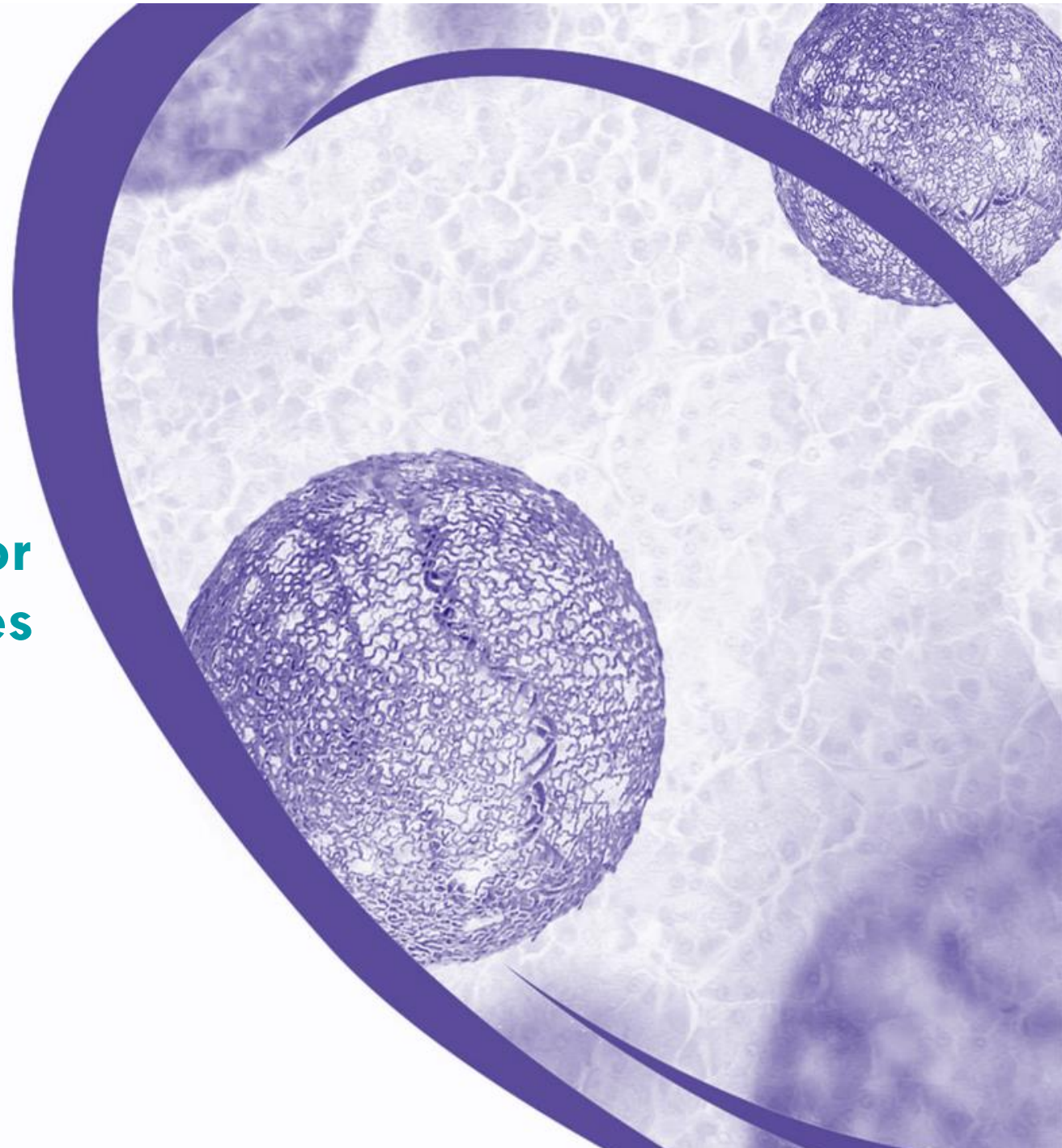




## A Novel DNA Vaccine Approach for Prophylactic & Therapeutic Vaccines

Khursheed Anwer, PhD., MBA

Viruses and Cells - Gordon Research Conference  
May 21-26, Barcelona, Spain



# PlaCCine- Next Generation Covid Vaccine Technology

Well-Suited to Address the Needs of Future Vaccines

## Known Limitations of Current Covid Vaccines

- Short-lived responses (4-6 months) requiring frequent boosts
- Low cross-reactivity to new variants
- Poor stability at workable temperatures
- Poor cytolytic T-cell responses limiting clearance
- Antigenicity causing adverse events
- Challenges in manufacturing & subunit mixtures

# PlaCCine – A Novel DNA Vaccine Platform

## Key Attributes

### Multi-valent

- Multiple antigens from a single plasmid
- Breadth of Immune Responses

### Durable Responses

- Durable antigen expression/exposure

### Novel Formulation

- Independent of virus, device, or LNPs

### Flexible Manufacturing

- “Plug & Play”

