


Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data
Prepared by: Geoff Flood
Approved by: Rachael Price

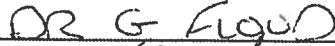

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Kit lot no: **KRBA306/A** Expiry date: **22 Mar 2021**

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: 21 Jan 2021
Performed by: A Lee
Signature: 
Position: Principal Technician

Authorised by: 
Signature: 
Position: Head of Quality Control
Date: 22ND JAN 2021

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Kit lot no:	<u>KRBA306/A</u>	Expiry date:	<u>22 Mar 2021</u>
Labelled Receptor lot no:	<u>RBA306</u>	Expiry date:	<u>22 Mar 2021</u>
Reconstitution buffer lot no:	<u>161B</u>	Expiry date:	<u>26 Aug 2021</u>
Precipitation enhancer lot no:	<u>PE176</u>	Expiry date:	<u>22 Oct 2021</u>
Anti human IgG lot no:	<u>178Gag</u>	Expiry date:	<u>24 Oct 2021</u>
Normal Human serum lot no:	<u>DLA111v</u>	Expiry date:	<u>24 Oct 2021</u>
Washing solution lot no:	<u>397W</u>	Expiry date:	<u>30 Sep 2021</u>
Negative control lot no:	<u>124Nk</u>	Expiry date:	<u>24 Oct 2021</u>
Positive control lot no:	<u>114PCac</u>	Expiry date:	<u>24 Oct 2021</u>

Total cpm in 50 μ L of labelled receptor: 77529

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1134	-
Positive control (range)	8676	4.7 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	4889	2.3
K3/2	3351	1.4
(B) K4 (lot <u> E </u>)	2243	0.69
K4/2	1652	0.32
(C) K5 (lot <u> C </u>)	12117	6.8
K5/2	7977	4.2
ϵ -specific serum	7831	4.1
MG7a	17278	10.0
MG6b	13996	7.9

Specific activity of toxin (K): 199 Ci/mmol % Counter Efficiency: 73.4%

Receptor labelling date: 18 Jan 2021 Receptor expiry date: 22 Mar 2021