

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: 05 September 2024

Kit lot number: 3INK348

Kit expiry date: 01 November 2024

125I - Insulin	Lot No.	IT348R	Expiry Date:	01 NOV 2024
Assay Buffer	Lot No.	MIAB155	Expiry Date:	10 DEC 2025
Anti-human IgG	Lot No.	193PG	Expiry Date:	26 FEB 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

Total cpm in 25 µl 125I - Insulin 29019

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.5		
INS-Ab calibrator:			
0.4 u/mL	2.0		
1 u/mL	3.1		
10 u/mL	16.4		
50 u/mL	60.0		
Control I	3.1	1.0	0.5 - 1.5
Control II	19.8	11.9	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 Date: 11 Sep 2024

Authorised by: DR G Flood

Performed by: J Bradbury

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Head of Operations

Date: 11th SEP 2024