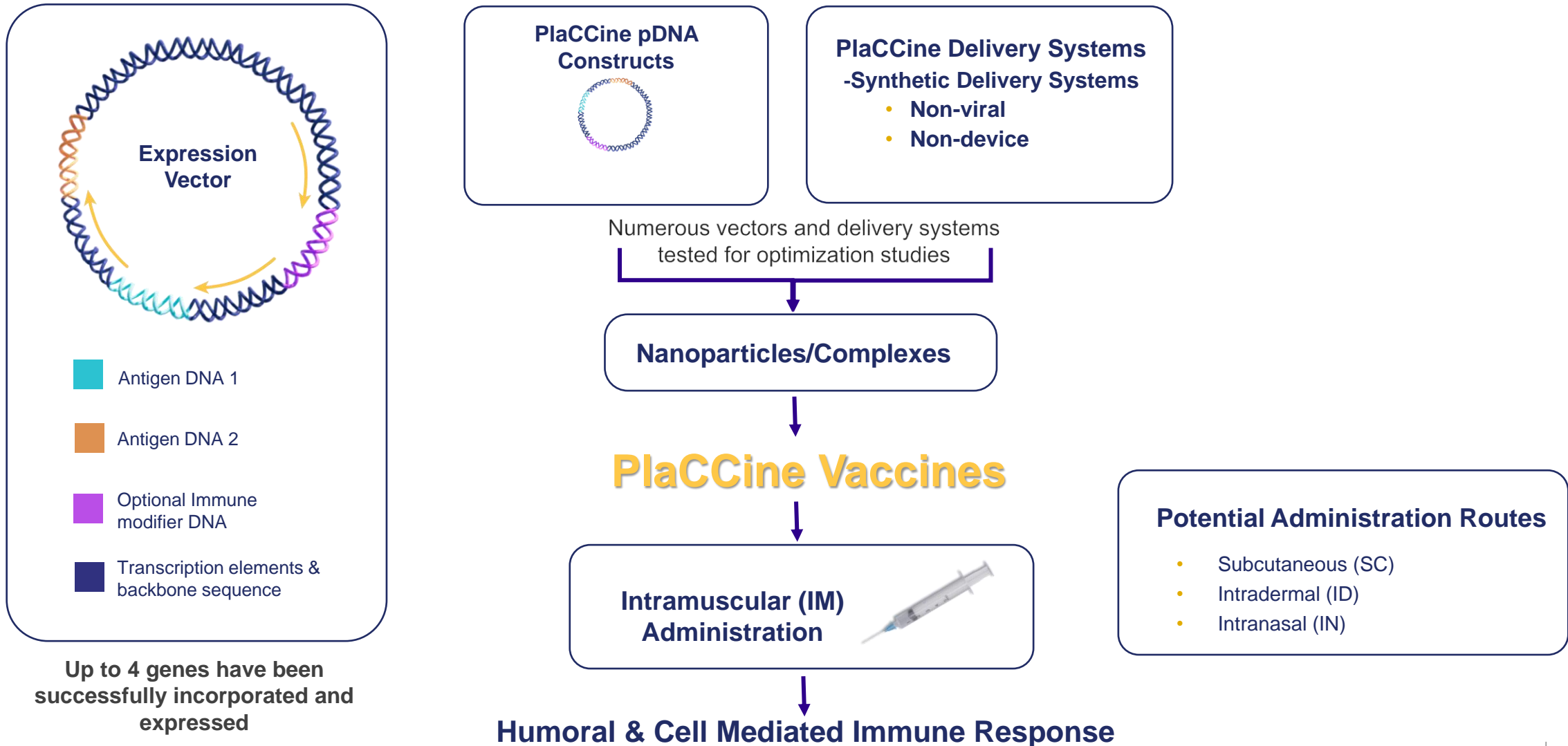
### Stable at $\geq 4^{\circ}\text{C}$

- > 9 months

***Durable and broad-spectrum immunity and immune quality, longer shelf-life at workable temperature and flexible manufacturing warrants PLACCINE as an alternative to current vaccine approaches***

# PlaCCine Technology Platform

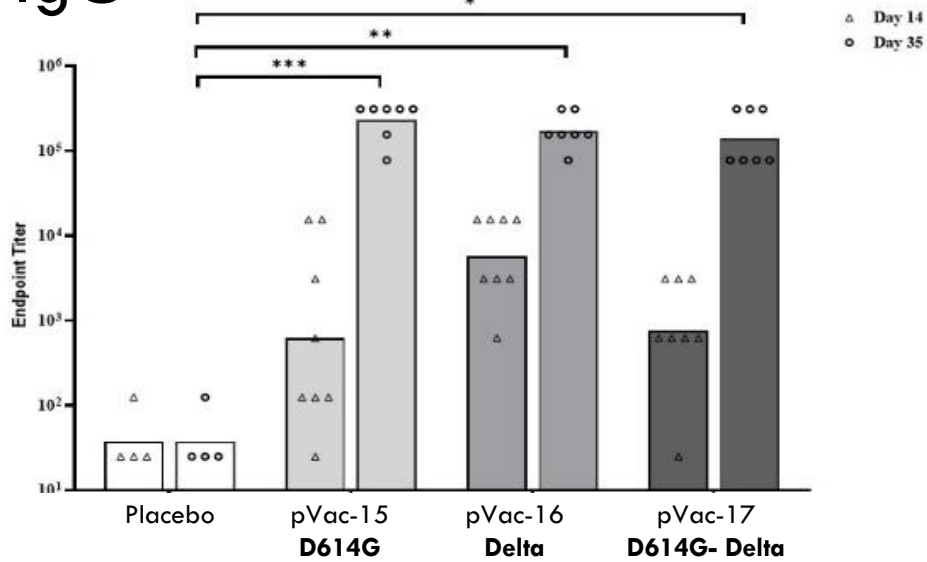
Multicistronic or Single Antigen Vector Formulations Independent of Virus or Device



# Evidence of Immunogenicity of Prototype PlaCCine Vaccines in Mice

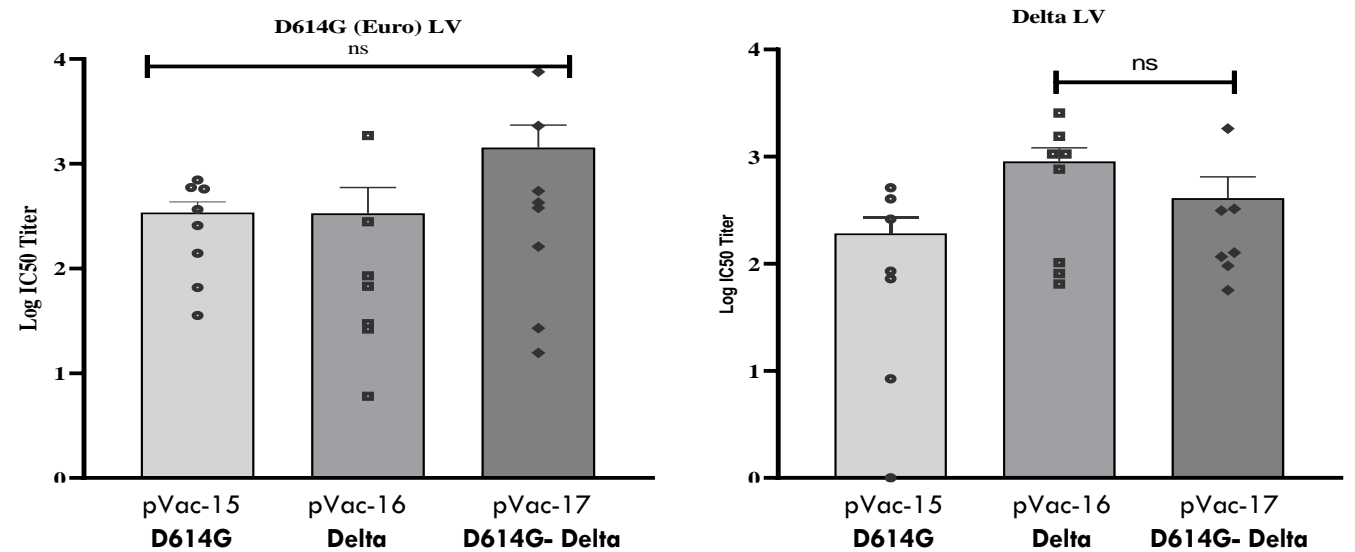
## Monovalent & Bivalent Spike Vaccines against Different SARS-CoV-2 Variants

