Title:

Quality Control Record Sheet Insulin Ab 3 QC Data

Prepared by: Geoff Flood

Approved by: Janet Bradbury

Document:

wi/qcrs/0.08b

Revision:

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Date: Page

1 of 1

Tracer iodination date: 03 October 2024

Kit lot number: 3INK349

Kit expiry date: 29 November 2024

125 <sub>I - Insulin</sub>	Lot No.	IT349R	Expiry Date:	29 NOV 2024
Assay Buffer	Lot No.	MIAB156	Expiry Date:	06 JAN 2026
Anti-human IgG	Lot No.	193PG	Expiry Date:	26 FEB 2026
Calibrators	Lot No.	IMS38E	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa38E/IMCb38E	Expiry Date:	26 FEB 2025

Total cpm in 25  $\mu$ l 125<sub>I</sub> - Insulin 28171

Sample	% 125 <sub>l - Insulin</sub> bound	<u>u/mL</u>	Range u/mL
Negative control	0.6		
INS-Ab calibrator:			
0.4 u/mL	1.8		
1 u/mL	3.8		
10 u/mL	15.5		
50 u/mL	60.8		
Control I	3.7	0.93	0.5 - 1.7
Control II	19.4	12.2	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:

08 Oct 2024

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: DR G FOOD

Signature:

Position:

Head of Quality Control

Date: 874

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