

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: K21E32A **Expiry date:** 26 December 2023
Reagent Lot Numbers:

Coated Wells: <u>21E32</u>	Expiry date: <u>14 May 2024</u>
21-OH-Biotin: <u>21EB23e</u>	Expiry date: <u>26 December 2023</u>
Recon. Buffer for 21-OH-Biotin: <u>21ER26</u>	Expiry date: <u>05 April 2024</u>
SA-POD: <u>GEP529</u>	Expiry date: <u>01 June 2024</u>
Diluent for SA-POD: <u>2RPD80</u>	Expiry date: <u>18 May 2025</u>
Reaction Enhancer: <u>IES115</u>	Expiry date: <u>10 February 2024</u>
Peroxidase Substrate: <u>PTS128</u>	Expiry date: <u>10 March 2024</u>
Stop Solution: <u>HESP122</u>	Expiry date: <u>14 December 2024</u>
Concentrated Wash: <u>CW341</u>	Expiry date: <u>12 June 2025</u>
Calibrators: <u>21C32a</u>	Expiry date: <u>26 December 2023</u>
Reference Preparation: <u>21ERP32a</u>	Expiry date: <u>26 December 2023</u>
Negative Control: <u>21NC32a</u>	Expiry date: <u>26 December 2023</u>
Positive Controls: <u>21PCa/b32a</u>	Expiry date: <u>26 December 2023</u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.236	0.067
1 units per mL	0.705	0.207
10 units per mL	2.017	0.597
100 units per mL	4.154	1.222
	(derived from Abs at 405nm)	
Reference Preparation	0.675	0.197
Negative Control	0.029	0.005
Positive Control I	0.842	0.246
Positive Control II	1.902	0.562

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	1.33	0.8 – 1.8	124.7	124.9	70 - 160
Positive II	8.56	8.52	5 - 11	281.8	285.3	160 - 360

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: Wendy Dowler
 Signature: [Signature]
 Position: Section Leader
 Date: 10 January 2023

Authorised by: DR G Flood
 Signature: [Signature]
 Position: HEAD OF QC
 Date: 2nd MAR 2023