

Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	<u>KRBA305/A</u>	Expiry date:	<u>15 Feb 2021</u>
Labelled Receptor lot no:	<u>RBA305</u>	Expiry date:	<u>15 Feb 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>178Gaf</u>	Expiry date:	<u>03 Oct 2021</u>
Normal Human serum lot no:	<u>DLA111u</u>	Expiry date:	<u>03 Oct 2021</u>
Washing solution lot no:	<u>396W</u>	Expiry date:	<u>25 Sep 2021</u>
Negative control lot no:	<u>124Nh</u>	Expiry date:	<u>03 Oct 2021</u>
Positive control lot no:	<u>114PCab</u>	Expiry date:	<u>03 Oct 2021</u>

Total cpm in 50µL of labelled receptor: 77714

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1188	-
Positive control (range)	8907	4.9 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	4760	2.3
K3/2	3484	1.5
(B) K4 (lot <u> E </u>)	2073	0.56
K4/2	1652	0.30
(C) K5 (lot <u> C </u>)	12309	7.1
K5/2	7967	4.3
ε-specific serum	7136	3.8
MG7a	18919	11.3
MG6b	14409	8.4

Specific activity of toxin (K): 196 Ci/mmol % Counter Efficiency: 72.3%
Receptor labelling date: 14 Dec 2020 Receptor expiry date: 15 Feb 2021

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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: 17 Dec 2020
Performed by: R.Price
Signature: *R Price*
Position: Principal Scientist

Authorised by: *DR G FLOOD*
Signature: *G Flood*
Position: Head of Quality Control
Date: 19th DEC 2020