

Prepared by: Geoff Flood  
Approved by: Rachael Price

Kit lot no:	<b>KRBA345</b>	Expiry date:	<b>18 Mar 2024</b>
Labelled Receptor lot no:	<b>RBA345</b>	Expiry date:	<b>18 Mar 2024</b>
Reconstitution buffer lot no:	<b>171B</b>	Expiry date:	<b>18 Jul 2024</b>
Precipitation enhancer lot no:	<b>PE193</b>	Expiry date:	<b>29 Oct 2024</b>
Anti human IgG lot no:	<b>182Gb</b>	Expiry date:	<b>21 Oct 2024</b>
Normal Human serum lot no:	<b>DLA126g</b>	Expiry date:	<b>21 Oct 2024</b>
Washing solution lot no:	<b>443W</b>	Expiry date:	<b>14 Oct 2024</b>
Negative control lot no:	<b>141Nd</b>	Expiry date:	<b>21 Oct 2024</b>
Positive control lot no:	<b>116PCan</b>	Expiry date:	<b>21 Oct 2024</b>

Total cpm in 50µL of labelled receptor: **72196**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1316	-
Positive control (range)	10055	4.3 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>      B      </u> )	6113	2.4
K3/2	4308	1.5
(B) K4 (lot <u>      F      </u> )	2717	0.70
K4/2	1963	0.32
(C) K5 (lot <u>      C      </u> )	12688	5.7
K5/2	8541	3.6
ε-specific serum	7747	3.2
MG7a	20540	9.6
MG6b	14812	6.7

Specific activity of toxin (K): **250** Ci/mmol % Counter Efficiency: **72.3%**

Receptor labelling date: **15 Jan 2024** Receptor expiry date: **18 Mar 2024**

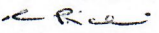
Title: **Quality Control Record Sheet**  
**RBA AChRAb Assay QC data**  
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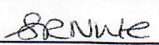
Document: **wi/qcrs/0.14a**  
Revision: **7**  
Date: **6 Sep 2018**  
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	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: **22 Jan 2024**  
Performed by: **R.Price**  
Signature: ****  
Position: **Principal Scientist**

Authorised by: **SARAH NUTE**  
Signature: ****  
Position: **py Head of Quality Control**  
Date: **23 JAN 2024.**