

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><b>KRBA330</b></u>	Expiry date:	<u><b>23 Jan 2023</b></u>
Labelled Receptor lot no:	<u><b>RBA330</b></u>	Expiry date:	<u><b>23 Jan 2023</b></u>
Reconstitution buffer lot no:	<u><b>167B</b></u>	Expiry date:	<u><b>15 Apr 2023</b></u>
Precipitation enhancer lot no:	<u><b>PE186</b></u>	Expiry date:	<u><b>10 Aug 2023</b></u>
Anti human IgG lot no:	<u><b>180Gk</b></u>	Expiry date:	<u><b>27 Aug 2023</b></u>
Normal Human serum lot no:	<u><b>DLA120g</b></u>	Expiry date:	<u><b>27 Aug 2023</b></u>
Washing solution lot no:	<u><b>426W</b></u>	Expiry date:	<u><b>31 Aug 2023</b></u>
Negative control lot no:	<u><b>139Ne</b></u>	Expiry date:	<u><b>27 Aug 2023</b></u>
Positive control lot no:	<u><b>116PCu</b></u>	Expiry date:	<u><b>27 Aug 2023</b></u>

Total cpm in 50µL of labelled receptor: **77325**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1583	-
Positive control (range)	9980	5.2 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u> )	5876	2.6
K3/2	4178	1.6
(B) K4 (lot <u>E</u> )	2547	0.59
K4/2	1968	0.24
(C) K5 (lot <u>C</u> )	13252	7.2
K5/2	8530	4.3
ε-specific serum	6675	3.1
MG7a	18580	10.5
MG6b	14950	8.2

Specific activity of toxin (K): **201** Ci/mmol % Counter Efficiency: **73.5%**

Receptor labelling date: **21 Nov 2022** Receptor expiry date: **23 Jan 2023**



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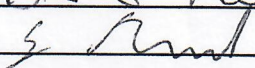
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **24 Nov 2022**  
Performed by: **A Lee**  
Signature:   
Position: **Principal Technician**

Authorised by: **DR G Flood**  
Signature:   
Position: **Head of Quality Control**  
Date: **25<sup>TH</sup> NOV 2022**