

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>KRBA340</u>	Expiry date:	<u>31 Oct 2023</u>
Labelled Receptor lot no:	<u>RBA340</u>	Expiry date:	<u>31 Oct 2023</u>
Reconstitution buffer lot no:	<u>170B</u>	Expiry date:	<u>25 Apr 2024</u>
Precipitation enhancer lot no:	<u>PE191</u>	Expiry date:	<u>19 Jun 2024</u>
Anti human IgG lot no:	<u>180Gah</u>	Expiry date:	<u>03 Jun 2024</u>
Normal Human serum lot no:	<u>DLA120w</u>	Expiry date:	<u>03 Jun 2024</u>
Washing solution lot no:	<u>437W</u>	Expiry date:	<u>07 Jun 2024</u>
Negative control lot no:	<u>139Nu</u>	Expiry date:	<u>03 Jun 2024</u>
Positive control lot no:	<u>116PCaf</u>	Expiry date:	<u>03 Jun 2024</u>

Total cpm in 50µL of labelled receptor: 76630

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1252	-
Positive control (range)	8871	4.8 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u> )	4613	2.1
K3/2	3458	1.4
(B) K4 (lot <u>F</u> )	2370	0.70
K4/2	1959	0.44
(C) K5 (lot <u>C</u> )	12365	7.0
K5/2	8183	4.3
ε-specific serum	9831	5.4
MG7a	17480	10.2
MG6b	13979	8.0

Specific activity of toxin (K): 199 Ci/mmol % Counter Efficiency: 72.3%

Receptor labelling date: 29 Aug 2023 Receptor expiry date: 31 Oct 2023

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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: 01 Sep 2023  
 Performed by: A.Lee  
 Signature: *pp. A Lee*  
 Position: Principal Technician

Authorised by: *DR G Flood*  
 Signature: *[Signature]*  
 Position: Head of Quality Control  
 Date: 4<sup>TH</sup> SEP 2023