Title:

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

Document: Revision:

Date:

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Prepared by: G. Flood

Approved by: W. Dowler

Expiry date: K21E35A 21 January 2025 Kit lot number:

Decree 41 of Noushaus

ļ	Reagent Lot Numbers:		
	Coated Wells:	21E35	Expiry date:
	21-OH-Biotin:	21EB25b	Expiry date:
	Recon. Buffer for 21-OH-Biotin:	21ER28	Expiry date:
	SA-POD:	GEP609	Expiry date:
	Diluent for SA-POD:	2RPD81	Expiry date:
	Reaction Enhancer:	IES120	Expiry date:
	Peroxidase Substrate:	PTS134	Expiry date:
	Stop Solution:	HESP125	Expiry date:
	Concentrated Wash:	CW359	Expiry date:
	Calibrators:	21C35a	Expiry date:
	Reference Preparation:	21ERP35a	Expiry date:
	Negative Control:	21NC35a	Expiry date:
	Positive Controls:	21PCa/b35a	Expiry date:

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21 January 2025

Curve and Controls: Incubation temp: 21°C

	Absorbance at 450 nm	Absorbance at 405 nm
0.3 units per mL	0.214	0.062
1 units per mL	0.561	0.165
10 units per mL	1.588	0.469
100 units per mL	3.707 (derived from Abs at 405nm)	1.090
Reference Preparation	0.570	0.165
Negative Control	0.038	0.010
Positive Control I	0.667	0.194
Positive Control II	1.569	0.463

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	1.39	1.36	0.8 - 1.9	117.0	117.6	70 - 160
Positive II	9.74	9.68	6 - 13	275.3	280.6	160 - 370

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 Ilsoniceelle Signature: Position: Senior Scientist 20 March 2024 Date:

Authorised by: Signature: Position: Date:

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