

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:	<b><u>KRBA331</u></b>	Expiry date:	<b><u>16 Feb 2023</u></b>
Labelled Receptor lot no:	<b><u>RBA331</u></b>	Expiry date:	<b><u>16 Feb 2023</u></b>
Reconstitution buffer lot no:	<b><u>168B</u></b>	Expiry date:	<b><u>01 Sep 2023</u></b>
Precipitation enhancer lot no:	<b><u>PE187</u></b>	Expiry date:	<b><u>09 Oct 2023</u></b>
Anti human IgG lot no:	<b><u>180Gn</u></b>	Expiry date:	<b><u>01 Oct 2023</u></b>
Normal Human serum lot no:	<b><u>DLA120h</u></b>	Expiry date:	<b><u>01 Oct 2023</u></b>
Washing solution lot no:	<b><u>427W</u></b>	Expiry date:	<b><u>27 Sep 2023</u></b>
Negative control lot no:	<b><u>139Nf</u></b>	Expiry date:	<b><u>01 Oct 2023</u></b>
Positive control lot no:	<b><u>116PCv</u></b>	Expiry date:	<b><u>01 Oct 2023</u></b>

Total cpm in 50µL of labelled receptor: **78626**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1403	-
Positive control (range)	10344	4.8 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u> )	5797	2.3
K3/2	3983	1.4
(B) K4 (lot <u>E</u> )	2755	0.72
K4/2	2198	0.42
(C) K5 (lot <u>C</u> )	13899	6.7
K5/2	9323	4.2
ε-specific serum	6126	2.5
MG7a	18240	9.0
MG6b	14721	7.1

Specific activity of toxin (K): **230** Ci/mmol % Counter Efficiency: **73.4%**

Receptor labelling date: **15 Dec 2022** Receptor expiry date: **16 Feb 2023**

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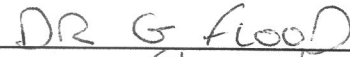

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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **19 Dec 2022**  
Performed by: **R.Price**  
Signature:   
Position: **Principal Scientist**

Authorised by:   
Signature:   
Position: **Head of Quality Control**  
Date: **20<sup>th</sup> DEC 2022**