

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

Prepared by: Geoff Flood
Approved by: Janet Bradbury

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Tracer iodination date: 05 NOVEMBER 2020

Kit lot number: 3INK298

Kit expiry date: 01 JANUARY 2021

125I - Insulin	Lot No. IT298R	Expiry Date: 01 JAN 2021
Assay Buffer	Lot No. MIAB122	Expiry Date: 01 FEB 2022
Anti-human IgG	Lot No. 172PG	Expiry Date: 22 APR 2022
Calibrators	Lot No. IMS35A	Expiry Date: 02 SEP 2022
Negative Control	Lot No. IN127	Expiry Date: 10 APR 2021
Kit Controls	Lot No. IMCa/b35A	Expiry Date: 02 SEP 2022

Total cpm in 25 µl 125I - Insulin 29793

<u>Sample</u>	<u>% 125I - Insulin bound</u>	<u>u/mL</u>	<u>Range u/mL</u>
Negative control	1.1		
INS-Ab calibrator:			
0.4 u/mL	2.3		
1 u/mL	4.2		
10 u/mL	17.3		
50 u/mL	53.6		
Control I	4.2	1.00	0.5 - 1.5
Control II	21.1	12.5	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: 10 Nov 2020

Performed by: Becky Coles

Signature: *Becky Coles*

Position: Senior Scientist

Authorised by: *DR G FLOOD*

Signature: *G Flood*

Position: Head of Quality Control

Date: 11th Nov 2020