

Title: **Quality Control Record Sheet
Insulin Ab 3 QC Data**

Prepared by: Geoff Flood
Approved by: Janet Bradbury

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Page **1 of 1**

Tracer iodination date: 03 December 2020

Kit lot number: 3INK299A

Kit expiry date: 29 January 2021

125I - Insulin	Lot No. IT299R	Expiry Date: 29 JAN 2021
Assay Buffer	Lot No. MIAB122	Expiry Date: 01 FEB 2022
Anti-human IgG	Lot No. 172PG	Expiry Date: 22 APR 2022
Calibrators	Lot No. IMS34E	Expiry Date: 06 FEB 2021
Negative Control	Lot No. IN127	Expiry Date: 10 APR 2021
Kit Controls	Lot No. IMCa34E/IMCb34E	Expiry Date: 06 FEB 2021

Total cpm in 25 µl 125I - Insulin 27593

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	<u>0.9</u>		
INS-Ab calibrator:			
0.4 u/mL	2.7		
1 u/mL	4.8		
10 u/mL	20.5		
50 u/mL	55.7		
Control I	4.9	1.0	0.6 – 1.7
Control II	23.0	11.6	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.

Assay Date: 08 Dec 2020

Performed by: pp Becky Coles

Signature: Becky Coles

Position: Senior Scientist

Authorised by: DR G Flood

Signature: G Flood

Position: Head of Quality Control

Date: 11th DEC 2020