

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

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

Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	KRBA374	Expiry date:	09 Jun 2026
Labelled Receptor lot no:	RBA374	Expiry date:	09 Jun 2026
Reconstitution buffer lot no:	179B	Expiry date:	29 Nov 2026
Precipitation enhancer lot no:	PE203	Expiry date:	23 Oct 2026
Anti human IgG lot no:	187Gp	Expiry date:	12 Jan 2027
Normal Human serum lot no:	DLA135d	Expiry date:	12 Jan 2027
Washing solution lot no:	478W	Expiry date:	17 Jan 2027
Negative control lot no:	147Ne	Expiry date:	12 Jan 2027
Positive control lot no:	118Pan	Expiry date:	12 Jan 2027

Total cpm in 50µL of labelled receptor: 75171

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1038	-
Positive control (range)	7822	4.8 (2.5 – 5.9)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>C</u>)	4386	2.4
K3/2	2785	1.2
(B) K4 (lot <u>F</u>)	2029	0.70
K4/2	1512	0.33
(C) K5 (lot <u>C</u>)	9863	6.2
K5/2	6485	3.8
ε-specific serum	5659	3.3
MG8a	19662	13.2
MG7b	11699	7.5

Specific activity of toxin (K): 166 Ci/mmol % Counter Efficiency: 76.7%

Receptor labelling date: 07 Apr 2026 Receptor expiry date: 09 Jun 2026

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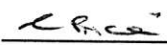
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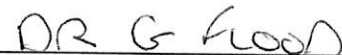
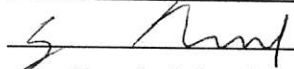
Document: **wi/qcrs/0.14a**
Revision: **7**
Date: **6 Sep 2018**
Page **2 of 2**

Kit lot no: **KRBA374** Expiry date: **09 Jun 2026**

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: 10 Apr 2026
Performed by: R.Price
Signature: 
Position: Principal Scientist

Authorised by: 
Signature: 
Position: Head of Quality Control
Date: 13TH APR 2026

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

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

Prepared by: Geoff Flood
 Approved by: Rachael Price

Re: AChRab Standard Curve (lot no. ASC21ac; expiry date. 12 Jan 2027)

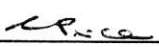
To use this standard curve, plot the mean cpm bound for each standard obtained in your assay against the corresponding nmol/litre value shown in the table below.


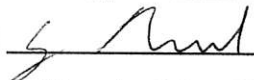
No ¹²⁵I decay correction is needed.

Our QC data for the standard curve, obtained with AChR lot **RBA374** are as follows:

Standard	Actual value at QC	
1	0.30	nmol/litre
2	0.91	nmol/litre
3	3.4	nmol/litre
4	9.4	nmol/litre
Value of positive control 118Pan read off standard curve = 4.5 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: 10 Apr 2026
 Performed by: R.Price
 Signature: 
 Position: Principal Scientist

Authorised by: 
 Signature: 
 Position: Head of Quality Control
 Date: 13TH APR 2026