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: <u>06 October 2022</u>

Kit lot number: 3INK323 Kit expiry date: 02 December 2022

125 <sub>I - Insulin</sub>	Lot No.	IT323R	Expiry Date:	02 DEC 2022
Assay Buffer	Lot No.	MIAB137	Expiry Date:	04 DEC 2023
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

30040 Total cpm in 25  $\mu$ l <sup>125</sup>l - Insulin

Sample	% 125 <sub>I - Insulin</sub> bound	<u>u/mL</u>	<u>Range</u> u/mL
Negative control	0.9		
INS-Ab calibrator:			
0.4 u/mL	2.3		
1 u/mL	4.3		
10 u/mL	16.5		
50 u/mL	51.3		
Control I	3.5	0.69	0.5 - 1.6
Control II	19.1	11.8	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 Oct 2022

Performed by:

J DAVIES

Signature:

Position:

Scientist

Authorised by: OR G FLOOD

Position: Head of Quality Control

Date: 12 TH OCT 2022