

# PELICRM<sub>197</sub>®

# VACCINE DEVELOPMENT JUST GOT A LITTLE EASIER

The only CRM197 you can buy used in global marketed vaccines

- The highest quality research and GMP grade CRM197 available, verified by independent analysis<sup>1</sup>
- Research and cGMP grade recombinant CRM197 carrier protein available, from milligrams to kilograms
- Drug Master File or equivalent information for international regulatory filings available for GMP customers
- Cost-effective solution for sourcing critical material for vaccine development and commercialization
- Manufacturing process validated through WHO pre-qualification of Pneumosil®

## CONSISTENT. SCALABLE. COMPLIANT.

The PeliCRM197® carrier protein is a recombinant, soluble CRM197 produced in *Pseudomonas fluorescens* using the Pfenex Expression Technology® platform.

Ideal for conjugate vaccine development, PeliCRM197 has been used in other applications such as Alzheimer's, immuno-oncology, and even anti-opioid product candidates. For over 10 years PeliCRM197 has been the field standard where the highest quality and consistency in CRM197 matter the most: your product.





## ANTI-IL-4 CONJUGATE VACCINE PREPARED WITH PRIMROSE BIO'S PELICRM197® IS MORE IMMUNOGENIC THAN KLH ANALOG

#### Background

Anti-interleukin 4 (IL-4) conjugate vaccines consist of IL-4 chemically coupled to a carrier protein. Immunizations with these vaccines, in combination with an adjuvant, elicit the production of polyclonal anti-IL-4 neutralizing antibodies in mice.

We aimed to evaluate two widely used carrier proteins, namely Primrose Bio's PeliCRM197® (a non-toxic diphtheria toxin mutant) and KLH (keyhole limpet hemocyanin), by manufacturing one vaccine with each carrier protein and comparing their immunogenicity in mice.

#### Methodology

- 1. BALB/c mice received four intramuscular injections of murine IL-4 conjugate vaccine (prepared with PeliCRM197 carrier protein or KLH) or PBS, all emulsified with a squalene oil-in-water adjuvant.
- 2. Blood collections were performed before dosing and at days 39, 60 and 120.
- 3. Serum samples of immunized mice were assessed for the presence of anti-mulL-4 antibodies by ELISA and their mulL-4 neutralizing capacities (NCSO) evaluated in a proliferative cellular bioassay using CTLL-2 cells.

#### Conclusion

These results indicate that the PeliCRM197 carrier protein is superior to KLH in mulL-4 conjugate vaccines, in both the quantity of anti-mulL-4 antibodies produced (antibody titers) and their quality (neutralizing capacities).

#### **Key Results**

In the group receiving the vaccine prepared with PeliCRM197 carrier protein (mulL-4-CRM197), anti-mulL-4 antibodies were detected in all mice (10/10), at all timepoints postimmunization, with a peak of the response at day 60 (median titer: 14364 dil-1).

In mice immunized with the vaccine prepared with KLH (mulL-4-KLH), the overall levels of anti-mulL-4 antibodies produced were weaker, with a peak of the response at day 60 (median titer: 7933 dil-1).

In this group, some mice (3/10) failed to produce anti-mulL-4 titers at all timepoints post-treatment. As expected, no mulL-4 binding antibodies were detected before dosing, or in the PBS control group at all timepoints.

The neutralizing capacities of the anti-mulL-4 antibodies were stronger in the group of mice immunized with the vaccine prepared with PeliCRM197 carrier protein versus KLH, with a greater number of responder mice at all timepoints post immunization.



#### BIOASSAY NEUTRALIZING CAPACITIES

	MUIL-4-CRM197				MUIL-4-KLH				PBS			
	DO	D39	D60	D120	DO	D39	D60	D120	DO	D39	D60	D120
RESPONDERS (NC50 > 200 DIL-1)	0/10	5/10	7/10	9/10	0/10	2/10	4/10	0/5	0/5	0/5	0/5	0/5



#### Contact

To learn more, please reach out to partnering@primrosebio.com

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