

Title: **Quality Control Record Sheet  
Insulin Ab 3 QC Data**

Document: wi/qcrs/0.08b

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Revision: 2

Approved by: Janet Bradbury

Date: 09.01.14

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Tracer iodination date: 05 October 2023

Kit lot number: 3INK336

Kit expiry date: 01 December 2023

125I - Insulin	Lot No.	IT336R	Expiry Date:	01 DEC 2023
Assay Buffer	Lot No.	MIAB146	Expiry Date:	01 JAN 2025
Anti-human IgG	Lot No.	184PG	Expiry Date:	26 DEC 2024
Calibrators	Lot No.	IMS38A	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa38A/IMCb38A	Expiry Date:	26 FEB 2025

Total cpm in 25 µl 125I - Insulin 28724

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.8		
INS-Ab calibrator:			
0.4 u/mL	2.6		
1 u/mL	4.2		
10 u/mL	16.1		
50 u/mL	51.1		
Control I	4.2	1.0	0.5 - 1.7
Control II	18.8	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: 10 Oct 2023

Authorised by: DR G FLOOD

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 11<sup>th</sup> Oct 2023