

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>KRBA303</u>	Expiry date:	<u>28 Dec 2020</u>
Labelled Receptor lot no:	<u>RBA303</u>	Expiry date:	<u>28 Dec 2020</u>
Reconstitution buffer lot no:	<u>160B</u>	Expiry date:	<u>10 Jun 2021</u>
Precipitation enhancer lot no:	<u>PE175</u>	Expiry date:	<u>27 Jul 2021</u>
Anti human IgG lot no:	<u>178Gac</u>	Expiry date:	<u>01 Aug 2021</u>
Normal Human serum lot no:	<u>DLA111r</u>	Expiry date:	<u>01 Aug 2021</u>
Washing solution lot no:	<u>392W</u>	Expiry date:	<u>06 Aug 2021</u>
Negative control lot no:	<u>124Nf</u>	Expiry date:	<u>01 Aug 2021</u>
Positive control lot no:	<u>110Paae</u>	Expiry date:	<u>01 Aug 2021</u>

Total cpm in 50 μ L of labelled receptor: 74008

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	872	-
Positive control (range)	9311	4.8 (3.4 – 7.0)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> </u> B.)	4897	2.3
K3/2	3480	1.5
(B) K4 (lot <u> </u> E <u> </u>)	2084	0.69
K4/2	1455	0.33
(C) K5 (lot <u> </u> C <u> </u>)	11894	6.3
K5/2	7581	3.8
ϵ -specific serum	5651	2.7
MG7a	17643	9.6
MG6b	14450	7.8

Specific activity of toxin (K): 218 Ci/mmol % Counter Efficiency: 72.3%

Receptor labelling date: 26 Oct 2020 Receptor expiry date: 28 Dec 2020

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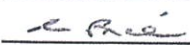
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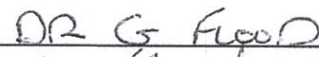

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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **29 Oct 2020**
Performed by: **R.Price**
Signature: 
Position: **Principal Scientist**

Authorised by: 
Signature: 
Position: **Head of Quality Control**
Date: **30th Oct 2020**