

Title: **Quality Control Record Sheet**  
**AChRab ELISA Kit QC Data**

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Approved by: **R Price**

Kit lot number: **KAE105C** Kit expiry date: **23 Jan 2024**

AChR MAb1 Coated Wells:	Lot No. <u>AE161</u>	Expiry Date <u>25 Jul 2024</u>
Foetal Type AChR:	Lot No. <u>AERF115f</u>	Expiry Date <u>23 Apr 2025</u>
Adult Type AChR:	Lot No. <u>AERA113f</u>	Expiry Date <u>23 Apr 2025</u>
Recon. Buffer for AChR:	Lot No. <u>ABR32</u>	Expiry Date <u>28 Mar 2024</u>
AChR MAb-Biotin:	Lot No. <u>AEB50f</u>	Expiry Date <u>23 Apr 2025</u>
Recon. Buffer for Mab-Biotin:	Lot No. <u>ABB40</u>	Expiry Date <u>28 Mar 2024</u>
Streptavidin Peroxidase (SA-POD):	Lot No. <u>GEP534</u>	Expiry Date <u>03 Jul 2024</u>
Diluent for SA-POD:	Lot No. <u>2RPD79</u>	Expiry Date <u>27 Oct 2024</u>
Peroxidase Substrate (TMB):	Lot No. <u>PTS132</u>	Expiry Date <u>02 Feb 2025</u>
Stop Solution:	Lot No. <u>ESP53</u>	Expiry Date <u>22 Jun 2026</u>
Concentrated Wash Solution:	Lot No. <u>ACW47</u>	Expiry Date <u>27 Apr 2024</u>
Calibrators:	Lot No. <u>AEC103</u>	Expiry Date <u>04 Jul 2024</u>
Controls:	Lot No. <u>AENC105; AEPCa/b104</u>	Expiry Date <u>04 Jul 2024</u>

**Calibrator Curve and Controls:**

Incubation temp: +22 °C

Calibrators	Absorbance at 450 nm	% Inhibition
Negative Control (0.2 nmol/L toxin bound)	<b>1.948</b>	<b>0</b>
Calibrator 0.5 nmol/L toxin bound	<b>1.474</b>	<b>24</b>
Calibrator 1.0 nmol/L toxin bound	<b>1.173</b>	<b>40</b>
Calibrator 6.5 nmol/L toxin bound	<b>0.444</b>	<b>77</b>
Calibrator 20 nmol/L toxin bound	<b>0.122</b>	<b>94</b>

Controls	Absorbance at 450 nm	% Inhibition	Concentration nmol/L toxin bound	Range nmol/L toxin bound
Positive Control AEPCa	<b>0.419</b>	<b>79</b>	<b>7.1</b>	<b>7.0+/-3.1</b>
Positive Control AEPCb	<b>1.172</b>	<b>40</b>	<b>0.98</b>	<b>1.15+/-0.55</b>

**Comments**

Foetal type AChR reconstituted with 0.7 mL reconstitution buffer for AChR

Adult type AChR reconstituted with 0.5 mL reconstituted foetal type AChR

MAb-Biotin reconstituted with 2.25 mL reconstitution buffer for MAb-Biotin

- Incubation (i) AChR/Samples Temp. +4 °C Time: 18hrs (16-20 hrs.)  
(ii) Samples Temp. +22 °C Time: 1hr (1 hr 500 shakes/min)  
(iii) MAb-Biotin Temp. +22 °C Time: 1hr (1 hr 500 shakes/min)  
(iv) SA-POD Temp. +22 °C Time: 30' (30 mins 500 shakes/min)  
(v) TMB Temp. +22 °C Time: 30' (30 mins dark)

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 performed by: R.Price  
Signature: *R Price*  
Position: Principal Scientist  
Date: 23 Feb 2023

Authorised by: *DR G Flood*  
Signature: *G Flood*  
Position: HEAD OF QC  
Date: 4<sup>th</sup> APR 2023