primrose bio

# PELICRM197®

# 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[1]
- 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.


1. Hickey JM et al., Jour. Pharm. Sci., 2018 (1806-19)

CASE STUDY

# 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-muIL-4 antibodies by ELISA and their muIL-4 neutralizing capacities (NCS0) evaluated in a proliferative cellular bioassay using CTLL-2 cells.

## Conclusion

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

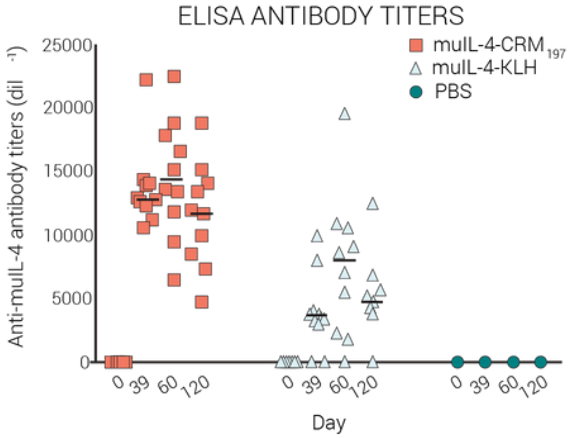
## Key Results

In the group receiving the vaccine prepared with PeliCRM197 carrier protein (muIL-4-CRM197), anti-muIL-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 (muIL-4-KLH), the overall levels of anti-muIL-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-muIL-4 titers at all timepoints post-treatment. As expected, no muIL-4 binding antibodies were detected before dosing, or in the PBS control group at all timepoints.

The neutralizing capacities of the anti-muIL-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 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | D0 | D39 | D60 | D120 | D0 | D39 | D60 | D120 | D0 | 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**
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