

Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	<u>KRBA314/A</u>	Expiry date:	<u>02 Nov 2021</u>
Labelled Receptor lot no:	<u>RBA314</u>	Expiry date:	<u>02 Nov 2021</u>
Reconstitution buffer lot no:	<u>164B</u>	Expiry date:	<u>16 Apr 2022</u>
Precipitation enhancer lot no:	<u>PE179</u>	Expiry date:	<u>23 May 2022</u>
Anti human IgG lot no:	<u>179Gn</u>	Expiry date:	<u>05 Jun 2022</u>
Normal Human serum lot no:	<u>DLA116f</u>	Expiry date:	<u>05 Jun 2022</u>
Washing solution lot no:	<u>408W</u>	Expiry date:	<u>08 Jun 2022</u>
Negative control lot no:	<u>124Nw</u>	Expiry date:	<u>05 Jun 2022</u>
Positive control lot no:	<u>114PCan</u>	Expiry date:	<u>05 Jun 2022</u>

Total cpm in 50µL of labelled receptor: **73269**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1195	-
Positive control (range)	8629	4.5 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	5212	2.5
K3/2	3829	1.6
(B) K4 (lot <u>E</u>)	2366	0.72
K4/2	1869	0.41
(C) K5 (lot <u>C</u>)	11767	6.5
K5/2	8050	4.2
ε-specific serum	8473	4.5
MG7a	17734	10.1
MG6b	13724	7.7

Specific activity of toxin (K): **204** Ci/mmol % Counter Efficiency: **72.3%**

Receptor labelling date: **31 Aug 2021** Receptor expiry date: **02 Nov 2021**

Title: **Quality Control Record Sheet**
RBA AChRAb Assay QC data
Prepared by: Geoff Flood
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Document: **wi/qcrs/0.14a**
Revision: **7**
Date: **6 Sep 2018**
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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: **03 Sep 2021**
Performed by: **A Lee**
Signature: *A Lee*
Position: **Principal Technician**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **Head of Quality Control**
Date: *3RD SEP 2021*