IgG

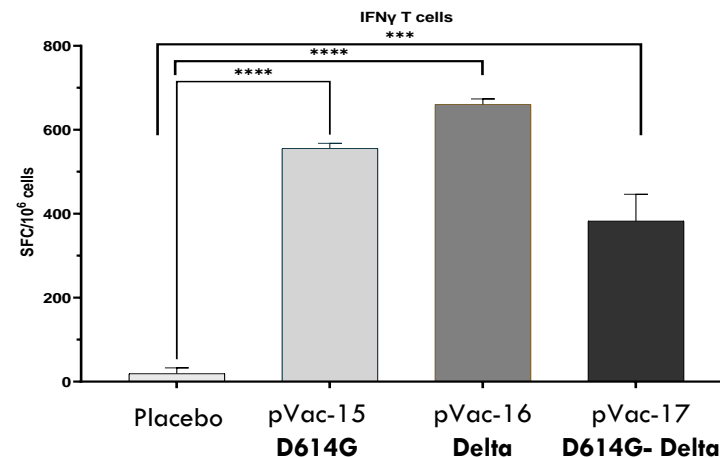


\* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\*\*  $P < 0.0001$

nAB



T-cell



Peptide pools were 15 mers overlapping by 11 aa that encompassed the S1 protein from Wuhan Strain.

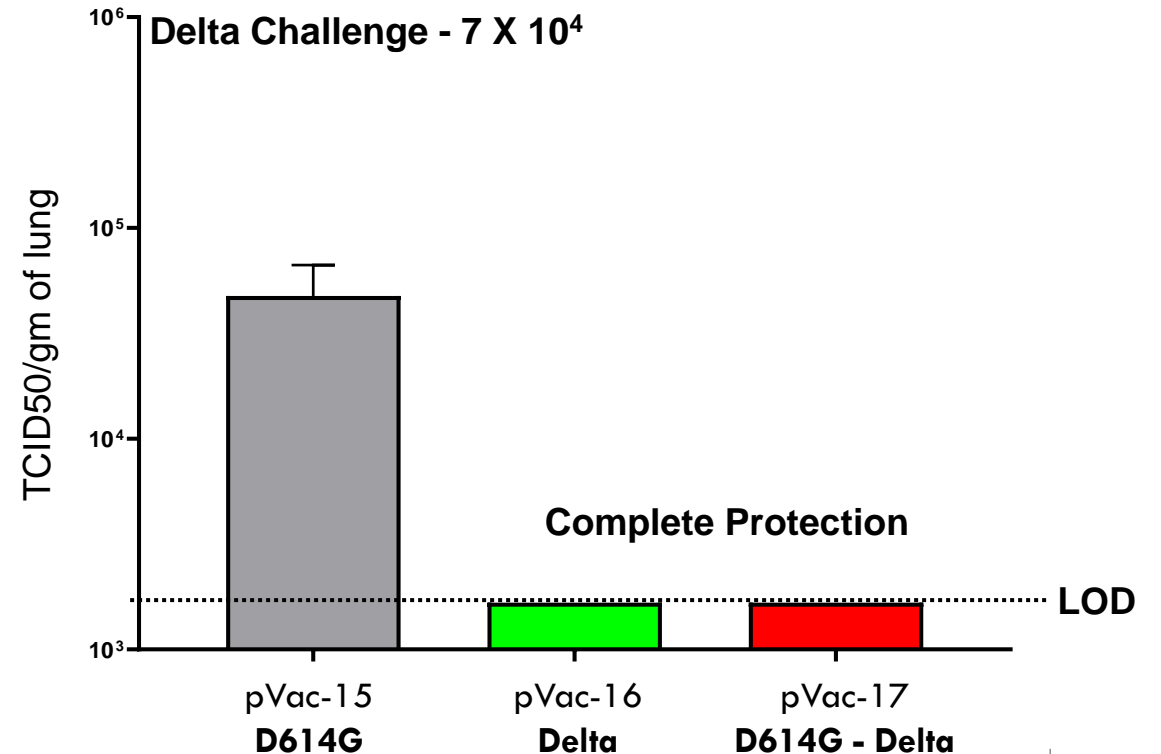
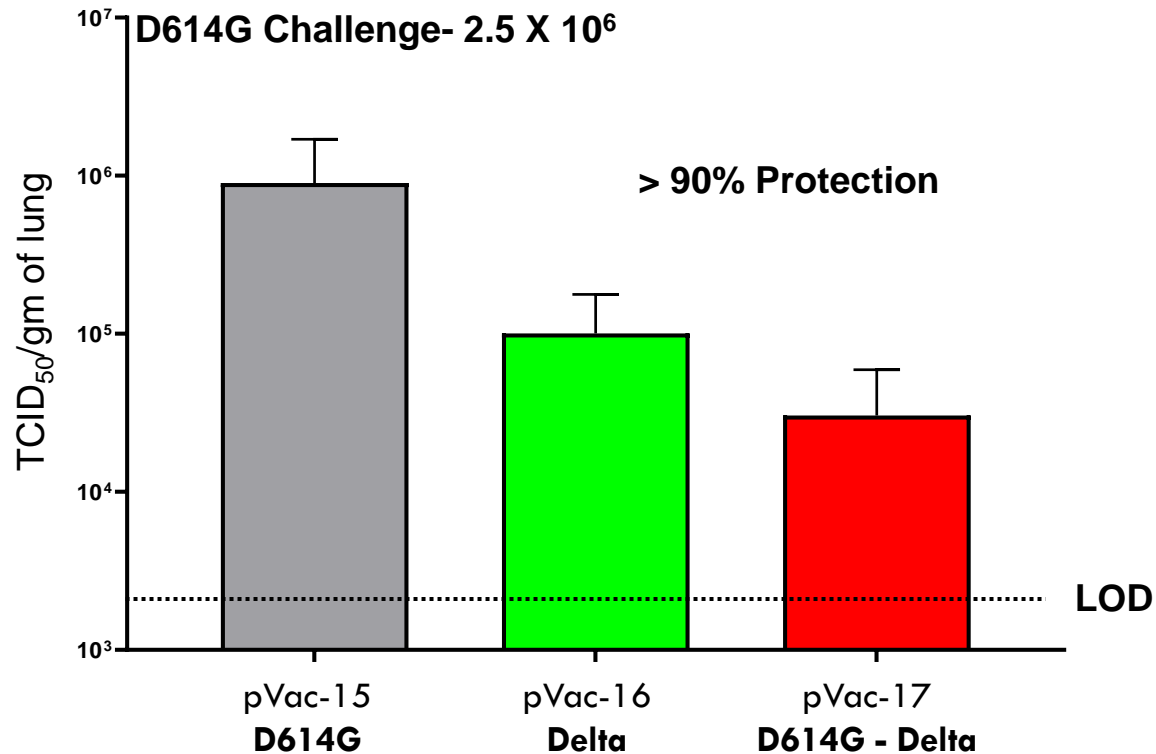
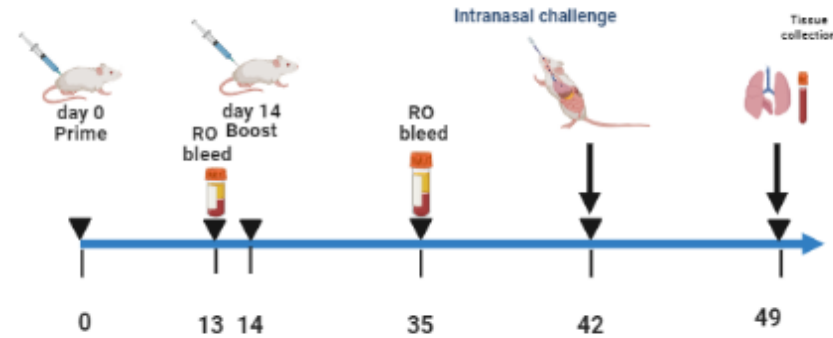
\* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\*\*  $P < 0.0001$

