

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

Prepared by: Geoff Flood
 Approved by: Rachael Price

Document: **wi/qcrs/0.14a**
 Revision: **7**
 Date: **6 Sep 2018**
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Kit lot no:	<u>KRBA334</u>	Expiry date:	<u>15 May 2023</u>
Labelled Receptor lot no:	<u>RBA334</u>	Expiry date:	<u>15 May 2023</u>
Reconstitution buffer lot no:	<u>168B</u>	Expiry date:	<u>01 Sep 2023</u>
Precipitation enhancer lot no:	<u>PE188</u>	Expiry date:	<u>03 Jan 2024</u>
Anti human IgG lot no:	<u>180Gw</u>	Expiry date:	<u>19 Dec 2023</u>
Normal Human serum lot no:	<u>DLA120n</u>	Expiry date:	<u>19 Dec 2023</u>
Washing solution lot no:	<u>430W</u>	Expiry date:	<u>19 Dec 2023</u>
Negative control lot no:	<u>139Nk</u>	Expiry date:	<u>19 Dec 2023</u>
Positive control lot no:	<u>116PCy</u>	Expiry date:	<u>19 Dec 2023</u>

Total cpm in 50 μ L of labelled receptor: **80948**

Serum sample (5 μ L)	cpm bound	nmole/litre toxin bound
Negative control	1324	-
Positive control (range)	10974	5.0 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u> B </u>)	6504	2.7
K3/2	4629	1.7
(B) K4 (lot <u> F </u>)	2518	0.62
K4/2	1872	0.29
(C) K5 (lot <u> C </u>)	14023	6.6
K5/2	9368	4.2
ϵ -specific serum	6362	2.6
MG7a	20640	10.1
MG6b	15644	7.5

Specific activity of toxin (K): **238** Ci/mmol % Counter Efficiency: **73.5%**
 Receptor labelling date: **13 Mar 2023** Receptor expiry date: **15 May 2023**

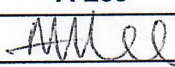
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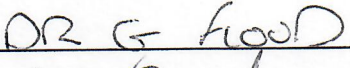
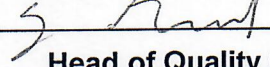
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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

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: **16 Mar 2023**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: 
Signature: 
Position: **Head of Quality Control**
Date: **17th MAR 2023**