

Title: **Quality Control Record Sheet**  
**RBA AChR Ab Assay QC data**

Prepared by: Geoff Flood  
 Approved by: Rachael Price

Document: **wi/qcrs/0.14a**  
 Revision: **7**  
 Date: **6 Sep 2018**  
 Page **1 of 2**

Kit lot no:	<u>KRBA327</u>	Expiry date:	<u>01 Nov 2022</u>
Labelled Receptor lot no:	<u>RBA327</u>	Expiry date:	<u>01 Nov 2022</u>
Reconstitution buffer lot no:	<u>167B</u>	Expiry date:	<u>15 Apr 2023</u>
Precipitation enhancer lot no:	<u>PE185</u>	Expiry date:	<u>21 Jun 2023</u>
Anti human IgG lot no:	<u>180Gc</u>	Expiry date:	<u>04 Jun 2023</u>
Normal Human serum lot no:	<u>DLA120d</u>	Expiry date:	<u>04 Jun 2023</u>
Washing solution lot no:	<u>423W</u>	Expiry date:	<u>09 Jun 2023</u>
Negative control lot no:	<u>139Nb</u>	Expiry date:	<u>04 Jun 2023</u>
Positive control lot no:	<u>116PCp</u>	Expiry date:	<u>04 Jun 2023</u>

Total cpm in 50 $\mu$ L of labelled receptor: 76692

Serum sample (5 $\mu$ L)	cpm bound	nmole/litre toxin bound
Negative control	1263	-
Positive control (range)	8208	4.6 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>      B      </u> )	4627	2.2
K3/2	3053	1.2
(B) K4 (lot <u>      E      </u> )	2323	0.71
K4/2	1745	0.32
(C) K5 (lot <u>      C      </u> )	11942	7.1
K5/2	7883	4.4
$\epsilon$ -specific serum	11079	6.5
MG7a	16551	10.2
MG6b	13630	8.2

Specific activity of toxin (K): 187 Ci/mmol % Counter Efficiency: 72.3%  
 Receptor labelling date: 30 Aug 2022 Receptor expiry date: 01 Nov 2022

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Page **2 of 2**

Kit lot no: **KRBA327**      Expiry date: **01 Nov 2022**

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: **02 Sep 2022**  
Performed by: **A Lee**  
Signature: *pp. A Lee*  
Position: **Principal Technician**

Authorised by: *Jill Clark*  
Signature: *JH Clark*  
Position: **Head of Quality Control**  
Date: **05 SEP 2022**

Title: **Quality Control Record Sheet**  
**ACHRAb Standard Curve QC Data**

Prepared by: Geoff Flood  
Approved by: Rachael Price

Document: **wi/qcrs/0.14SCb**  
Revision: **3**  
Date: **6 Sep 2018**  
Page **1 of 1**

**Re: AChRAb Standard Curve (lot no. ASC20b; expiry date. 04 Jun 2023 )**

*To use this standard curve, plot the mean cpm bound for each standard obtained in your assay against the corresponding nmol/litre value shown in the table below.*

*No  $^{125}\text{I}$  decay correction is needed.*

Our QC data for the standard curve, obtained with AChR lot **RBA327** are as follows:

Standard	Actual value at QC	
1	0.29	nmol/litre
2	1.1	nmol/litre
3	3.9	nmol/litre
4	8.6	nmol/litre
Value of positive control <b>116PCp</b> read off standard curve = 4.5 nmol/litre		
(Range: 2.8-6.4 nmol/litre)		

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: 02 Sep 2022  
Performed by: A Lee  
Signature: pp. A Lee  
Position: Principal Technician

Authorised by: JILL CLARK  
Signature: Jill Clark  
Position: pp Head of Quality Control  
Date: 05 SEP 2022