

Prepared by: Geoff Flood
Approved by: Rachael Price

Kit lot no:	<u>KRBA380</u>	Expiry date:	<u>23 Nov 2026</u>
Labelled Receptor lot no:	<u>RBA380</u>	Expiry date:	<u>23 Nov 2026</u>
Reconstitution buffer lot no:	<u>180B</u>	Expiry date:	<u>14 Mar 2027</u>
Precipitation enhancer lot no:	<u>PE205</u>	Expiry date:	<u>09 Apr 2027</u>
Anti human IgG lot no:	<u>187Gx</u>	Expiry date:	<u>27 Jun 2027</u>
Normal Human serum lot no:	<u>DLA135m</u>	Expiry date:	<u>27 Jun 2027</u>
Washing solution lot no:	<u>486W</u>	Expiry date:	<u>26 Jun 2027</u>
Negative control lot no:	<u>147Nn</u>	Expiry date:	<u>27 Jun 2027</u>
Positive control lot no:	<u>123Pa</u>	Expiry date:	<u>27 Jun 2027</u>

Total cpm in 50µL of labelled receptor: 75200

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1118	-
Positive control (range)	9380	4.6 (2.9 – 6.9)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>C</u>)	5080	2.2
K3/2	3341	1.2
(B) K4 (lot <u>F</u>)	2577	0.81
K4/2	1833	0.39
(C) K5 (lot <u>C</u>)	11895	5.9
K5/2	7710	3.6
ε-specific serum	7848	3.7
MG8a	22355	11.7
MG7b	13644	6.9

Specific activity of toxin (K): 215 Ci/mmol % Counter Efficiency: 76.0%

Receptor labelling date: 21 Sep 2026 Receptor expiry date: 23 Nov 2026

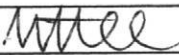
Title: **Quality Control Record Sheet**
RBA AChRab Assay QC data
Prepared by: Geoff Flood
Approved by: Rachael Price

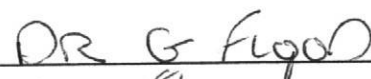
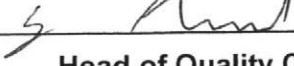
Document: **wi/qcrs/0.14a**
Revision: **7**
Date: **6 Sep 2018**
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Kit lot no: **KRBA380** Expiry date: **23 Nov 2026**

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: **25 Sep 2026**
Performed by: **A Lee**
Signature: 
Position: **Principal Technician**

Authorised by: 
Signature: 
Position: **Head of Quality Control**
Date: **25TH SEP 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. ASC22c; expiry date. 27 Jun 2027)

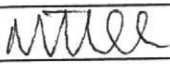
To use this standard curve, plot the mean cpm bound for each standard obtained in your assay against the corresponding nmol/litre value shown in the table below.

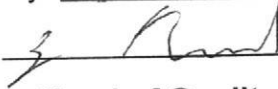
No ¹²⁵I decay correction is needed.

Our QC data for the standard curve, obtained with AChR lot **RBA380** are as follows:

Standard	Actual value at QC	
1	0.29	nmol/litre
2	1.0	nmol/litre
3	3.7	nmol/litre
4	7.4	nmol/litre
Value of positive control 123Pa read off standard curve = 4.4 nmol/litre		
(Range: 2.9-6.9 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: 25 Sep 2026
Performed by: A Lee
Signature: 
Position: Principal Technician

Authorised by: 
Signature: 
Position: Head of Quality Control
Date: 25TH SEP 2026