

Title: **Quality Control Record Sheet  
Fast TRAb ELISA QC Data**

Document: **wi/qcrs/0.12g**

Prepared by: **G. Flood**

Revision: **4**

Approved by: **K. E. Louch**

Date: **11.05.21**

Page **1 of 1**

Kit Lot Number: FTE469A	Kit Expiry Date: 23 <sup>rd</sup> MARCH 2026
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Kit Manufacture Date: 24<sup>th</sup> MARCH 2025

**Reagent Lot Numbers:**

TSH Receptor Coated Wells:	3ER469	Expiry date:	10 <sup>th</sup> MAY 2026
M22 Peroxidase:	FMPOD194	Expiry date:	4 <sup>th</sup> DECEMBER 2026
Recon Buffer for M22-POD:	4MPD68	Expiry date:	28 <sup>th</sup> APRIL 2026
Peroxidase Substrate (TMB):	PTS140	Expiry date:	26 <sup>th</sup> MAY 2027
Start Buffer:	2ETEL104	Expiry date:	24 <sup>th</sup> JULY 2026
Stop Solution:	ESP56	Expiry date:	12 <sup>th</sup> SEPTEMBER 2028
Conc. Wash Solution:	TEW289	Expiry date:	11 <sup>th</sup> SEPTEMBER 2027
Calibrators:	4TES39	Expiry date:	7 <sup>th</sup> OCTOBER 2026
Controls:	4TES39N/P	Expiry date:	7 <sup>th</sup> OCTOBER 2026

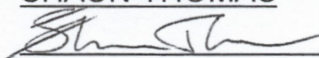
**Calibrator Curve and Controls:**

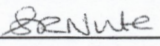
Incubation temp: 20.8°C

Calibrator Concentration (IU/L)	Absorbance at 450 nm	% Inhibition
1	1.779	25
2	1.513	37
8	0.722	70
40	0.197	92

Control	Absorbance at 450 nm	% Inhibition	Concentration (IU/L)	Range
Negative	2.386	0	-	-
Positive	1.213	49	3.45	1.9 – 4.3 IU/L

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: SHAUN THOMAS  
 Signature:   
 Position: SENIOR SCIENTIST  
 Date: 17<sup>th</sup> FEBRUARY 2025

Authorised by: SARAH NUTE  
 Signature:   
 Position: pp HEAD OF QC  
 Date: 07 MAR 2025