

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: K21E41A **Expiry date:** 19 January 2027

Reagent Lot Numbers:

Coated Wells: <u> 21E41 </u>	Expiry date: <u> 17 May 2027 </u>
21-OH-Biotin: <u> 21EB29 </u>	Expiry date: <u> 19 January 2027 </u>
Recon. Buffer for 21-OH-Biotin: <u> 21ER31 </u>	Expiry date: <u> 10 June 2027 </u>
SA-POD: <u> GEP769 </u>	Expiry date: <u> 20 July 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> PTS146 </u>	Expiry date: <u> 13 July 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> 21C41a </u>	Expiry date: <u> 19 January 2027 </u>
Reference Preparation: <u> 21ERP41a </u>	Expiry date: <u> 19 January 2027 </u>
Negative Control: <u> 21NC41a </u>	Expiry date: <u> 19 January 2027 </u>
Positive Controls: <u> 21PCa/b41a </u>	Expiry date: <u> 19 January 2027 </u>

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.183	0.051
1 units per mL	0.678	0.197
10 units per mL	1.970	0.581
100 units per mL	3.887 (derived from Abs at 405nm)	1.143
Reference Preparation	0.655	0.189
Negative Control	0.021	0.005
Positive Control I	0.767	0.221
Positive Control II	1.884	0.553

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	1.21	1.19	0.8 – 1.8	117.1	116.9	75 – 165
Positive II	8.84	8.72	5 - 12	287.6	292.6	165 – 375

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: Hannah Sanyaolu
Position: Senior Scientist
Date: 02 April 2026

Authorised by: DR G FLOOD
Signature: G Flood
Position: HEAD OF QC
Date: 9TH APR 2026