

Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	<u>KRBA337</u>	Expiry date:	<u>07 Aug 2023</u>
Labelled Receptor lot no:	<u>RBA337</u>	Expiry date:	<u>07 Aug 2023</u>
Reconstitution buffer lot no:	<u>169B</u>	Expiry date:	<u>19 Dec 2023</u>
Precipitation enhancer lot no:	<u>PE190</u>	Expiry date:	<u>15 May 2024</u>
Anti human IgG lot no:	<u>180Gac</u>	Expiry date:	<u>11 Mar 2024</u>
Normal Human serum lot no:	<u>DLA120t</u>	Expiry date:	<u>11 Mar 2024</u>
Washing solution lot no:	<u>434W</u>	Expiry date:	<u>14 Mar 2024</u>
Negative control lot no:	<u>139Np</u>	Expiry date:	<u>11 Mar 2024</u>
Positive control lot no:	<u>116PCac</u>	Expiry date:	<u>11 Mar 2024</u>

Total cpm in 50 μ L of labelled receptor: **76465**

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1497	-
Positive control (range)	10086	4.4 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	6156	2.4
K3/2	4500	1.5
(B) K4 (lot <u>F</u>)	2879	0.70
K4/2	2083	0.30
(C) K5 (lot <u>C</u>)	13805	6.3
K5/2	9311	4.0
ϵ -specific serum	7255	2.9
MG7a	19850	9.3
MG6b	16311	7.5

Specific activity of toxin (K): **244** Ci/mmol % Counter Efficiency: **73.5%**

Receptor labelling date: **05 Jun 2023** Receptor expiry date: **07 Aug 2023**

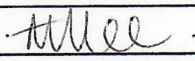
Title: **Quality Control Record Sheet**
RBA AChRAb Assay QC data
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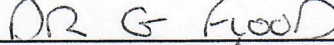
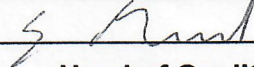
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Page **2 of 2**

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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: **08 Jun 2023**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: ****
Signature: ****
Position: **Head of Quality Control**
Date: **9TH JUN 2023**