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:

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Tracer iodination date: 02 January 2025

Kit lot number: 3INK352

Kit expiry date: 28 February 2025

125 _{I - Insulin}	Lot No.	IT352R	Expiry Date:	28 FEB 2025
Assay Buffer	Lot No.	MIAB159	Expiry Date:	06 APR 2026
Anti-human IgG	Lot No.	194PG	Expiry Date:	17 APR 2026
Calibrators	Lot No.	IMS39A	Expiry Date:	27 FEB 2026
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa39A/IMCb39A	Expiry Date:	27 FEB 2026

30232 Total cpm in 25 μ l ¹²⁵l - Insulin

Sample	% 125 _{l - Insulin} bound	<u>u/mL</u>	Range u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	2.4		
1 u/mL	3.5		
10 u/mL	16.8		
50 u/mL	59.1		
Control I	3.5	1.00	0.5 - 1.5
Control II	19.7	11.7	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 D	ate:
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08 Jan 2025

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: OR G FLOOD

Position: Head of Quality Control