

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>KRBA313/A</u>	Expiry date:	<u>04 Oct 2021</u>
Labelled Receptor lot no:	<u>RBA313</u>	Expiry date:	<u>04 Oct 2021</u>
Reconstitution buffer lot no:	<u>163B</u>	Expiry date:	<u>30 Jan 2022</u>
Precipitation enhancer lot no:	<u>PE179</u>	Expiry date:	<u>23 May 2022</u>
Anti human IgG lot no:	<u>179Gm</u>	Expiry date:	<u>08 May 2022</u>
Normal Human serum lot no:	<u>DLA116e</u>	Expiry date:	<u>08 May 2022</u>
Washing solution lot no:	<u>407W</u>	Expiry date:	<u>12 May 2022</u>
Negative control lot no:	<u>124Nv</u>	Expiry date:	<u>08 May 2022</u>
Positive control lot no:	<u>114PCam</u>	Expiry date:	<u>08 May 2022</u>

Total cpm in 50 μ L of labelled receptor: 77875

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1423	-
Positive control (range)	9348	4.8 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	5165	2.3
K3/2	3970	1.5
(B) K4 (lot <u> E </u>)	2570	0.69
K4/2	1975	0.33
(C) K5 (lot <u> C </u>)	12416	6.6
K5/2	8345	4.2
ϵ -specific serum	8752	4.4
MG7a	17212	9.5
MG6b	14339	7.8

Specific activity of toxin (K): 204 Ci/mmol % Counter Efficiency: 73.4%

Receptor labelling date: 02 Aug 2021 Receptor expiry date: 04 Oct 2021

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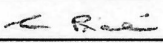
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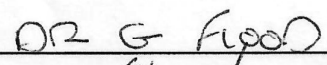
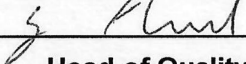
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **05 Aug 2021**
Performed by: **R.Price**
Signature: ****
Position: **Principal Scientist**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **6th AUG 2021**