Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood

Approved by: Janet Bradbury

Document:

wi/qcrs/0.08b

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Tracer iodination date: 31 October 2024

Kit lot number: 3INK350

Kit expiry date: 27 December 2024

125 _{I - Insulin}	Lot No.	IT350R	Expiry Date:	27 DEC 2024
Assay Buffer	Lot No.	MIAB157	Expiry Date:	10 FEB 2026
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

Total cpm in 25 µl 125I - Insulin

29393

Sample	% 125 _{l - Insulin} bound	<u>u/mL</u>	Range u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	1.8		
1 u/mL	3.6		
10 u/mL	15.0		
50 u/mL	57.8		
Control I	3.6	1.0	0.5 – 1.7
Control II	17.9	11.7	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:

06 Nov 2024

Performed by:

A HUCKLE

Signature:

Position: Senior Technician Authorised by: <u>OR G FLOOD</u>

Position: Head of Quality Control

Date: 6T1

NOV 2024