

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

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Prepared by: Geoff Flood
Approved by: Janet Bradbury

Tracer iodination date: 05 January 2021

Kit lot number: 3INK300

Kit expiry date: 03 March 2021

125I - Insulin	Lot No. IT300R	Expiry Date: 03 MAR 2021
Assay Buffer	Lot No. MIAB124	Expiry Date: 29 APR 2022
Anti-human IgG	Lot No. 172PG	Expiry Date: 22 APR 2022
Calibrators	Lot No. IMS35A	Expiry Date: 02 SEP 2022
Negative Control	Lot No. IN127	Expiry Date: 10 APR 2021
Kit Controls	Lot No. IMCa35A/IMCb35A	Expiry Date: 02 SEP 2022

Total cpm in 25 µl 125I - Insulin 27019

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	<u>1.1</u>		
INS-Ab calibrator:			
0.4 u/mL	2.3		
1 u/mL	4.2		
10 u/mL	16.6		
50 u/mL	52.1		
Control I	4.1	0.95	0.5 - 1.5
Control II	20.5	12.7	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: 12 Jan 2021

Performed by: A Huckle

Signature: A. Huckle

Position: Snr Technician

Authorised by: DR G Flood

Signature: G Flood

Position: Head of Quality Control

Date: 13th JAN 2021