ERP33a</u>	Expiry date: <u>16 April 2024</u>
Negative Control: <u>21NC33a</u>	Expiry date: <u>16 April 2024</u>
Positive Controls: <u>21PCa/b33a</u>	Expiry date: <u>16 April 2024</u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.259	0.077
1 units per mL	0.673	0.200
10 units per mL	1.808	0.535
100 units per mL	3.522	1.036
	(derived from Abs at 405nm)	
Reference Preparation	0.697	0.206
Negative Control	0.027	0.008
Positive Control I	0.793	0.235
Positive Control II	1.792	0.532

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	1.34	1.34	0.8 – 1.8	113.8	114.1	70 - 160
Positive II	9.75	9.84	5 - 13	257.1	258.3	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: Phalisha Valji
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Date: 09 June 2023

Authorised by: DR G Flood
Signature: [Signature]
Position: HEAD OF QC
Date: 30th JUN 2023