

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

Document: **wi/qcrs/0.08b**
 Revision: **2**
 Date: **09.01.14**
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Prepared by: Geoff Flood
 Approved by: Janet Bradbury

Tracer iodination date: 28 January 2021

Kit lot number: 3INK301

Kit expiry date: 26 March 2021

125I - Insulin	Lot No. IT301R	Expiry Date: 26 MAR 2021
Assay Buffer	Lot No. MIAB124	Expiry Date: 29 APR 2022
Anti-human IgG	Lot No. 173PG	Expiry Date: 06 JUL 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 28501

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	<u>0.8</u>		
INS-Ab calibrator:			
0.4 u/mL	1.8		
1 u/mL	3.5		
10 u/mL	13.5		
50 u/mL	49.2		
Control I	3.3	0.86	0.5 - 1.5
Control II	18.1	13.3	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.

Assay Date: 03 Feb 2021

Authorised by: DR G FLOOD

Performed by: J DAVIES

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Scientist

Date: 3RD FEB 2021