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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Tracer iodination date: <u>07 September 2023</u>

Kit lot number: 3INK335B

Kit expiry date: 03 November 2023

125 <sub>I -</sub> Insulin	Lot No.	IT335R	Expiry Date:	03 NOV 2023
Assay Buffer	Lot No.	MIAB146	Expiry Date:	01 JAN 2025
Anti-human IgG	Lot No.	184PG	Expiry Date:	26 DEC 2024
Calibrators	Lot No.	IMS37E	Expiry Date:	25 MAY 2024
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa37E/IMCb37E	Expiry Date:	25 MAY 2024

Total cpm in 25  $\mu$ l <sup>125</sup>l - Insulin

30143

Sample	% 125 <sub>I - Insulin</sub> bound	<u>u/mL</u>	Range u/mL
Negative control	0.9		
INS-Ab calibrator:			
0.4 u/mL	2.1		
1 u/mL	3.5		
10 u/mL	15.9		
50 u/mL	53.0		
Control I	3.9	1.4	0.5 - 1.6
Control II	19.7	12.5	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:

12 Sep 2023

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: DR G FLOOD

Signature:

Position: Head of Quality Control

Date: 12 T SEP 2023