# Protection Against Viral Challenge in PlaCCine-Vaccinated hACE2:K16 Mice

## A Bivalent Vaccine Effective Against Multiple Spike Antigen Variants

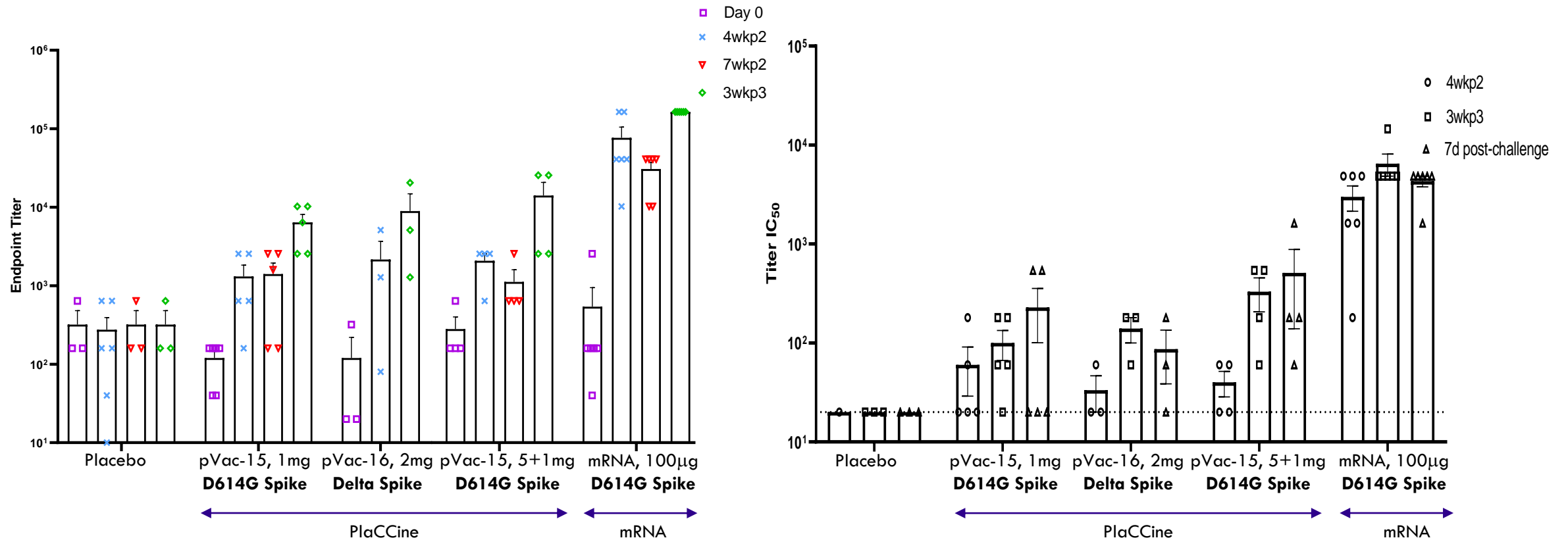
- Formulation: PlaCCine including an adjuvant
- Dose - 125 µg DNA

