

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**
 Page **1 of 2**

Kit lot no:	<u>KRBA335</u>	Expiry date:	<u>13 Jun 2023</u>
Labelled Receptor lot no:	<u>RBA335</u>	Expiry date:	<u>13 Jun 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>180Gx</u>	Expiry date:	<u>16 Jan 2024</u>
Normal Human serum lot no:	<u>DLA120p</u>	Expiry date:	<u>16 Jan 2024</u>
Washing solution lot no:	<u>432W</u>	Expiry date:	<u>19 Jan 2024</u>
Negative control lot no:	<u>139Nm</u>	Expiry date:	<u>16 Jan 2024</u>
Positive control lot no:	<u>116PCaa</u>	Expiry date:	<u>16 Jan 2024</u>

Total cpm in 50µL of labelled receptor: **77197**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1307	-
Positive control (range)	9633	4.6 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	5667	2.4
K3/2	4078	1.5
(B) K4 (lot <u> F </u>)	2636	0.73
K4/2	2069	0.42
(C) K5 (lot <u> C </u>)	12822	6.4
K5/2	8774	4.1
ε-specific serum	6367	2.8
MG7a	18029	9.2
MG6b	14725	7.4

Specific activity of toxin (K): **222** Ci/mmol % Counter Efficiency: **73.4%**

Receptor labelling date: **11 Apr 2023** Receptor expiry date: **13 Jun 2023**

Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data


Prepared by: Geoff Flood
Approved by: Rachael Price

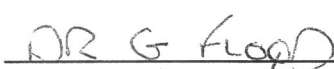

Document: **wi/qcrs/0.14a**
Revision: **7**
Date: **6 Sep 2018**
Page **2 of 2**

Kit lot no: **KRBA335** Expiry date: **13 Jun 2023**

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: **14 Apr 2023**
Performed by: **R.Price**
Signature: 
Position: **Principal Scientist**

Authorised by: 
Signature: 
Position: **Head of Quality Control**
Date: **17th APR 2023**