

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

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

Revision: **4**

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Date: **11.05.21**

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

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Kit Lot Number: FTE465A	Kit Expiry Date: 1 <sup>st</sup> DECEMBER 2025
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Kit Manufacture Date: 2<sup>nd</sup> DECEMBER 2024

**Reagent Lot Numbers:**

TSH Receptor Coated Wells:	3ER465	Expiry date:	26 <sup>th</sup> FEBRUARY 2026
M22 Peroxidase:	FMPOD189	Expiry date:	30 <sup>th</sup> MAY 2026
Recon Buffer for M22-POD:	4MPD67	Expiry date:	23 <sup>rd</sup> JANUARY 2026
Peroxidase Substrate (TMB):	PTS140B	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:	TEW287	Expiry date:	5 <sup>th</sup> JUNE 2027
Calibrators:	4TES38A	Expiry date:	21 <sup>st</sup> JANUARY 2026
Controls:	4TES38AN/P	Expiry date:	21 <sup>st</sup> JANUARY 2026

**Calibrator Curve and Controls:**

Incubation temp: 21.3°C

Calibrator Concentration (IU/L)	Absorbance at 450 nm	% Inhibition
1	1.846	24
2	1.568	35
8	0.807	67
40	0.163	93

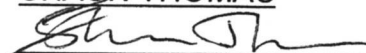
Control	Absorbance at 450 nm	% Inhibition	Concentration (IU/L)	Range
Negative	2.430	0	-	-
Positive	1.419	42	2.68	1.4 – 3.6 IU/L

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:

8<sup>th</sup> NOVEMBER 2024

Authorised by :

DR G FLOOD

Signature:



Position:

HEAD OF QC

Date:

19<sup>th</sup> NOV 2024