

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>KRBA324/A</u>	Expiry date:	<u>08 Aug 2022</u>
Labelled Receptor lot no:	<u>RBA324</u>	Expiry date:	<u>08 Aug 2022</u>
Reconstitution buffer lot no:	<u>166B</u>	Expiry date:	<u>07 Jan 2023</u>
Precipitation enhancer lot no:	<u>PE184</u>	Expiry date:	<u>21 Apr 2023</u>
Anti human IgG lot no:	<u>179Gac</u>	Expiry date:	<u>20 Feb 2023</u>
Normal Human serum lot no:	<u>DLA116v</u>	Expiry date:	<u>12 Mar 2023</u>
Washing solution lot no:	<u>419W</u>	Expiry date:	<u>17 Mar 2023</u>
Negative control lot no:	<u>137Na</u>	Expiry date:	<u>12 Mar 2023</u>
Positive control lot no:	<u>116Pck</u>	Expiry date:	<u>12 Mar 2023</u>

Total cpm in 50µL of labelled receptor: 73546

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1166	-
Positive control (range)	7758	5.0 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	4104	2.2
K3/2	3020	1.4
(B) K4 (lot <u>E</u>)	1978	0.61
K4/2	1627	0.35
(C) K5 (lot <u>C</u>)	10723	7.2
K5/2	7248	4.6
ε-specific serum	8164	5.3
MG7a	14706	10.3
MG6b	12051	8.2

Specific activity of toxin (K): 165 Ci/mmol % Counter Efficiency: 72.3%

Receptor labelling date: 06 Jun 2022 Receptor expiry date: 08 Aug 2022

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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: **13 Jun 2022**
Performed by: **R.Price**
Signature: ***R. Price***
Position: **Principal Scientist**

Authorised by: ***DR G Flood***
Signature: ***G Flood***
Position: **Head of Quality Control**
Date: **14TH JUN 2022**