

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

Document: wi/qcrs/0.08b

Revision: 2

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Date: 09.01.14

Approved by: Janet Bradbury

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Tracer iodination date: 11 July 2024

Kit lot number: 3INK346

Kit expiry date: 06 September 2024

125I - Insulin	Lot No.	IT346R	Expiry Date:	06 SEP 2024
Assay Buffer	Lot No.	MIAB153	Expiry Date:	22 SEP 2025
Anti-human IgG	Lot No.	192PG	Expiry Date:	20 DEC 2025
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 28490

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.9		
INS-Ab calibrator:			
0.4 u/mL	2.7		
1 u/mL	3.6		
10 u/mL	15.0		
50 u/mL	51.9		
Control I	3.5	0.87	0.5 - 1.5
Control II	19.7	13.2	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: 16 Jul 2024

Authorised by: DR G Flood

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 16TH JULY 2024