

Title: **Quality Control Record Sheet**
TRAb ELISA Version 3A QC Data

Document: **wi/qcrs/0.12e**

Revision: **5**

Prepared by: **G Flood**

Date: **11/05/21**

Approved by: **K Louch**

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Kit Lot Number: 3ATERK452 Kit Expiry Date: 25th FEBRUARY 2025

Kit Manufacture Date: 26th FEBRUARY 2024

TSH Receptor Coated Wells:	Lot No. <u>3ER452</u>	Expiry Date <u>10th JUNE 2025</u>
M22-Biotin:	Lot No. <u>LMB149</u>	Expiry Date <u>2nd APRIL 2025</u>
Streptavidin Peroxidase (SA-POD):	Lot No. <u>RPOD51</u>	Expiry Date <u>14th AUGUST 2026</u>
Diluent for SA-POD:	Lot No. <u>2RPD81</u>	Expiry Date <u>3rd APRIL 2026</u>
Peroxidase Substrate (TMB):	Lot No. <u>PTS136E</u>	Expiry Date <u>12th JUNE 2026</u>
Start Buffer:	Lot No. <u>2ETEL103</u>	Expiry Date <u>11th NOVEMBER 2025</u>
Stop Solution:	Lot No. <u>ESP55</u>	Expiry Date <u>11th JANUARY 2028</u>
Conc. Wash Solution:	Lot No. <u>TEW281</u>	Expiry Date <u>20th SEPTEMBER 2026</u>
Calibrators:	Lot No. <u>3TES44A</u>	Expiry Date <u>26th OCTOBER 2025</u>
Controls:	Lot No. <u>3TES44AP/44AN</u>	Expiry Date <u>26th OCTOBER 2025</u>

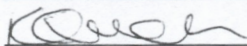
Calibrator Curve and Controls:

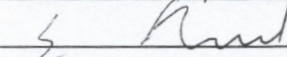
Incubation temp: 21 °C

Calibrator Concentration (IU/L)	Absorbance at 450 nm	% Inhibition
0.4	1.790	19
1	1.488	33
2.5	0.944	57
10	0.251	89
30	0.086	96

Control	Absorbance at 450 nm	% Inhibition	Concentration (IU/L)	Range
Negative	2.204	-	-	-
Positive	1.038	53	2.16	1.2-2.8 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: KATE LOUCH
 Signature: 
 Position: HEAD OF SECTION
 Date: 19th FEBRUARY 2024

Authorised by: DR G FLOOD
 Signature: 
 Position: HEAD OF QC
 Date: 21ST FEB 2024