

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>KRBA333</u>	Expiry date:	<u>17 Apr 2023</u>
Labelled Receptor lot no:	<u>RBA333</u>	Expiry date:	<u>17 Apr 2023</u>
Reconstitution buffer lot no:	<u>168B</u>	Expiry date:	<u>01 Sep 2023</u>
Precipitation enhancer lot no:	<u>PE188</u>	Expiry date:	<u>03 Jan 2024</u>
Anti human IgG lot no:	<u>180Gu</u>	Expiry date:	<u>19 Nov 2023</u>
Normal Human serum lot no:	<u>DLA120m</u>	Expiry date:	<u>19 Nov 2023</u>
Washing solution lot no:	<u>429W</u>	Expiry date:	<u>23 Nov 2023</u>
Negative control lot no:	<u>139Nh</u>	Expiry date:	<u>19 Nov 2023</u>
Positive control lot no:	<u>116PCx</u>	Expiry date:	<u>19 Nov 2023</u>

Total cpm in 50 $\mu$ L of labelled receptor: 79312

Serum sample (5 $\mu$ L)	cpm bound	nmole/litre toxin bound
Negative control	1402	-
Positive control (range)	9784	4.8 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>      B      </u> )	5796	2.5
K3/2	3896	1.4
(B) K4 (lot <u>      E      </u> )	2487	0.62
K4/2	2019	0.35
(C) K5 (lot <u>      C      </u> )	13529	7.0
K5/2	8912	4.3
$\epsilon$ -specific serum	6730	3.1
MG7a	18566	9.9
MG6b	14471	7.5

Specific activity of toxin (K): 216 Ci/mmol % Counter Efficiency: 73.5%

Receptor labelling date: 13 Feb 2023 Receptor expiry date: 17 Apr 2023


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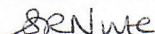
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **16 Feb 2023**  
Performed by: **A Lee**  
Signature:   
Position: **Principal Technician**

Authorised by: **SARAH NUTE**  
Signature:   
Position: **pp Head of Quality Control**  
Date: **17 FEB 2023**