

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: 23 January 2025

Kit lot number: 3INK353

Kit expiry date: 21 March 2025

125I - Insulin	Lot No.	IT353R	Expiry Date:	21 MAR 2025
Assay Buffer	Lot No.	MIAB160	Expiry Date:	02 MAY 2026
Anti-human IgG	Lot No.	195PG	Expiry Date:	25 MAY 2026
Calibrators	Lot No.	IMS39B	Expiry Date:	27 FEB 2026
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa39B/IMCb39B	Expiry Date:	27 FEB 2026

Total cpm in 25 µl 125I - Insulin 29925

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	2.4		
1 u/mL	3.7		
10 u/mL	16.8		
50 u/mL	60.0		
Control I	3.9	1.3	0.5 - 1.5
Control II	20.7	12.2	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: 30 Jan 2025
 Performed by: A Huckle
 Signature: A. Huckle
 Position: Senior Technician

Authorised by: DR G FLOOD
 Signature: [Signature]
 Position: Head of Quality Control
 Date: 30TH JAN 2025