

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>KRBA307/A</u>	Expiry date:	<u>19 Apr 2021</u>
Labelled Receptor lot no:	<u>RBA307</u>	Expiry date:	<u>19 Apr 2021</u>
Reconstitution buffer lot no:	<u>161B</u>	Expiry date:	<u>26 Aug 2021</u>
Precipitation enhancer lot no:	<u>PE176</u>	Expiry date:	<u>22 Oct 2021</u>
Anti human IgG lot no:	<u>179Gd</u>	Expiry date:	<u>21 Nov 2021</u>
Normal Human serum lot no:	<u>DLA111w</u>	Expiry date:	<u>21 Nov 2021</u>
Washing solution lot no:	<u>400W</u>	Expiry date:	<u>25 Nov 2021</u>
Negative control lot no:	<u>124Nm</u>	Expiry date:	<u>21 Nov 2021</u>
Positive control lot no:	<u>114PCad</u>	Expiry date:	<u>21 Nov 2021</u>

Total cpm in 50µL of labelled receptor: 76076

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1114	-
Positive control (range)	8761	4.9 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	4813	2.4
K3/2	3344	1.4
(B) K4 (lot <u> E </u>)	2082	0.62
K4/2	1666	0.35
(C) K5 (lot <u> C </u>)	11783	6.8
K5/2	7909	4.4
ε-specific serum	7569	4.1
MG7a	16241	9.7
MG6b	14018	8.3

Specific activity of toxin (K): 192 Ci/mmol % Counter Efficiency: 73.4%

Receptor labelling date: 15 Feb 2021 Receptor expiry date: 19 Apr 2021

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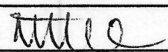
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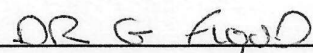
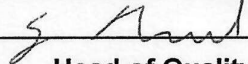
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **18 Feb 2021**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **19TH FEB 2021**