

Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data

Document: **wi/qcrs/0.14a**

Revision: **7**

Date: **6 Sep 2018**

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Prepared by: Geoff Flood
 Approved by: Rachael Price

Kit lot no:	<u>KRBA320/A</u>	Expiry date:	<u>21 Apr 2022</u>
Labelled Receptor lot no:	<u>RBA320</u>	Expiry date:	<u>21 Apr 2022</u>
Reconstitution buffer lot no:	<u>165B</u>	Expiry date:	<u>01 Sep 2022</u>
Precipitation enhancer lot no:	<u>PE182</u>	Expiry date:	<u>07 Dec 2022</u>
Anti human IgG lot no:	<u>179Gw</u>	Expiry date:	<u>20 Nov 2022</u>
Normal Human serum lot no:	<u>DLA116p</u>	Expiry date:	<u>20 Nov 2022</u>
Washing solution lot no:	<u>414W</u>	Expiry date:	<u>25 Nov 2022</u>
Negative control lot no:	<u>124Nad</u>	Expiry date:	<u>20 Nov 2022</u>
Positive control lot no:	<u>116PCe</u>	Expiry date:	<u>20 Nov 2022</u>

Total cpm in 50µL of labelled receptor: 76830

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1258	-
Positive control (range)	9170	4.8 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	4915	2.2
K3/2	3662	1.5
(B) K4 (lot <u>E</u>)	2277	0.62
K4/2	1880	0.38
(C) K5 (lot <u>C</u>)	12269	6.7
K5/2	8136	4.2
ε-specific serum	9638	5.1
MG7a	17779	10.1
MG6b	14579	8.1

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

Receptor labelling date: 17 Feb 2022 Receptor expiry date: 21 Apr 2022


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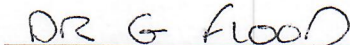
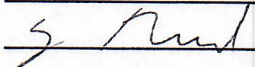
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **21 Feb 2022**
Performed by: **R.Price**
Signature: ****
Position: **Principal Scientist**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **22ND FEB 2022**