

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

Document: **wi/qcrs/0.08b**
 Revision: **2**
 Date: **09.01.14**
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Prepared by: **Geoff Flood**
 Approved by: **Janet Bradbury**

Tracer iodination date: 10 August 2023

Kit lot number: 3INK334

Kit expiry date: 06 October 2023

125I - Insulin	Lot No.	IT334R	Expiry Date:	06 OCT 2023
Assay Buffer	Lot No.	MIAB144	Expiry Date:	15 OCT 2024
Anti-human IgG	Lot No.	184PG	Expiry Date:	26 DEC 2024
Calibrators	Lot No.	IMS38	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa38/IMCb38	Expiry Date:	26 FEB 2025

Total cpm in 25 µl 125I - Insulin 28550

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	1.0		
INS-Ab calibrator:			
0.4 u/mL	2.2		
1 u/mL	4.1		
10 u/mL	14.5		
50 u/mL	50.9		
Control I	4.1	1.0	0.5 – 1.4
Control II	18.2	12.6	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: 16 Aug 2023

Authorised by: DR G Flood

Performed by: A Huckle

Signature: [Signature]

Signature: A. Huckle

Position: Head of Quality Control

Position: Senior Technician

Date: 17th AUG 2023