Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood

Approved by: Janet Bradbury

Document: Revision:

wi/qcrs/0.08b

Date:

09.01.14

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Tracer iodination date: 16 May 2024

Kit lot number: 3INK344

Kit expiry date: 12 July 2024

125 _I - Insulin	Lot No.	IT344R	Expiry Date:	12 JUL 2024
Assay Buffer	Lot No.	MIAB152	Expiry Date:	25 AUG 2025
Anti-human IgG	Lot No.	189PG	Expiry Date:	27 SEP 2025
Calibrators	Lot No.	IMS38D	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa38D/IMCb38D	Expiry Date:	26 FEB 2025

Total cpm in 25 μ l 1251 - Insulin

28321

Sample	% 125 _{- Insulin}	<u>u/mL</u>	Range u/mL
Negative control	0.5		
INS-Ab calibrator:			
0.4 u/mL	1.7		
1 u/mL	3.5		
10 u/mL	15.5		
50 u/mL	58.5		
Control I	3.7	1.3	0.5 - 1.7
Control II	18.7	11.9	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:

22 May 2024

Performed by:

J DAVIES

Signature:

Senior Scientist Position:

Authorised by: OR G FLOOR

Signature:

Position:

Head of Quality Control

Date: 22 HD MAY 2024