

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:	KRBA375	Expiry date:	<u>07 Jul 2026</u>
Labelled Receptor lot no:	RBA375	Expiry date:	<u>07 Jul 2026</u>
Reconstitution buffer lot no:	179B	Expiry date:	<u>29 Nov 2026</u>
Precipitation enhancer lot no:	PE204	Expiry date:	<u>28 Jan 2027</u>
Anti human IgG lot no:	187Gr	Expiry date:	<u>10 Feb 2027</u>
Normal Human serum lot no:	DLA135e	Expiry date:	<u>10 Feb 2027</u>
Washing solution lot no:	479W	Expiry date:	<u>13 Feb 2027</u>
Negative control lot no:	147Nf	Expiry date:	<u>10 Feb 2027</u>
Positive control lot no:	118Pap	Expiry date:	<u>10 Feb 2027</u>

Total cpm in 50µL of labelled receptor: 76450

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1285	-
Positive control (range)	10706	4.4 (2.5 – 5.9)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot _____ C)	6944	2.7
K3/2	4285	1.4
(B) K4 (lot _____ F)	2880	0.75
K4/2	2154	0.41
(C) K5 (lot _____ C)	13648	5.8
K5/2	9408	3.8
ε-specific serum	8282	3.3
MG8a	25907	11.6
MG7b	15921	6.9

Specific activity of toxin (K): 252 Ci/mmol % Counter Efficiency: 76.0%

Receptor labelling date: 05 May 2026 Receptor expiry date: 07 Jul 2026

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Kit lot no:

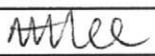
KRBA375

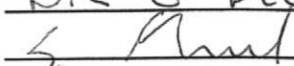
Expiry date:

07 Jul 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: **08 May 2026**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: 
Signature: 
Position: **Head of Quality Control**
Date: **11th MAY 2026**

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**
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Re: AChRab Standard Curve (lot no. ASC21ad; expiry date. 10 Feb 2027)

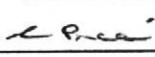
To use this standard curve, plot the mean cpm bound for each standard obtained in your assay against the corresponding nmol/litre value shown in the table below.

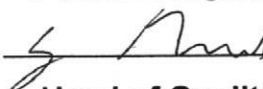
No 125 I decay correction is needed.

Our QC data for the standard curve, obtained with AChR lot **RBA375** are as follows:

Standard	Actual value at QC	
1	0.38	nmol/litre
2	1.0	nmol/litre
3	3.5	nmol/litre
4	7.8	nmol/litre
Value of positive control 118Pap 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: 13 May 2026
Performed by: R.Price
Signature: 
Position: Principal Scientist

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