

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**
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Kit lot no:	<u>KRBA329</u>	Expiry date:	<u>26 Dec 2022</u>
Labelled Receptor lot no:	<u>RBA329</u>	Expiry date:	<u>26 Dec 2022</u>
Reconstitution buffer lot no:	<u>167B</u>	Expiry date:	<u>15 Apr 2023</u>
Precipitation enhancer lot no:	<u>PE186</u>	Expiry date:	<u>10 Aug 2023</u>
Anti human IgG lot no:	<u>180Gg</u>	Expiry date:	<u>30 Jul 2023</u>
Normal Human serum lot no:	<u>DLA120f</u>	Expiry date:	<u>30 Jul 2023</u>
Washing solution lot no:	<u>425W</u>	Expiry date:	<u>03 Aug 2023</u>
Negative control lot no:	<u>139Nd</u>	Expiry date:	<u>30 Jul 2023</u>
Positive control lot no:	<u>116PCt</u>	Expiry date:	<u>30 Jul 2023</u>

Total cpm in 50µL of labelled receptor: **75261**

Serum sample (5 µL)	cpm bound	nmole/litre toxin bound
Negative control	1422	-
Positive control (range)	9438	5.0 (2.8 – 6.4)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot <u>B</u>)	5326	2.5
K3/2	3716	1.4
(B) K4 (lot <u>E</u>)	2369	0.60
K4/2	1924	0.32
(C) K5 (lot <u>C</u>)	12912	7.2
K5/2	8635	4.5
ε-specific serum	6902	3.4
MG7a	18009	10.4
MG6b	15056	8.6

Specific activity of toxin (K): **197** Ci/mmol % Counter Efficiency: **73.5%**
 Receptor labelling date: **24 Oct 2022** Receptor expiry date: **26 Dec 2022**

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RBA AChRAb Assay QC data

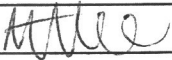
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Kit lot no: **KRBA329** Expiry date: **26 Dec 2022**

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: **27 Oct 2022**
Performed by: **A Lee**
Signature: ****
Position: **Principal Technician**

Authorised by: **SARAH NUTE**
Signature: ****
Position: **pp Head of Quality Control**
Date: **28 OCT 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**
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Re: AChRAb Standard Curve (lot no. ASC20d; expiry date. 30 Jul 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 ¹²⁵I decay correction is needed.


Our QC data for the standard curve, obtained with AChR lot **RBA329** are as follows:

Standard	Actual value at QC	
1	0.24	nmol/litre
2	1.1	nmol/litre
3	4.0	nmol/litre
4	9.1	nmol/litre
Value of positive control 116Pct read off standard curve = 4.9 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: 27 Oct 2022

Performed by: A Lee

Signature: 

Position: Principal Technician

Authorised by: SARAH NUTE

Signature: 

Position:  Head of Quality Control

Date: 28 OCT 2022