Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

Prepared by: Geoff Flood Approved by: Janet Bradbury Document: Revision:

wi/qcrs/0.08b

09.01.14

Date: Page

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Tracer iodination date: 23 March 2023

Kit lot number: 3INK329

Kit expiry date: 19 May 2023

125 _{I - Insulin}	Lot No.	IT329R	Expiry Date:	19 MAY 2023
Assay Buffer	Lot No.	MIAB141	Expiry Date:	26 JUN 2024
Anti-human IgG	Lot No.	182PG	Expiry Date:	16 JUL 2024
Calibrators	Lot No.	IMS37B	Expiry Date:	25 MAY 2024
Negative Control	Lot No.	IN131	Expiry Date:	06 JUL 2024
Kit Controls	Lot No.	IMCa37B/IMCb37B	Expiry Date:	25 MAY 2024

29771 Total cpm in 25 μ l ¹²⁵l - Insulin

Sample	% 125 _{l - Insulin} bound	<u>u/mL</u>	Range u/mL
Negative control	1.0		
INS-Ab calibrator:			
0.4 u/mL	2.6		
1 u/mL	4.2		
10 u/mL	16.3		
50 u/mL	54.0		
Control I	4.1	0.93	0.5 – 1.6
Control II	21.0	13.1	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:
MSSav	Date.

28 Mar 2023

Performed by:

Signature:

Position:

Senior Scientist

Authorised by: DR G FLOOD

Position: Head of Quality Control

Date: 28Th MAR 2023