

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>KRBA325</u>	Expiry date:	<u>05 Sep 2022</u>
Labelled Receptor lot no:	<u>RBA325</u>	Expiry date:	<u>05 Sep 2022</u>
Reconstitution buffer lot no:	<u>166B</u>	Expiry date:	<u>07 Jan 2023</u>
Precipitation enhancer lot no:	<u>PE184</u>	Expiry date:	<u>21 Apr 2023</u>
Anti human IgG lot no:	<u>179Gae</u>	Expiry date:	<u>20 Feb 2023</u>
Normal Human serum lot no:	<u>DLA120b</u>	Expiry date:	<u>10 Apr 2023</u>
Washing solution lot no:	<u>420W</u>	Expiry date:	<u>14 Apr 2023</u>
Negative control lot no:	<u>138Na</u>	Expiry date:	<u>10 Apr 2023</u>
Positive control lot no:	<u>116PCm</u>	Expiry date:	<u>10 Apr 2023</u>

Total cpm in 50µL of labelled receptor: **78304**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1426	-
Positive control (range)	8875	5.5 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	4705	2.4
K3/2	3646	1.6
(B) K4 (lot <u> E </u>)	2214	0.58
K4/2	1821	0.29
(C) K5 (lot <u> C </u>)	11985	7.8
K5/2	7914	4.8
ε-specific serum	9758	6.2
MG7a	16812	11.4
MG6b	13211	8.7

Specific activity of toxin (K): **168** Ci/mmol % Counter Efficiency: **72.3%**

Receptor labelling date: **04 Jul 2022** Receptor expiry date: **05 Sep 2022**

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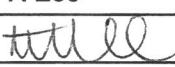
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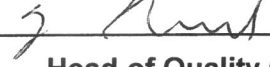
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **07 Jul 2022**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **8TH JULY 2022**