

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>KRBA342</b></u>	Expiry date:	<u><b>25 Dec 2023</b></u>
Labelled Receptor lot no:	<u><b>RBA342</b></u>	Expiry date:	<u><b>25 Dec 2023</b></u>
Reconstitution buffer lot no:	<u><b>170B</b></u>	Expiry date:	<u><b>25 Apr 2024</b></u>
Precipitation enhancer lot no:	<u><b>PE192</b></u>	Expiry date:	<u><b>07 Aug 2024</b></u>
Anti human IgG lot no:	<u><b>180Gam</b></u>	Expiry date:	<u><b>29 Jul 2024</b></u>
Normal Human serum lot no:	<u><b>DLA126d</b></u>	Expiry date:	<u><b>29 Jul 2024</b></u>
Washing solution lot no:	<u><b>440W</b></u>	Expiry date:	<u><b>01 Aug 2024</b></u>
Negative control lot no:	<u><b>141Na</b></u>	Expiry date:	<u><b>29 Jul 2024</b></u>
Positive control lot no:	<u><b>116PCah</b></u>	Expiry date:	<u><b>29 Jul 2024</b></u>

Total cpm in 50µL of labelled receptor: **76848**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1537	-
Positive control (range)	10565	4.9 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot _____ B _____)	6271	2.6
K3/2	4432	1.6
(B) K4 (lot _____ F _____)	2804	0.68
K4/2	2142	0.33
(C) K5 (lot _____ C _____)	13055	6.2
K5/2	8794	3.9
ε-specific serum	8728	3.9
MG7a	19797	9.9
MG6b	15778	7.7

Specific activity of toxin (K): **230** Ci/mmol % Counter Efficiency: **73.5%**

Receptor labelling date: **23 Oct 2023** Receptor expiry date: **25 Dec 2023**

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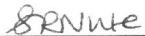
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **26 Oct 2023**  
Performed by: **A Lee**  
Signature: ****  
Position: **Principal Technician**

Authorised by: **SARAH NUTE**  
Signature: ****  
Position: **Head of Quality Control**  
Date: **27 OCT 2023**