7 days post challenge



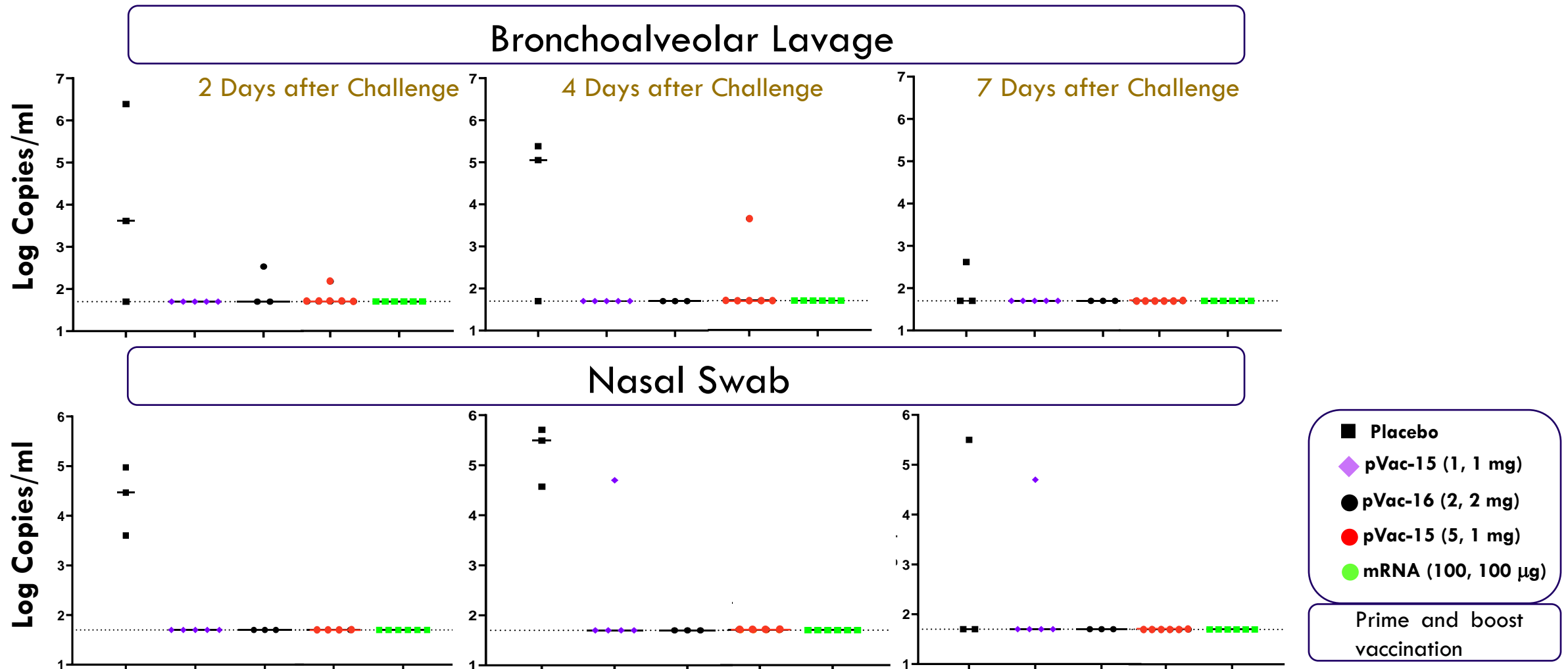
# Robust IgG and Neutralizing Antibody Responses to PlaCCine Vaccines in NHP

## Monovalent Vaccines against Different Spike Antigen Variants



# Complete Protection Against Viral Challenge is Comparable to mRNA Vaccine

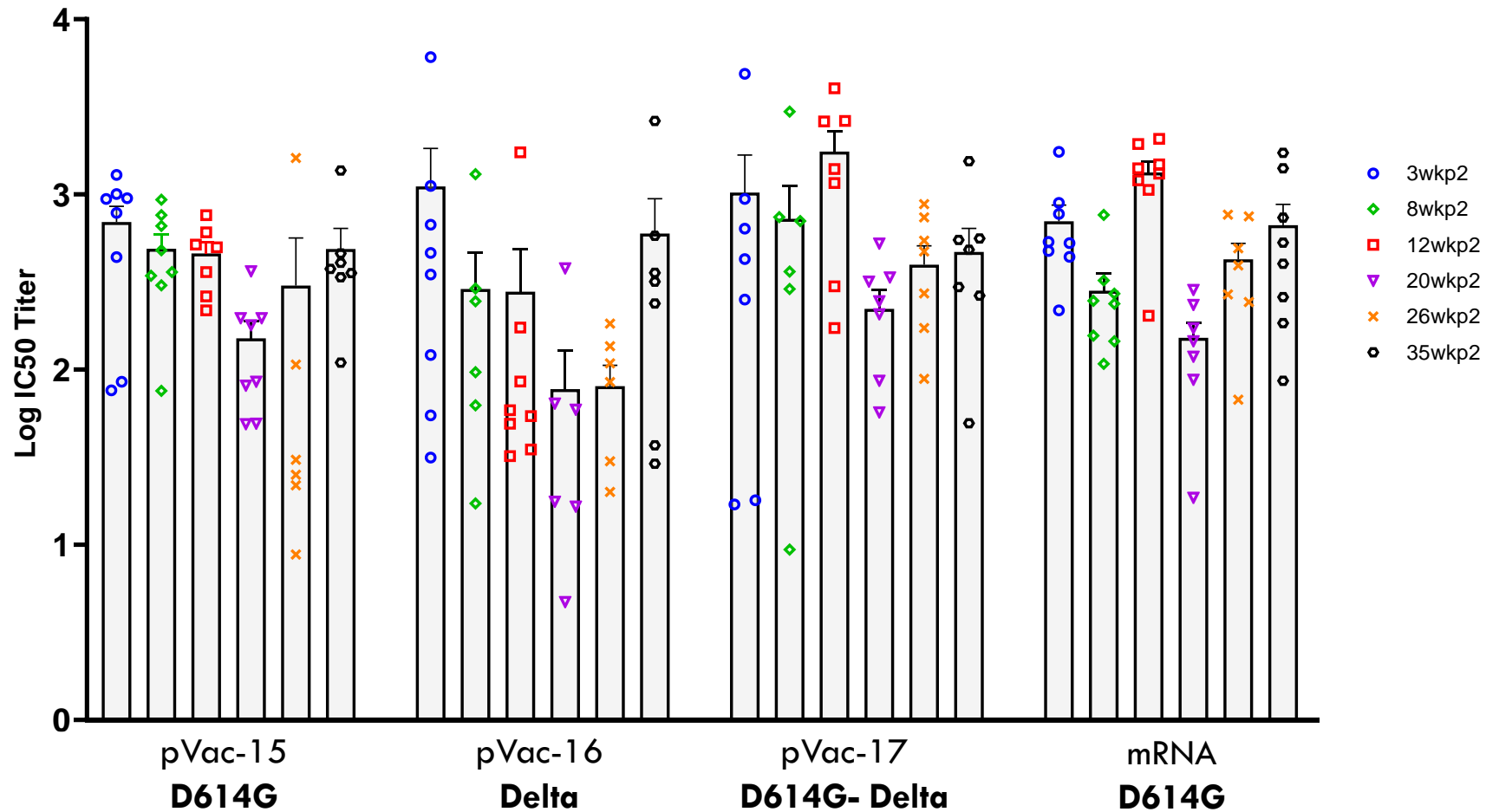
NHP data Challenge dose:  $1 \times 10^6$  TCID<sub>50</sub>





