

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

Document: **wi/qcrs/0.08b**

Revision: **2**

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Date: **09.01.14**

Approved by: Janet Bradbury

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Tracer iodination date: 25 February 2021

Kit lot number: 3INK302

Kit expiry date: 23 April 2021

125I - Insulin	Lot No. <b>IT302R</b>	Expiry Date: <b>23 APR 2021</b>
Assay Buffer	Lot No. <b>MIAB125</b>	Expiry Date: <b>14 JUN 2022</b>
Anti-human IgG	Lot No. <b>173PG</b>	Expiry Date: <b>06 JUL 2022</b>
Calibrators	Lot No. <b>IMS35A</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>IMCa35<sup>A</sup>/IMCb35A</b>	Expiry Date: <b>02 SEP 2022</b>

Total cpm in 25 µl 125I - Insulin 29927

<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	1.9		
1 u/mL	3.3		
10 u/mL	13.1		
50 u/mL	47.7		
Control I	3.2	0.91	<b>0.5 – 1.5</b>
Control II	16.6	12.5	<b>9 - 17</b>

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: 02 Mar 2021

Authorised by: DR G FLOOD

Performed by: A Huckle

Signature: *[Signature]*

Signature: *[Signature]*

Position: Head of Quality Control

Position: Snr Technician

Date: 4<sup>TH</sup> MAR 2021