Title:

Quality Control Record Sheet Insulin Ab 3 QC Data

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Approved by: Janet Bradbury

Document:

wi/qcrs/0.08b

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Tracer iodination date: 20 March 2025

Kit lot number: 3INK355

Kit expiry date: 16 May 2025

125 _{I - Insulin}	Lot No.	IT355R	Expiry Date:	16 MAY 2025
Assay Buffer	Lot No.	MIAB161	Expiry Date:	21 JUN 2026
Anti-human IgG	Lot No.	196PG	Expiry Date:	03 AUG 2026
Calibrators	Lot No.	IMS39E	Expiry Date:	27 FEB 2026
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa39E/IMCb39E	Expiry Date:	27 FEB 2026

30735 Total cpm in 25 μ l 1251 - Insulin

Sample	% 125 _{I - Insulin} bound	<u>u/mL</u>	Range u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	2.2		
1 u/mL	3.6		
10 u/mL	16.1		
50 u/mL	58.2		
Control I	3.2	0.73	0.5 - 1.5
Control II	20.7	12.7	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:	25 Mar 2025	Authorised by: SARAH NUTE
Performed by:	J DAVIES	Signature: Senute
Signature:		Position: Head of Quality Control
Position:	Senior Scientist	Date: 25 MAR 2025