Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood Approved by: Janet Bradbury Document: Revision:

wi/qcrs/0.08b

Date:

09.01.14

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Tracer iodination date: <u>05 January 2023</u>

Kit lot number: 3INK326

Kit expiry date: 03 March 2023

| 125 _I - Insulin | Lot No. | IT326R | Expiry Date: | 03 MAR 2023 |
|----------------------------|---------|-----------------|--------------|-------------|
| Assay Buffer | Lot No. | MIAB139 | Expiry Date: | 09 MAR 2024 |
| Anti-human IgG | Lot No. | 181PG | Expiry Date: | 20 MAR 2024 |
| Calibrators | Lot No. | IMS37B | Expiry Date: | 25 MAY 2024 |
| Negative Control | Lot No. | IN130 | Expiry Date: | 10 OCT 2023 |
| Kit Controls | Lot No. | IMCa37B/IMCb37B | Expiry Date: | 25 MAY 2024 |

Total cpm in 25 μ l ¹²⁵l - Insulin 27334

| Sample | % 125 _{l - Insulin} bound | <u>u/mL</u> | Range u/mL |
|--------------------|---------------------------------------|-------------|---------------|
| Negative control | 1.1 | | |
| INS-Ab calibrator: | | | |
| 0.4 u/mL | 2.5 | | |
| 1 u/mL | 4.5 | | |
| 10 u/mL | 17.2 | | |
| 50 u/mL | 55.0 | | |
| | | | |
| Control I | 4.4 | 0.95 | 0.5 – 1.6 |
| Control II | 20.8 | 12.3 | 7 - 17 |

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 at the time of testing.

Assay Date:

11 Jan 2023

J DAVIES

Performed by:

Signature: ____

Position: Scientist

Authorised by: DR G FLOOD

Position: Head of Quality Control

Date: 117 JAN 2023