

Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data

Document: **wi/qcrs/0.14a**
Revision: **7**
Date: **6 Sep 2018**
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Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	<u>KRBA323/A</u>	Expiry date:	<u>11 Jul 2022</u>
Labelled Receptor lot no:	<u>RBA323</u>	Expiry date:	<u>11 Jul 2022</u>
Reconstitution buffer lot no:	<u>166B</u>	Expiry date:	<u>07 Jan 2023</u>
Precipitation enhancer lot no:	<u>PE183</u>	Expiry date:	<u>25 Jan 2023</u>
Anti human IgG lot no:	<u>179Gaa</u>	Expiry date:	<u>15 Feb 2023</u>
Normal Human serum lot no:	<u>DLA116u</u>	Expiry date:	<u>15 Feb 2023</u>
Washing solution lot no:	<u>418W</u>	Expiry date:	<u>20 Feb 2023</u>
Negative control lot no:	<u>136Na</u>	Expiry date:	<u>15 Feb 2023</u>
Positive control lot no:	<u>116PCh</u>	Expiry date:	<u>15 Feb 2023</u>

Total cpm in 50 μ L of labelled receptor: 79997

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1472	-
Positive control (range)	9828	5.6 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	5232	2.5
K3/2	3795	1.6
(B) K4 (lot <u> E </u>)	2372	0.60
K4/2	2019	0.37
(C) K5 (lot <u> C </u>)	11986	7.0
K5/2	8066	4.4
ϵ -specific serum	7911	4.3
MG7a	16981	10.4
MG6b	13422	8.0

Specific activity of toxin (K): 186 Ci/mmol % Counter Efficiency: 72.3%
Receptor labelling date: 09 May 2022 Receptor expiry date: 11 Jul 2022

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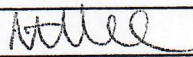
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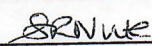
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **12 May 2022**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: **SARAH NUTE**
Signature: 
Position: **PP Head of Quality Control**
Date: **13 MAY 2022**