

Title: **Quality Control Record Sheet**
CIS TPO Ab CT QC Data

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 Revision: **4**
 Date: **16.11.07**
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Prepared by: G Flood
 Approved by: S Nute

Kit Lot Number: KCTP664

Kit expiry date: 27 SEP 2021

125 μ l - TPO	Lot No. TP3300	Expiry Date. 27 SEP 2021
Calibrators	Lot No. HTP32f	Expiry Date. 11 JAN 2022
Controls	Lot No. HTPCa/b29f	Expiry Date. 11 JAN 2022
Anti-hTPO coated tubes	Lot No. MTP537	Expiry Date. 13 APR 2022
Assay diluent	Lot No. DL495	Expiry Date. 29 JUN 2022
Concentrated wash	Lot No. MWC45	Expiry Date. 18 MAY 2022

Total counts: 47754 cpm

<u>Calibrator</u>	<u>cpm</u>	<u>% binding</u>
0 u/ml	<u>30579</u>	<u>64.0</u>
70 u/ml	<u>27761</u>	<u>58.1</u>
250 u/ml	<u>26546</u>	<u>55.6</u>
750 u/ml	<u>21026</u>	<u>44.0</u>
2500 u/ml	<u>9986</u>	<u>20.9</u>
10000 u/ml	<u>1815</u>	<u>3.8</u>

<u>CONTROL</u>	<u>cpm</u>	<u>% binding</u>	<u>u/ml</u>	<u>Range (u/ml)</u>
I	<u>25536</u>	<u>53.5</u>	<u>343.8</u>	210 - 390
II	<u>19855</u>	<u>41.6</u>	<u>864.6</u>	660 - 1080
IH22	<u>22164</u>	<u>46.4</u>	<u>643.8</u>	400 - 840
IH23	<u>18685</u>	<u>39.1</u>	<u>986.5</u>	650 - 1450
IH24	<u>6259</u>	<u>13.1</u>	<u>4230.3</u>	3500 - 6500

Comments

Incubation Temperature: 20.0 °C Time: 60 minutes

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: 07 JUL 2021

Authorised by: DR G Flood

Performed by: SARAH NUTE

Signature: *S. Nute*

Signature: *S. Nute*

Position: Head of Quality Control

Position: SECTION LEADER

Date: 8th JUL 2021