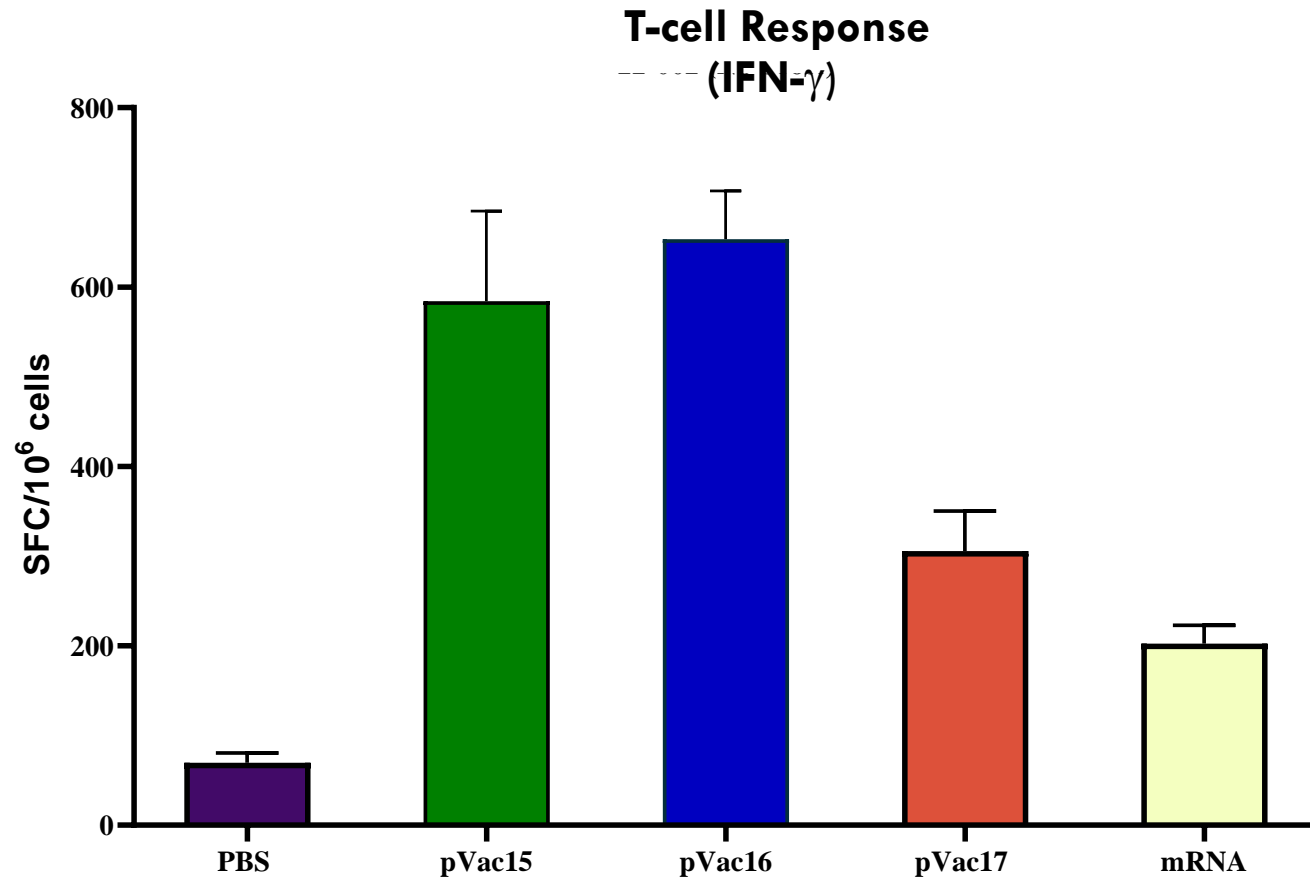
# Persistent nAB Titers for >14 months after a PlaCCine Covid Vaccine in Mice

