

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

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

Tracer iodination date: 20 May 2021

Kit lot number: 3INK305

Kit expiry date: 16 July 2021

125I - Insulin	Lot No. <b>IT305R</b>	Expiry Date: <b>16 JUL 2021</b>
Assay Buffer	Lot No. <b>MIAB126</b>	Expiry Date: <b>08 AUG 2022</b>
Anti-human IgG	Lot No. <b>174PG</b>	Expiry Date: <b>11 SEP 2022</b>
Calibrators	Lot No. <b>IMS35C</b>	Expiry Date: <b>02 SEP 2022</b>
Negative Control	Lot No. <b>IN128</b>	Expiry Date: <b>26 JUN 2022</b>
Kit Controls	Lot No. <b>IMCa35C/IMCb35C</b>	Expiry Date: <b>02 SEP 2022</b>

Total cpm in 25 µl 125I - Insulin 28640

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	0.9		
INS-Ab calibrator:			
0.4 u/mL	2.0		
1 u/mL	3.1		
10 u/mL	15.4		
50 u/mL	54.8		
Control I	3.2	1.15	<del>0.5 - 1.5</del> <del>0.6 - 1.7</del> <i>rw</i>
Control II	20.0	12.9	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: 25 May 2021  
Performed by: J Bradbury  
Signature: *J Bradbury*  
Position: Head of Operations

Authorised by: *DR G Flood*  
Signature: *J Flood*  
Position: Head of Quality Control  
Date: 26<sup>th</sup> MAY 2021