Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

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

wi/qcrs/0.08b

Revision: Date:

09.01.14

Page

1 of 1

Tracer iodination date: 08 September 2022

Kit lot number: 3INK322

Kit expiry date: 04 November 2022

| 125 <sub>I</sub> - Insulin | Lot No. | IT322R        | Expiry Date: | 04 NOV 2022 |
|----------------------------|---------|---------------|--------------|-------------|
| Assay Buffer               | Lot No. | MIAB137       | Expiry Date: | 04 DEC 2023 |
| Anti-human IgG             | Lot No. | 179PG         | Expiry Date: | 05 NOV 2023 |
| Calibrators                | Lot No. | IMS37         | Expiry Date: | 25 MAY 2024 |
| Negative Control           | Lot No. | IN130         | Expiry Date: | 10 OCT 2023 |
| Kit Controls               | Lot No. | IMCa37/IMCb37 | Expiry Date: | 25 MAY 2024 |

29332 Total cpm in 25  $\mu$ l <sup>125</sup>l - Insulin

| Sample             | % 125 <sub>I - Insulin</sub><br>bound | <u>u/mL</u> | Range<br>u/mL |
|--------------------|---------------------------------------|-------------|---------------|
| Negative control   | 0.9                                   |             |               |
| INS-Ab calibrator: |                                       |             |               |
| 0.4 u/mL           | 2.1                                   |             |               |
| 1 u/mL             | 3.69                                  |             |               |
| 10 u/mL            | 15.6                                  |             |               |
| 50 u/mL            | 52.3                                  |             |               |
| Control I          | 4.0                                   | 1.07        | 0.5 - 1.6     |
| Control II         | 17.3                                  | 11.1        | 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:

13 Sep 2022

Performed by:

J DAVIES

Signature:

Position:

Scientist

Authorised by: DR G FLOOD

Signature: \_\_\_\_\_\_\_\_\_

Position: Head of Quality Control

Date: 15 Tu SEP 2022