

Title: **Quality Control Record Sheet**
RBA AChR Ab 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:	KRBA328	Expiry date:	28 Nov 2022
Labelled Receptor lot no:	RBA328	Expiry date:	28 Nov 2022
Reconstitution buffer lot no:	167B	Expiry date:	15 Apr 2023
Precipitation enhancer lot no:	PE186	Expiry date:	10 Aug 2023
Anti human IgG lot no:	180Ge	Expiry date:	02 Jul 2023
Normal Human serum lot no:	DLA120e	Expiry date:	02 Jul 2023
Washing solution lot no:	424W	Expiry date:	05 Jul 2023
Negative control lot no:	139Nc	Expiry date:	02 Jul 2023
Positive control lot no:	116PCr	Expiry date:	02 Jul 2023

Total cpm in 50µL of labelled receptor: **77148**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1339	-
Positive control (range)	9327	5.1 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	4917	2.3
K3/2	3807	1.6
(B) K4 (lot <u>E</u>)	2361	0.66
K4/2	1818	0.31
(C) K5 (lot <u>C</u>)	12095	6.9
K5/2	7924	4.2
ε-specific serum	6884	3.6
MG7a	17896	10.6
MG6b	14475	8.4

Specific activity of toxin (K): **194** Ci/mmol % Counter Efficiency: **72.3%**

Receptor labelling date: **26 Sep 2022** Receptor expiry date: **28 Nov 2022**


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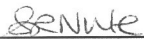
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Kit lot no: **KRBA328** Expiry date: **28 Nov 2022**

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: **29 Sep 2022**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: **SARAH NUTE**
Signature: ****
Position: **Head of Quality Control**
Date: **30 SEP 2022**