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: 02 November 2023

Kit lot number: 3INK337

Kit expiry date: 29 December 2023

125 <sub>I - Insulin</sub>	Lot No.	IT337R	Expiry Date:	29 DEC 2023
Assay Buffer	Lot No.	MIAB147	Expiry Date:	17 FEB 2025
Anti-human IgG	Lot No.	185PG	Expiry Date:	21 FEB 2025
Calibrators	Lot No.	IMS38B	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa38B/IMCb38B	Expiry Date:	26 FEB 2025

28184 Total cpm in 25  $\mu$ l <sup>125</sup>l - Insulin

Sample	% 125 <sub>l - Insulin</sub> bound	u/mL	Range u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	1.9		
1 u/mL	4.0		
10 u/mL	18.0		
50 u/mL	58.7		
Control I	4.0	1.00	0.5 – 1.7
Control II	21.2	11.9	8 – 18

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:
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08 Nov 2023

Performed by:

J DAVIES

Signature: \_\_

Position:

Senior Scientist

Authorised by: DR G FLOOD

Position: Head of Quality Control

Date: 97 NOV 2023