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

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Revision: **2**
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Prepared by: G. Flood
Approved by: W. Dowler

Kit lot number: K21E38A **Expiry date:** 23 December 2025

Reagent Lot Numbers:

Coated Wells:	21E38	Expiry date:	11 May 2026
21-OH-Biotin:	21EB27b	Expiry date:	23 December 2025
Recon. Buffer for 21-OH-Biotin:	21ER29	Expiry date:	28 February 2026
SA-POD:	GEP680	Expiry date:	09 June 2026
Diluent for SA-POD:	2RPD83	Expiry date:	10 October 2026
Reaction Enhancer:	IES128	Expiry date:	08 April 2026
Peroxidase Substrate:	PTS138	Expiry date:	17 October 2026
Stop Solution:	HESP135	Expiry date:	23 September 2026
Concentrated Wash:	CW414	Expiry date:	14 April 2027
Calibrators:	21C38a	Expiry date:	23 December 2025
Reference Preparation:	21ERP38a	Expiry date:	23 December 2025
Negative Control:	21NC38a	Expiry date:	23 December 2025
Positive Controls:	21PCa/b38a	Expiry date:	23 December 2025

Curve and Controls: **Incubation temp:** 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.249	0.073
1 units per mL	0.752	0.222
10 units per mL	2.140	0.633
100 units per mL	4.525 (derived from Abs at 405nm)	1.331
Reference Preparation	0.776	0.227
Negative Control	0.031	0.010
Positive Control I	0.961	0.282
Positive Control II	2.312	0.688

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	1.54	1.51	0.8 – 1.9	123.8	124.2	70 – 170
Positive II	12.31	12.52	6 - 15	297.9	303.1	170 - 410

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: HSanyaolu
Position: Senior Scientist
Date: 20 February 2025

Authorised by: DR G FLOOD
Signature:
Position: HEAD OF QC
Date: 20TH FEB 2025