## Key Feature Required in a Next Generation Vaccine



# Cytotoxic T-cell Response Detectable for >14-months in Mice

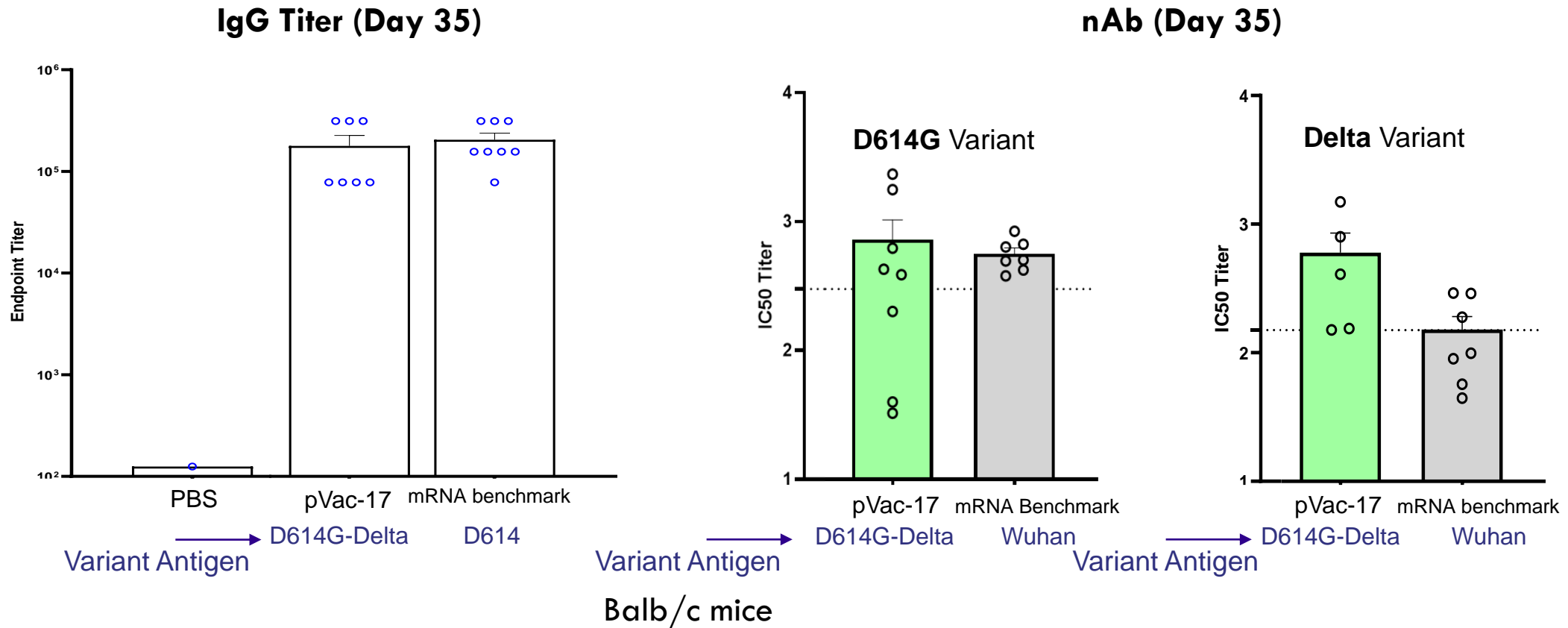
Potentially Durable Protection from Infection, Mice were immunized at days 0 and 14. Mice were sacrificed at week 60 to assess cellular immune responses.



Peptide pools were 15 mers overlapping by 11 aa that encompassed the S1 protein from ancestral strain

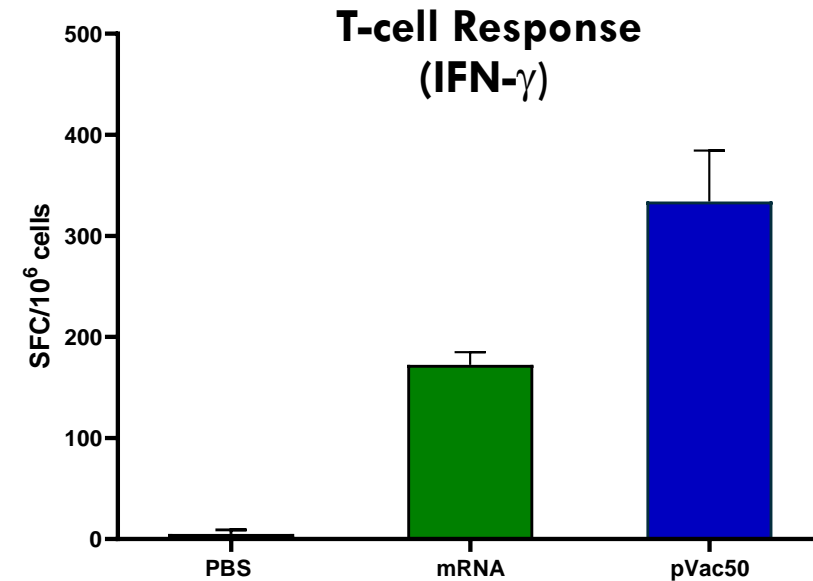
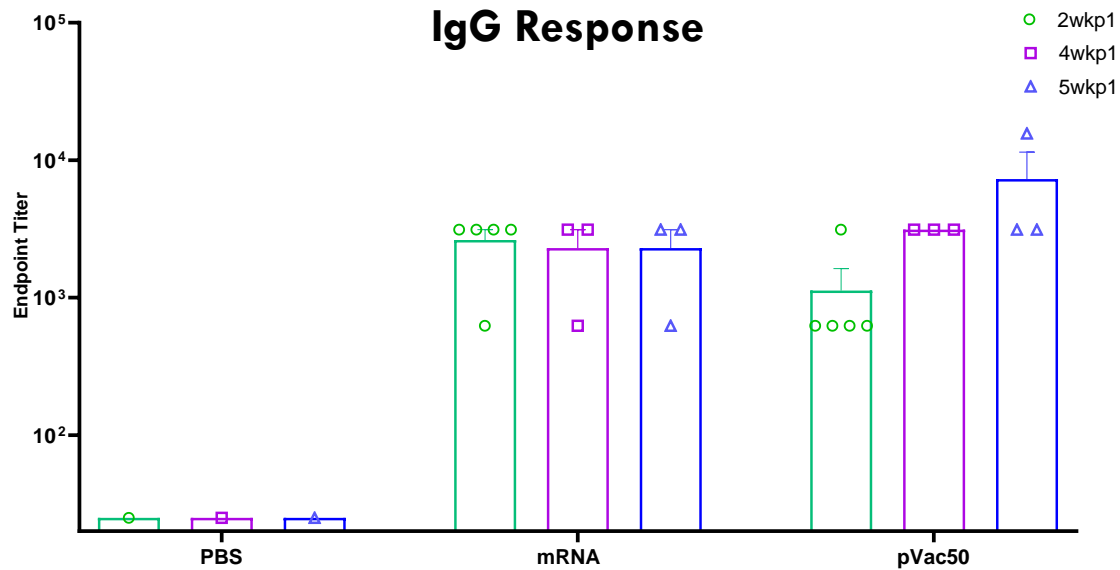
# Potent Cross-reactivity with Emerging Variant Following PlaCCine Vaccination

