

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:	KRBA312/A	Expiry date:	06 Sep 2021
Labelled Receptor lot no:	RBA312	Expiry date:	06 Sep 2021
Reconstitution buffer lot no:	163B	Expiry date:	30 Jan 2022
Precipitation enhancer lot no:	PE178	Expiry date:	14 Apr 2022
Anti human IgG lot no:	179Gk	Expiry date:	11 Apr 2022
Normal Human serum lot no:	DLA116d	Expiry date:	11 Apr 2022
Washing solution lot no:	405W	Expiry date:	14 Apr 2022
Negative control lot no:	124Nu	Expiry date:	11 Apr 2022
Positive control lot no:	114PCak	Expiry date:	11 Apr 2022

Total cpm in 50µL of labelled receptor: **77250**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1207	-
Positive control (range)	9579	5.8 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	4851	2.5
K3/2	3559	1.6
(B) K4 (lot <u> E </u>)	2034	0.57
K4/2	1757	0.38
(C) K5 (lot <u> C </u>)	11544	7.2
K5/2	7894	4.6
ε-specific serum	8354	4.9
MG7a	16126	10.3
MG6b	13340	8.4

Specific activity of toxin (K): **177** Ci/mmol % Counter Efficiency: **73.4%**

Receptor labelling date: **05 Jul 2021** Receptor expiry date: **06 Sep 2021**

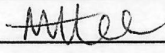
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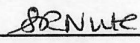
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **08 Jul 2021**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: **SARAH NUTE**
Signature: ****
Position: **pp Head of Quality Control**
Date: **09 JUL 2021**