

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>KRBA341</u>	Expiry date:	<u>27 Nov 2023</u>
Labelled Receptor lot no:	<u>RBA341</u>	Expiry date:	<u>27 Nov 2023</u>
Reconstitution buffer lot no:	<u>170B</u>	Expiry date:	<u>25 Apr 2024</u>
Precipitation enhancer lot no:	<u>PE191</u>	Expiry date:	<u>19 Jun 2024</u>
Anti human IgG lot no:	<u>180Gak</u>	Expiry date:	<u>01 Jul 2024</u>
Normal Human serum lot no:	<u>DLA126c</u>	Expiry date:	<u>01 Jul 2024</u>
Washing solution lot no:	<u>438W</u>	Expiry date:	<u>04 Jul 2024</u>
Negative control lot no:	<u>139Nv</u>	Expiry date:	<u>01 Jul 2024</u>
Positive control lot no:	<u>116PCag</u>	Expiry date:	<u>01 Jul 2024</u>

Total cpm in 50µL of labelled receptor: **76809**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1546	-
Positive control (range)	10904	5.5 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	5498	2.3
K3/2	4138	1.5
(B) K4 (lot <u> F </u>)	2757	0.71
K4/2	2029	0.28
(C) K5 (lot <u> C </u>)	13181	6.8
K5/2	9025	4.4
ε-specific serum	9743	4.8
MG7a	19041	10.2
MG6b	15402	8.1

Specific activity of toxin (K): **212** Ci/mmol % Counter Efficiency: **73.5%**

Receptor labelling date: **25 Sep 2023** Receptor expiry date: **27 Nov 2023**

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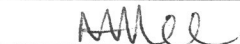
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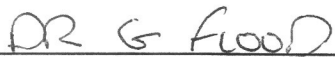

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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **28 Sep 2023**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **29TH SEP 2023**