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: 18 April 2024

Kit lot number: 3INK343

Kit expiry date: 14 June 2024

125 <sub>I - Insulin</sub>	Lot No.	IT343R	Expiry Date:	14 JUN 2024
Assay Buffer	Lot No.	MIAB152	Expiry Date:	25 AUG 2025
Anti-human IgG	Lot No.	188PG	Expiry Date:	14 JUL 2025
Calibrators	Lot No.	IMS38C	Expiry Date:	26 FEB 2025
Negative Control	Lot No.	IN132	Expiry Date:	04 JUL 2025
Kit Controls	Lot No.	IMCa38C/IMCb38C	Expiry Date:	26 FEB 2025

Total cpm in 25  $\mu$ l <sup>125</sup>l - Insulin 29942

Sample	% 125 <sub>l - Insulin</sub> bound	<u>u/mL</u>	Range u/mL
Negative control	0.7		
INS-Ab calibrator:			
0.4 u/mL	2.5		
1 u/mL	4.7		
10 u/mL	19.0		
50 u/mL	62.8		
Control I	4.9	1.1	0.5 – 1.7
Control II	22.9	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:

24 Apr 2024

Performed by: Fiona Ryrie

Signature: Fiona nyriu

Position:

Scientist

Authorised by: DR G FLOOD

Signature: \_\_\_\_\_

Position: Head of Quality Control

Date: 25TA APR 2024