## Key Feature Required in a Next Generation Covid Vaccine



# Durable IgG & T-cell Responses after a Single Injection

## Favorable comparison to an approved mRNA Vaccine



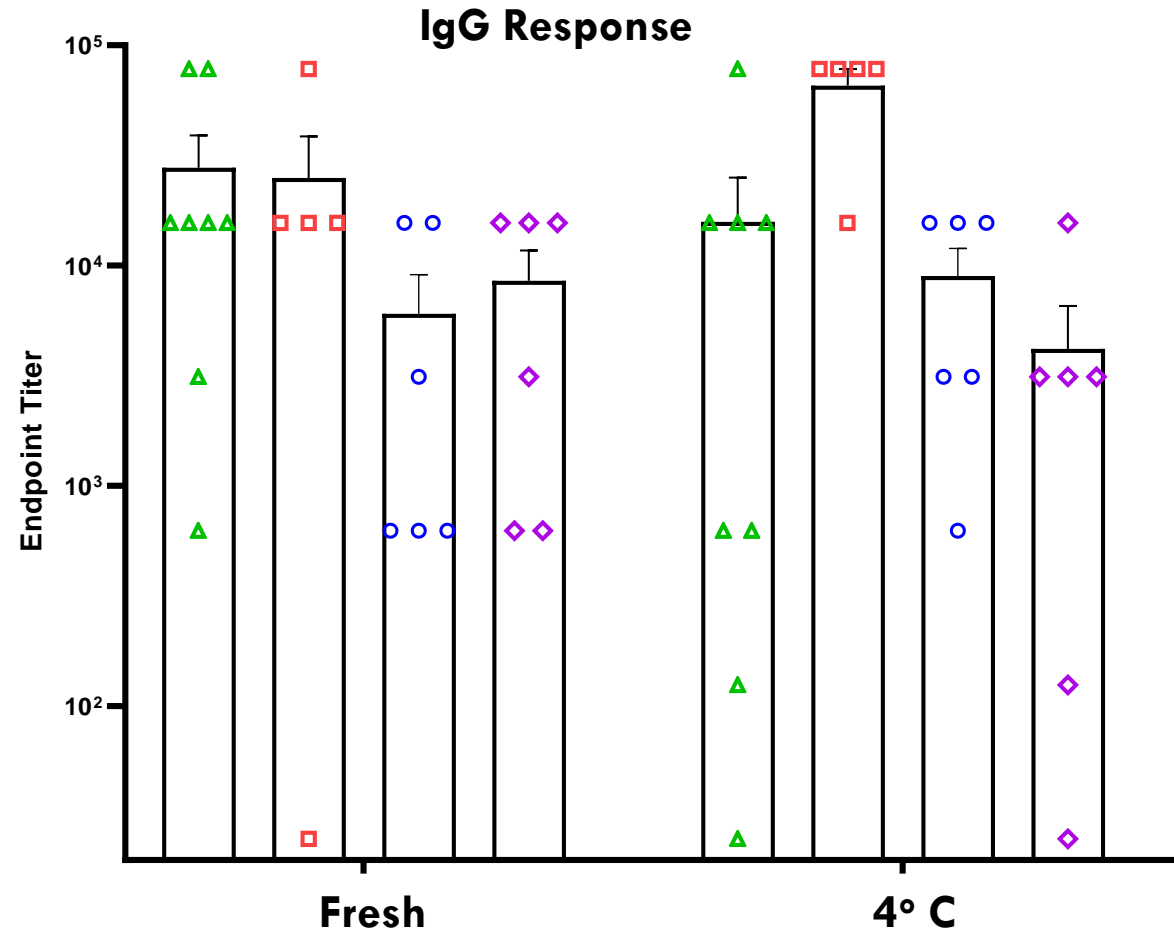
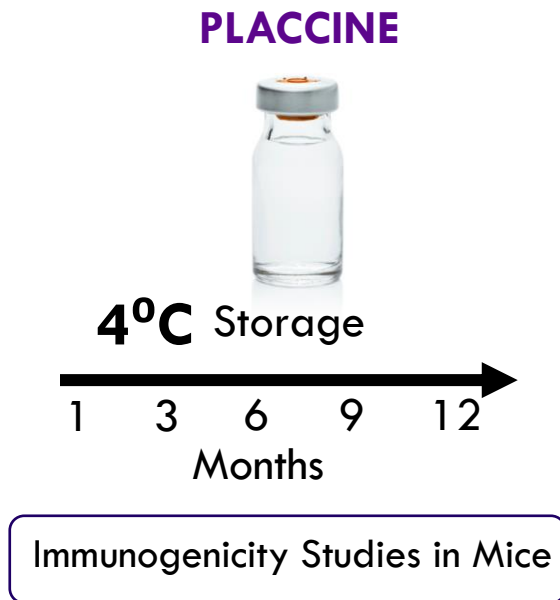
Peptide pools were 15 mers overlapping by 11 aa that encompassed the S1 protein from ancestral strain

Additional Studies on Immune Quality Comparison are in Progress

# > 9-month Shelf-life at 4°C; One-month at Room Temperature

Addressing Key Limitation of mRNA Vaccine Especially in Developing Countries

- Vector: pVac-17 (D614G-Delta)
- Formulation: PlaCCine



# PlaCCine: Next Generation Covid Vaccine Technology

## Well-Suited to Address the Needs of Future Vaccines

- Rapid design & development of vaccines to new variants or targets (3-months from receipt of new antigen sequence(s))
- DNA-based vaccines independent of virus, device or LNPs
- Robust humoral and cellular responses in NHP and mice
- Bivalent vaccines equally protective against multiple strains
- Long-lasting nAB responses and T-cell responses lasting >14 months in mice
- Stable at 4°C for >9 months
- Simple, rapid, and scalable manufacturing
- IND enabling studies in progress, IND in 4Q 2023
- First in-human clinical trial in 1Q 2024