

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:	<u>KRBA336</u>	Expiry date:	<u>11 Jul 2023</u>
Labelled Receptor lot no:	<u>RBA336</u>	Expiry date:	<u>11 Jul 2023</u>
Reconstitution buffer lot no:	<u>169B</u>	Expiry date:	<u>19 Dec 2023</u>
Precipitation enhancer lot no:	<u>PE189</u>	Expiry date:	<u>19 Feb 2024</u>
Anti human IgG lot no:	<u>180Gaa</u>	Expiry date:	<u>14 Feb 2024</u>
Normal Human serum lot no:	<u>DLA120r</u>	Expiry date:	<u>14 Feb 2024</u>
Washing solution lot no:	<u>433W</u>	Expiry date:	<u>24 Feb 2024</u>
Negative control lot no:	<u>139Nn</u>	Expiry date:	<u>14 Feb 2024</u>
Positive control lot no:	<u>116PCab</u>	Expiry date:	<u>14 Feb 2024</u>

Total cpm in 50 μ L of labelled receptor: 77000

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1475	-
Positive control (range)	8771	4.9 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	5038	2.4
K3/2	3591	1.4
(B) K4 (lot <u>F</u>)	2567	0.73
K4/2	1962	0.33
(C) K5 (lot <u>C</u>)	11907	7.0
K5/2	7458	4.0
ϵ -specific serum	7113	3.8
MG7a	15631	9.5
MG6b	13161	7.9

Specific activity of toxin (K): 185 Ci/mmol % Counter Efficiency: 73.5%

Receptor labelling date: 09 May 2023 Receptor expiry date: 11 Jul 2023

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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: **12 May 2023**
Performed by: **A Lee**
Signature: *A Lee*
Position: **Principal Technician**

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: **Head of Quality Control**
Date: **15TH MAY 2023**