

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>KRBA332</u>	Expiry date:	<u>20 Mar 2023</u>
Labelled Receptor lot no:	<u>RBA332</u>	Expiry date:	<u>20 Mar 2023</u>
Reconstitution buffer lot no:	<u>168B</u>	Expiry date:	<u>01 Sep 2023</u>
Precipitation enhancer lot no:	<u>PE187</u>	Expiry date:	<u>09 Oct 2023</u>
Anti human IgG lot no:	<u>180Gr</u>	Expiry date:	<u>22 Oct 2023</u>
Normal Human serum lot no:	<u>DLA120k</u>	Expiry date:	<u>22 Oct 2023</u>
Washing solution lot no:	<u>428W</u>	Expiry date:	<u>21 Oct 2023</u>
Negative control lot no:	<u>139Ng</u>	Expiry date:	<u>22 Oct 2023</u>
Positive control lot no:	<u>116PCw</u>	Expiry date:	<u>22 Oct 2023</u>

Total cpm in 50µL of labelled receptor: 75491

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1290	-
Positive control (range)	9297	4.9 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	5196	2.4
K3/2	3792	1.5
(B) K4 (lot <u>E</u>)	2306	0.63
K4/2	1922	0.39
(C) K5 (lot <u>C</u>)	12676	7.0
K5/2	8209	4.3
ε-specific serum	6023	2.9
MG7a	16712	9.5
MG6b	14007	7.8

Specific activity of toxin (K): 201 Ci/mmol % Counter Efficiency: 73.5%
 Receptor labelling date: 16 Jan 2023 Receptor expiry date: 20 Mar 2023


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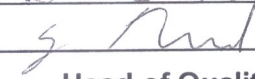
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **19 Jan 2023**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: **DR G Flood**
Signature: 
Position: **Head of Quality Control**
Date: **20th JAN 2023**