

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: 3ATERK464A Kit Expiry Date: 1st DECEMBER 2025

Kit Manufacture Date: 2nd DECEMBER 2024

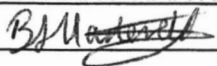
TSH Receptor Coated Wells:	Lot No. <u>3ER464</u>	Expiry Date <u>4th FEBRUARY 2026</u>
M22-Biotin:	Lot No. <u>LMB151</u>	Expiry Date <u>23rd JANUARY 2026</u>
Streptavidin Peroxidase (SA-POD):	Lot No. <u>RPOD52</u>	Expiry Date <u>4th JUNE 2027</u>
Diluent for SA-POD:	Lot No. <u>2RPD83</u>	Expiry Date <u>10th OCTOBER 2026</u>
Peroxidase Substrate (TMB):	Lot No. <u>PTS140C</u>	Expiry Date <u>26th MAY 2027</u>
Start Buffer:	Lot No. <u>2ETEL104</u>	Expiry Date <u>24th JULY 2026</u>
Stop Solution:	Lot No. <u>ESP56</u>	Expiry Date <u>12th SEPTEMBER 2028</u>
Conc. Wash Solution:	Lot No. <u>TEW287</u>	Expiry Date <u>5th JUNE 2027</u>
Calibrators:	Lot No. <u>3TES45</u>	Expiry Date <u>3rd MARCH 2026</u>
Controls:	Lot No. <u>3TES45P/45N</u>	Expiry Date <u>3rd MARCH 2026</u>

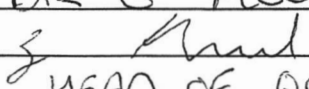
Calibrator Curve and Controls: Incubation temp: 21.1 °C

Calibrator Concentration (IU/L)	Absorbance at 450 nm	% Inhibition
0.4	1.882	17
1	1.585	30
2.5	1.089	52
10	0.323	86
30	0.114	95

Control	Absorbance at 450 nm	% Inhibition	Concentration (IU/L)	Range
Negative	2.264	-	-	-
Positive	1.170	48	2.19	1.4-3.0 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: BETHANY HARTEVELD
 Signature: 
 Position: SCIENTIST
 Date: 31st OCTOBER 2024

Authorised by : DR G FLOOD
 Signature: 
 Position: HEAD OF QC
 Date: 29th NOV 2024