

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>KRBA311/A</u>	Expiry date:	<u>09 Aug 2021</u>
Labelled Receptor lot no:	<u>RBA311</u>	Expiry date:	<u>09 Aug 2021</u>
Reconstitution buffer lot no:	<u>163B</u>	Expiry date:	<u>30 Jan 2022</u>
Precipitation enhancer lot no:	<u>PE178</u>	Expiry date:	<u>14 Apr 2022</u>
Anti human IgG lot no:	<u>179Gh</u>	Expiry date:	<u>13 Mar 2022</u>
Normal Human serum lot no:	<u>DLA116c</u>	Expiry date:	<u>13 Mar 2022</u>
Washing solution lot no:	<u>404W</u>	Expiry date:	<u>17 Mar 2022</u>
Negative control lot no:	<u>124Nt</u>	Expiry date:	<u>13 Mar 2022</u>
Positive control lot no:	<u>114PCah</u>	Expiry date:	<u>13 Mar 2022</u>

Total cpm in 50µL of labelled receptor: 77451

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1265	-
Positive control (range)	9567	4.8 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot_____B_____)	5318	2.3
K3/2	3784	1.5
(B) K4 (lot_____E_____)	2493	0.71
K4/2	1866	0.35
(C) K5 (lot_____C_____)	12399	6.4
K5/2	8205	4.0
ε-specific serum	8777	4.4
MG7a	17400	9.3
MG6b	14304	7.6

Specific activity of toxin (K): 215 Ci/mmol % Counter Efficiency: 72.3%

Receptor labelling date: 07 Jun 2021 Receptor expiry date: 09 Aug 2021

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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: **10 Jun 2021**
Performed by: **pp R Price**
Signature: **[Signature]**
Position: **Principal Scientist**

Authorised by: **DR G Flood**
Signature: **[Signature]**
Position: **Head of Quality Control**
Date: **11TH JUN 2021**