

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

Document: **wi/qcrs/40**

Revision: **2**

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Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: K21E40C **Expiry date:** 22 November 2026

Reagent Lot Numbers:

Coated Wells: <u> 21E40 </u>	Expiry date: <u> 14 January 2027 </u>
21-OH-Biotin: <u> 21EB28d </u>	Expiry date: <u> 22 November 2026 </u>
Recon. Buffer for 21-OH-Biotin: <u> 21ER31 </u>	Expiry date: <u> 10 June 2027 </u>
SA-POD: <u> GEP746 </u>	Expiry date: <u> 07 April 2027 </u>
Diluent for SA-POD: <u> 2RPD86 </u>	Expiry date: <u> 13 November 2028 </u>
Reaction Enhancer: <u> IES135 </u>	Expiry date: <u> 10 December 2027 </u>
Peroxidase Substrate: <u> PTS144 </u>	Expiry date: <u> 17 February 2028 </u>
Stop Solution: <u> HESP145 </u>	Expiry date: <u> 13 October 2027 </u>
Concentrated Wash: <u> CW480 </u>	Expiry date: <u> 21 April 2028 </u>
Calibrators: <u> 21C40b </u>	Expiry date: <u> 22 November 2026 </u>
Reference Preparation: <u> 21ERP40b </u>	Expiry date: <u> 22 November 2026 </u>
Negative Control: <u> 21NC40b </u>	Expiry date: <u> 22 November 2026 </u>
Positive Controls: <u> 21PCa/b40b </u>	Expiry date: <u> 22 November 2026 </u>

Curve and Controls: Incubation temp: 22°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.210	0.061
1 units per mL	0.614	0.180
10 units per mL	1.991	0.589
100 units per mL	4.250 (derived from Abs at 405nm)	1.250
Reference Preparation	0.619	0.182
Negative Control	0.017	0.005
Positive Control I	0.750	0.219
Positive Control II	1.991	0.589

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	1.36	1.35	0.8 – 1.9	121.2	120.3	75 – 165
Positive II	10.01	9.98	6 - 13	321.6	323.6	185 - 425

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
Signature: H Sanyaolu
Position: Senior Scientist
Date: 22 January 2026

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 10th FEB 2026