Title:

Quality Control Record Sheet

Insulin Ab 3 QC Data

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

wi/qcrs/0.08b

Revision: Date:

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Tracer iodination date: 06 January 2022

Kit lot number: 3INK313

Kit expiry date: 04 March 2022

125 _I - Insulin	Lot No.	IT313R		
		HOION	Expiry Date:	04 MAR 2022
Assay Buffer	Lot No.	MIAB131	Expiry Date:	12 MAR 2023
Anti-human IgG	Lot No.	176PG	Expiry Date:	
Calibrators	1		Expiry Date:	20 MAR 2023
	Lot No.	IMS36B	Expiry Date:	15 JUN 2023
Negative Control	Lot No.	IN128	Expiry Date:	26 JUN 2022
Kit Controls	Lot No.	IMCa/b36B		
		IIVICa/D30B	Expiry Date:	15 JUN 2023

Total cpm in 25 μ l 125 l - Insulin 29597

<u>Sample</u>	% 125 _{l - Insulin} bound	<u>u/mL</u>	Range
Negative control	0.6		u/mL
INS-Ab calibrator:			
0.4 u/mL	2.1		
1 u/mL	3.4		
10 u/mL	15.8		
50 u/mL	56.9		
Control I 3.5		1.1	0.5 - 1.4
Control II 19.6		12.3	9 - 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.

Date:

11 January 2022

Performed by:

J Bradbury

Signature: _

Position:

Head of Operations

Authorised by: DR & FLOOR

Head of Quality Control

Date: __12 T1

JAN 2022