Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood Approved by: Janet Bradbury Document: Revision:

wi/qcrs/0.08b

09.01.14

Date: Page

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Tracer iodination date: 16 April 2025

Kit lot number: 3INK356

Kit expiry date: 12 June 2025

125 _{I - Insulin}	Lot No.	IT356R	Expiry Date:	12 JUN 2025
Assay Buffer	Lot No.	MIAB163	Expiry Date:	24 AUG 2026
Anti-human IgG	Lot No.	196PG	Expiry Date:	03 AUG 2026
	Lot No.	IMS40	Expiry Date:	26 FEB 2027
Calibrators	Lot No.	IN132	Expiry Date:	04 JUL 2025
Negative Control		IMCa40/IMCb40	Expiry Date:	26 FEB 2027
Kit Controls	Lot No.	IIVICa40/IIVICb40	Expiry Date.	

Total cpm in 25 μ l ¹²⁵l - Insulin 28785

Sample	% 125 _{I - Insulin} bound	<u>u/mL</u>	<u>Range</u> u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	2.0		
1 u/mL	3.7		
10 u/mL	15.3		
50 u/mL	56.9		
Control I	3.4	0.81	0.45 - 1.45
Control II	18.1	11.7	6 - 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 D	ate:
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23 Apr 2025

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: OR G FLOOD

Position: Head of Quality Control

Date: 23 RP APR 2025