

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

Document: **wi/qcrs/0.08b**
Revision: **2**
Date: **09.01.14**
Page **1 of 1**

Prepared by: Geoff Flood
Approved by: Janet Bradbury

Tracer iodination date: 25 March 2021

Kit lot number: 3INK303

Kit expiry date: 21 May 2021

125I - Insulin	Lot No. IT303R	Expiry Date: 21 MAY 2021
Assay Buffer	Lot No. MIAB125	Expiry Date: 14 JUN 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. IN128	Expiry Date: 26 JUN 2022
Kit Controls	Lot No. IMCa35A/IMCb35A	Expiry Date: 02 SEP 2022

Total cpm in 25 µl 125I - Insulin 28912

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	<u>1.0</u>		
INS-Ab calibrator:			
0.4 u/mL	2.1		
1 u/mL	3.8		
10 u/mL	16.9		
50 u/mL	53.5		
Control I	3.9	1.1	0.5 – 1.5
Control II	20.9	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: 30 Mar 2021

Performed by: F Ryrie

Signature: Fiona Ryrie

Position: Scientific Assistant

Authorised by: DR G Flood

Signature: G Flood

Position: Head of Quality Control

Date: 31st MAR 2021