

Title: **Quality Control Record Sheet**
21-OH Ab ELISA Kit QC Data

Document: **wi/qcrs/40**
Revision: **2**
Date: **10.10.18**
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Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: K21E36C Expiry date: 01 July 2025

Reagent Lot Numbers:

Coated Wells: <u>21E36</u>	Expiry date: <u>04 September 2025</u>
21-OH-Biotin: <u>21EB26a</u>	Expiry date: <u>06 July 2025</u>
Recon. Buffer for 21-OH-Biotin: <u>21ER28</u>	Expiry date: <u>01 July 2025</u>
SA-POD: <u>GEP649</u>	Expiry date: <u>02 January 2026</u>
Diluent for SA-POD: <u>2RPD83</u>	Expiry date: <u>10 October 2026</u>
Reaction Enhancer: <u>IES128</u>	Expiry date: <u>08 April 2026</u>
Peroxidase Substrate: <u>PTS138</u>	Expiry date: <u>17 October 2026</u>
Stop Solution: <u>HESP130</u>	Expiry date: <u>08 February 2026</u>
Concentrated Wash: <u>CW382</u>	Expiry date: <u>18 July 2026</u>
Calibrators: <u>21C36b</u>	Expiry date: <u>06 July 2025</u>
Reference Preparation: <u>21ERP36b</u>	Expiry date: <u>06 July 2025</u>
Negative Control: <u>21NC36b</u>	Expiry date: <u>06 July 2025</u>
Positive Controls: <u>21PCa/b36b</u>	Expiry date: <u>06 July 2025</u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.250	0.074
1 units per mL	0.724	0.214
10 units per mL	1.746	0.515
100 units per mL	3.790 (derived from Abs at 405nm)	1.115
Reference Preparation	0.669	0.195
Negative Control	0.046	0.014
Positive Control I	0.783	0.229
Positive Control II	1.534	0.451

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	1.16	1.14	0.8 – 2.0	117.0	117.4	70 - 160
Positive II	7.04	6.95	5 - 12	229.3	231.3	150 - 330

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: [Signature]
Position: Scientist
Date: 12 July 2024

Authorised by: DR G Flood
Signature: [Signature]
Position: HEAD OF QC
Date: 24TH SEP 2024