

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: 30 November 2023

Kit lot number: 3INK338

Kit expiry date: 26 January 2024

125I - Insulin	Lot No. IT338R	Expiry Date: 26 JAN 2024
Assay Buffer	Lot No. MIAB147	Expiry Date: 17 FEB 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 29727

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.7		
INS-Ab calibrator:			
0.4 u/mL	2.0		
1 u/mL	4.1		
10 u/mL	17.6		
50 u/mL	62.9		
Control I	3.9	0.89	0.5 – 1.7
Control II	22.2	12.5	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: 06 Dec 2023

Performed by: A Huckle

Signature: A. Huckle

Position: Snr Technician

Authorised by: DR G FLOOD

Signature: [Signature]

Position: Head of Quality Control

Date: 6th DEC 2023