

Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data

Prepared by: Geoff Flood
 Approved by: Rachael Price

Document: **wi/qcrs/0.14a**
 Revision: **7**
 Date: **6 Sep 2018**
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Kit lot no:	<u>KRBA343</u>	Expiry date:	<u>22 Jan 2024</u>
Labelled Receptor lot no:	<u>RBA343</u>	Expiry date:	<u>22 Jan 2024</u>
Reconstitution buffer lot no:	<u>171B</u>	Expiry date:	<u>18 Jul 2024</u>
Precipitation enhancer lot no:	<u>PE192</u>	Expiry date:	<u>07 Aug 2024</u>
Anti human IgG lot no:	<u>180Gan</u>	Expiry date:	<u>26 Aug 2024</u>
Normal Human serum lot no:	<u>DLA126e</u>	Expiry date:	<u>26 Aug 2024</u>
Washing solution lot no:	<u>441W</u>	Expiry date:	<u>30 Aug 2024</u>
Negative control lot no:	<u>141Nb</u>	Expiry date:	<u>26 Aug 2024</u>
Positive control lot no:	<u>116PCak</u>	Expiry date:	<u>26 Aug 2024</u>

Total cpm in 50µL of labelled receptor: 76885

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound	
Negative control	1352	-	
Positive control (range)	9567	4.8	(2.8 – 6.4)
QC sera (neat and diluted in normal human serum)			
(A) K3 (lot <u>B</u>)	5511	2.4	
K3/2	3962	1.5	
(B) K4 (lot <u>F</u>)	2553	0.70	
K4/2	1997	0.37	
(C) K5 (lot <u>C</u>)	12561	6.5	
K5/2	7508	3.6	
ε-specific serum	8050	3.9	
MG7a	18467	9.9	
MG6b	14463	7.6	

Specific activity of toxin (K): 214 Ci/mmol % Counter Efficiency: 73.5%

Receptor labelling date: 20 Nov 2023 Receptor expiry date: 22 Jan 2024

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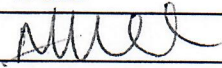
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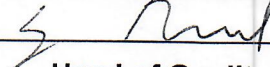
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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 and HBsAg at the time of testing.

Assay date: **23 Nov 2023**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: **DR G FLOOD**
Signature: 
Position: **Head of Quality Control**
Date: **24TH NOV 2023**