

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:                     K21E23D                     Expiry date:                     21 March 2021                    

**Reagent Lot Numbers:**

Coated Wells: <u>                    21E23                    </u>	Expiry date: <u>                    23 March 2021                    </u>
21-OH-Biotin: <u>                    21EB17b                    </u>	Expiry date: <u>                    21 March 2021                    </u>
Recon. Buffer for 21-OH-Biotin: <u>                    21ER22                    </u>	Expiry date: <u>                    01 June 2021                    </u>
SA-POD: <u>                    GEP346                    </u>	Expiry date: <u>                    19 June 2021                    </u>
Diluent for SA-POD: <u>                    2RPD73                    </u>	Expiry date: <u>                    31 October 2021                    </u>
Reaction Enhancer: <u>                    IES99                    </u>	Expiry date: <u>                    22 October 2021                    </u>
Peroxidase Substrate: <u>                    PTS118                    </u>	Expiry date: <u>                    21 July 2022                    </u>
Stop Solution: <u>                    HESP101                    </u>	Expiry date: <u>                    25 September 2021                    </u>
Concentrated Wash: <u>                    CW229                    </u>	Expiry date: <u>                    27 February 2022                    </u>
Calibrators: <u>                    21C23c                    </u>	Expiry date: <u>                    21 March 2021                    </u>
Reference Preparation: <u>                    21ERP23c                    </u>	Expiry date: <u>                    21 March 2021                    </u>
Negative Control: <u>                    21NC23c                    </u>	Expiry date: <u>                    21 March 2021                    </u>
Positive Controls: <u>                    21PCa/b23c                    </u>	Expiry date: <u>                    21 March 2021                    </u>

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

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.213	0.062
1 units per mL	0.721	0.209
10 units per mL	2.094	0.615
100 units per mL	4.206	1.177
	(derived from Abs at 405nm)	
Reference Preparation	0.607	0.173
Negative Control	0.024	0.004
Positive Control I	0.848	0.244
Positive Control II	1.961	0.575

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	1.29	1.27	0.9 – 1.9	139.7	141.0	70 - 170
Positive II	8.39	8.30	5 - 13	323.1	332.4	200 - 440

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:                     *Morwen Williams*                      
Position:                     Scientist                      
Date:                     24 March 2020                    

Authorised by:                     DR G FLOOD                      
Signature:                     *G Flood*                      
Position:                     HEAD OF QC                      
Date:                     17<sup>th</sup> JUN 2020