

Title: **Quality Control Record Sheet
TRAb Coated Tubes QC Data**

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 Revision: 4
 Date: 11.08.10
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Prepared by: G Flood
 Approved by: W M Williams

Kit Lot Number: KTCT358A

Kit expiry date: 07 Apr 2021

| | | | | |
|--------------------------|---------|----------|-------------|-------------|
| 125I -TSH Tracer: | Lot No. | TCT322 | Expiry Date | 07 Apr 2021 |
| TRAb Assay Coated Tubes: | Lot No. | 2RC949 | Expiry Date | 13 Jun 2021 |
| Calibrators: | Lot No. | 2CTC233 | Expiry Date | 20 Oct 2022 |
| Negative Control: | Lot No. | 2CTC233N | Expiry Date | 20 Oct 2022 |
| Positive Control: | Lot No. | 2CTC233P | Expiry Date | 20 Oct 2022 |
| Wash Buffer: | Lot No. | TEW134 | Expiry Date | 29 Sep 2023 |
| Start Buffer: | Lot No. | 2aAD106 | Expiry Date | 29 Mar 2022 |

Total counts: 84382 cpm

Temp. 21 °C

| | <u>u/Litre</u> | <u>% bound</u> | <u>% inhibition</u> | |
|-------------------|----------------|---------------------|---------------------|-----------------|
| Calibrator | | | | |
| 1 | 1 | 12.58 | 17 | |
| 2 | 2 | 10.82 | 29 | |
| 3 | 8 | 5.88 | 61 | |
| 4 | 40 | 1.65 | 89 | |
| CONTROL | <u>% bound</u> | <u>% inhibition</u> | <u>u/Litre</u> | <u>Range</u> |
| I (Negative) | 15.25 | - | - | |
| II (Positive) | 8.80 | 42 | 3.6 | 4.2 +/- 1.2 u/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 Date: 04 Feb 2021

Authorised by: SARAH NUTE

Performed by: Morwen Williams

Signature: SARAH NUTE

Signature: Morwen Williams

Position: Head of Quality Control

Position: Scientist

Date: 09 Feb 2021