

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: 21 March 2024

Kit lot number: 3INK342

Kit expiry date: 17 May 2024

125I - Insulin	Lot No.	IT342R	Expiry Date:	17 MAY 2024
Assay Buffer	Lot No.	MIAB151	Expiry Date:	21 JUL 2025
Anti-human IgG	Lot No.	188PG	Expiry Date:	14 JUL 2025
Calibrators	Lot No.	IMS38B	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa38B/IMCb38B	Expiry Date:	26 FEB 2025

Total cpm in 25 µl 125I - Insulin 30570

<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	2.0		
1 u/mL	4.2		
10 u/mL	16.2		
50 u/mL	58.7		
Control I	3.9	0.85	0.5 – 1.7
Control II	19.4	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: 26 Mar 2024

Authorised by: DR G FLOOD

Performed by: J Davies

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 3RD APR 2024