

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: 18 May 2023

Kit lot number: 3INK331

Kit expiry date: 14 July 2023

125I - Insulin	Lot No.	IT331R	Expiry Date:	14 JUL 2023
Assay Buffer	Lot No.	MIAB142	Expiry Date:	27 JUL 2024
Anti-human IgG	Lot No.	183PG	Expiry Date:	18 OCT 2024
Calibrators	Lot No.	IMS37E	Expiry Date:	25 MAY 2024
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa37E/IMCb37E	Expiry Date:	25 MAY 2024

Total cpm in 25 µl 125I - Insulin 27762

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	<u>0.9</u>		
INS-Ab calibrator:			
0.4 u/mL	2.2		
1 u/mL	4.2		
10 u/mL	16.0		
50 u/mL	52.1		
Control I	4.1	0.94	0.5 - 1.6
Control II	18.6	11.8	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: 24 May 2023

Authorised by: DR G FLOOD

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 24TH MAY 2023