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: 17 June 2021

Kit lot number: 3INK306

Kit expiry date: 13 August 2021

| 125 <sub>I - Insulin</sub> | Lot No. | IT306R    | Expiry Date: | 13 AUG 2021         |
|----------------------------|---------|-----------|--------------|---------------------|
| Assay Buffer               | Lot No. | MIAB127   | Expiry Date: | <b>203</b> SEP 2022 |
| Anti-human IgG             | Lot No. | 170PG     | Expiry Date: | 18 DEC 2021         |
| Calibrators                | Lot No. | IMS35C    | Expiry Date: | 02 SEP 2022         |
| Negative Control           | Lot No. | IN128     | Expiry Date: | 26 JUN 2022         |
| Kit Controls               | Lot No. | IMCa/b35C | Expiry Date: | 02 SEP 2022         |

Total cpm in 25 µl 125l - Insulin

29383

| <u>Sample</u>      | % 125 <sub>l - Insulin</sub><br>bound | <u>u/mL</u> | <u>Range</u><br>u/mL |
|--------------------|---------------------------------------|-------------|----------------------|
| Negative control   | 1.0                                   |             |                      |
| INS-Ab calibrator: |                                       |             |                      |
| 0.4 u/mL           | 2.2                                   |             |                      |
| 1 u/mL             | 4.3                                   |             |                      |
| 10 u/mL            | 19.1                                  |             |                      |
| 50 u/mL            | 56.4                                  |             |                      |
| Control I          | 3.9                                   | 0.84        | 0.5 – 1.5            |
| Control II         | 24.2                                  | 13.3        | 9 - 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:

22 Jun 2021

Performed by:

A Huckle

Signature:

Position:

Snr Technician

Authorised by: DR & FLOOD

Position: Head of Quality Control

Date: 23 20

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