

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

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Approved by: Janet Bradbury

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Tracer iodination date: 13 June 2024

Kit lot number: 3INK345

Kit expiry date: 09 August 2024

125I - Insulin	Lot No. IT345R	Expiry Date: 09 AUG 2024
Assay Buffer	Lot No. MIAB153	Expiry Date: 22 SEP 2025
Anti-human IgG	Lot No. 190PG	Expiry Date: ²¹ 15 NOV 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 30925

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	1.0		
INS-Ab calibrator:			
0.4 u/mL	2.6		
1 u/mL	3.5		
10 u/mL	15.5		
50 u/mL	52.4		
Control I	3.5	1.0	0.5 - 1.5
Control II	19.9	12.9	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: 19 Jun 2024

Authorised by: DR G Flood

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 19th Jun 2024