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

Prepared by: Geoff Flood
Approved by: Janet Bradbury

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Revision: **2**
Date: **09.01.14**
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Tracer iodination date: 28 January 2021

Kit lot number: 3INK301 Kit expiry date: 26 March 2021

^{125}I - Insulin	Lot No.	**IT301R**	Expiry Date:	**26 MAR 2021**
Assay Buffer	Lot No.	**MIAB124**	Expiry Date:	**29 APR 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.	**IN127**	Expiry Date:	**10 APR 2021**
Kit Controls	Lot No.	**IMCa35A/IMCb35A**	Expiry Date:	**02 SEP 2022**

Total cpm in 25 µl ^{125}I - Insulin 28501

Sample	**% ^{125}I - Insulin bound**	**u/mL**	**Range u/mL**
Negative control	0.8		
INS-Ab calibrator:			
0.4 u/mL	1.8		
1 u/mL	3.5		
10 u/mL	13.5		
50 u/mL	49.2		
Control I	3.3	0.86	**0.5 – 1.5**
Control II	18.1	13.3	**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: 03 Feb 2021
Performed by: J DAVIES
Signature:
Position: Scientist

Authorised by: DR G FLOYD
Signature:
Position: **Head of Quality Control**
Date: 3RD FEB 2021