

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

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Approved by: Janet Bradbury

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Tracer iodination date: 12 August 2021

Kit lot number: 3INK308

Kit expiry date: 08 October 2021

125I - Insulin	Lot No. IT308R	Expiry Date: 08 OCT 2021
Assay Buffer	Lot No. MIAB129	Expiry Date: 20 DEC 2022
Anti-human IgG	Lot No. 175PG	Expiry Date: 24 DEC 2022
Calibrators	Lot No. IMS35C	Expiry Date: 02 SEP 2022
Negative Control	Lot No. IN128	Expiry Date: 26 JUN 2022
Kit Controls	Lot No. IMCa35C/IMCb35C	Expiry Date: 02 SEP 2022

Total cpm in 25 µl 125I - Insulin 27879

<u>Sample</u>	<u>% 125I - Insulin</u> <u>bound</u>	<u>u/mL</u>	<u>Range</u> <u>u/mL</u>
Negative control	0.9		
INS-Ab calibrator:			
0.4 u/mL	2.1		
1 u/mL	3.9		
10 u/mL	19.4		
50 u/mL	55.0		
Control I	3.9	1.0	0.5 – 1.5
Control II	23.9	13.0	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: 18 Aug 2021

Performed by: J DAVIES

Signature: 

Position: Scientist

Authorised by: DR G FLOOD

Signature: 

Position: **Head of Quality Control**

Date: 19TH AUG 2021