Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood

Approved by: Janet Bradbury

Document:

wi/qcrs/0.08b

Revision:

09.01.14

Date: Page

1 of 1

Tracer iodination date: 28 November 2024

Kit lot number: 3INK351 Kit expiry date: 24 January 2025

125 _{I - Insulin}	Lot No.	IT351R	Expiry Date:	24 JAN 2025
Assay Buffer	Lot No.	MIAB157	Expiry Date:	10 FEB 2028 ~
Anti-human IgG	Lot No.	194PG	Expiry Date:	17 APR 2026
Calibrators	Lot No.	IMS38E	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa38E/IMCb38E	Expiry Date:	26 FEB 2025

28103 Total cpm in 25 μ l 1251 - Insulin

Sample	% 125 _{I - Insulin} bound	<u>u/mL</u>	Range u/mL
Negative control	0.5		
INS-Ab calibrator:			
0.4 u/mL	1.9		
1 u/mL	3.6		
10 u/mL	15.1		
50 u/mL	55.8		
Control I	3.7	1.1	0.5 - 1.7
Control II	18.4	12.0	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:

03 Dec 2024

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: DR G FLOOD

Position: Head of Quality Control

Date: 3 20 DEC 2024