Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

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

wi/qcrs/0.08b

Revision:

09.01.14

Date: Page

1 of 1

Tracer iodination date: 01 December 2022

Kit lot number: 3INK325

Kit expiry date: 27 January 2023

125 _I - Insulin	Lot No.	IT325R	Evning Date:	07.1411.000
_		1102011	Expiry Date:	27 JAN 2023
Assay Buffer	Lot No.	MIAB138	Expiry Date:	11 FEB 2024
Anti-human IgG	Lot No.	180PG	Expiry Date:	27 DEC 2023
Calibrators	Lot No.	IMS37A	Expiry Date:	25 MAY 2024
Negative Control	Lot No.	IN130	Expiry Date:	10 OCT 2023
Kit Controls	Lot No.	IMCa37A/IMCb37A	Expiry Date:	25 MAY 2024

Total cpm in 25 μ l 125_l - Insulin

29976

Sample	<u>% 125_{l - Insulin}</u> bound	u/mL	Range u/mL
Negative control	0.9		U/IIIL
INS-Ab calibrator:			
0.4 u/mL	2.4		
1 u/mL	4.3		
10 u/mL	16.6	2	
50 u/mL	53.1		
Control I	4.4	1.06	0.5 - 1.6
Control II	19.7	12.1	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 D	ate:	
---------	------	--

07 Dec 2022

Performed by:

Signature: A. Manc.

Position: Snr Technician

Authorised by: OR G FLOOD

Position: Head of Quality Control

Date: 7Th 06C 2022