

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

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Prepared by: **Geoff Flood**
Approved by: **Janet Bradbury**

Tracer iodination date: 04 January 2024

Kit lot number: 3INK339

Kit expiry date: 01 March 2024

125I - Insulin	Lot No. IT339R	Expiry Date: 01 MAR 2024
Assay Buffer	Lot No. MIAB148	Expiry Date: 09 MAR 2025
Anti-human IgG	Lot No. 186PG	Expiry Date: 19 MAR 2025
Calibrators	Lot No. IMS38B	Expiry Date: 26 FEB 2025
Negative Control	Lot No. IN131	Expiry Date: 06 JUL 2024
Kit Controls	Lot No. IMCa38B/IMCb38B	Expiry Date: 26 FEB 2025

Total cpm in 25 µl 125I - Insulin 28079

<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	2.2		
1 u/mL	4.5		
10 u/mL	20.3		
50 u/mL	60.6		
Control I	4.8	1.1	0.5 – 1.7
Control II	24.2	12.3	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: 10 Jan 2024

Authorised by: DR G Flood

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 11th JAN 2024