

Title: **Quality Control Record Sheet**  
**RBA AChR Ab 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>KRBA372</u>	Expiry date:	<u>13 Apr 2026</u>
Labelled Receptor lot no:	<u>RBA372</u>	Expiry date:	<u>13 Apr 2026</u>
Reconstitution buffer lot no:	<u>178B</u>	Expiry date:	<u>31 Jul 2026</u>
Precipitation enhancer lot no:	<u>PE203</u>	Expiry date:	<u>23 Oct 2026</u>
Anti human IgG lot no:	<u>187Gm</u>	Expiry date:	<u>15 Nov 2026</u>
Normal Human serum lot no:	<u>DLA135b</u>	Expiry date:	<u>15 Nov 2026</u>
Washing solution lot no:	<u>475W</u>	Expiry date:	<u>25 Nov 2026</u>
Negative control lot no:	<u>147Nc</u>	Expiry date:	<u>15 Nov 2026</u>
Positive control lot no:	<u>118Pak</u>	Expiry date:	<u>15 Nov 2026</u>

Total cpm in 50µL of labelled receptor: 75493

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1060	-
Positive control (range)	8234	4.6 (2.5 – 5.9)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>C</u> )	5028	2.6
K3/2	3053	1.3
(B) K4 (lot <u>F</u> )	2201	0.74
K4/2	1602	0.35
(C) K5 (lot <u>C</u> )	10487	6.1
K5/2	7001	3.8
ε-specific serum	7640	4.2
MG8a	20712	12.7
MG7b	12532	7.4

Specific activity of toxin (K): 184 Ci/mmol % Counter Efficiency: 76.0%

Receptor labelling date: 09 Feb 2026 Receptor expiry date: 13 Apr 2026

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**RBA AChRAb Assay QC data**

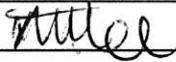
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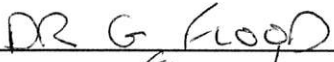
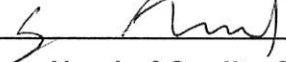
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Kit lot no: **KRBA372** Expiry date: **13 Apr 2026**

<b>Assay date (weeks after receptor labelling)</b>	<b>Decay factor (A)</b>
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 Feb 2026**  
Performed by: **A Lee**  
Signature:   
Position: **Principal Technician**

Authorised by:   
Signature:   
Position: **Head of Quality Control**  
Date: **13<sup>TH</sup> FEB 2026**

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

Document: **wi/qcrs/0.14SCb**

Revision: **3**

Prepared by: Geoff Flood

Date: **6 Sep 2018**

Approved by: Rachael Price

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**Re: AChRAb Standard Curve (lot no. ASC21aa; expiry date. 15 Nov 2026)**

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 <sup>125</sup>I decay correction is needed.

Our QC data for the standard curve, obtained with AChR lot **RBA372** are as follows:

Standard	Actual value at QC
1	0.30 nmol/litre
2	0.69 nmol/litre
3	3.3 nmol/litre
4	8.5 nmol/litre
Value of positive control <b>118Pak</b> read off standard curve = 4.4 nmol/litre	
(Range: 2.5-5.9 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: 12 Feb 2026

Authorised by: DR G FLOOD

Performed by: A Lee

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Principal Technician

Date: 13<sup>TH</sup> FEB 2026