# The key to gene therapy success

# Reliable testing of pre-existing anti-AAV immunogenicity

AAV vectors are vital for gene therapy, enabling the delivery of genetic material with precision. However, pre-existing immunity can neutralize them, hindering research. Pre-testing overcomes this barrier, ensuring reliable data and faster progress.

### The prevalence of pre-existing immunity

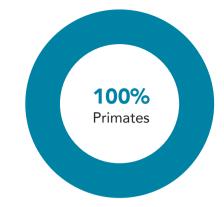
Pre-existing AAV immunity is a significant obstacle for gene therapy research.

Antibodies, present in much of the population neutralize therapeutic vectors, complicating both preclinical and clinical research.



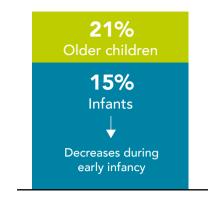
#### **Human prevalence**

Prevalence of pre-existing anti-AAV antibodies varies significantly by geography and serotype.1



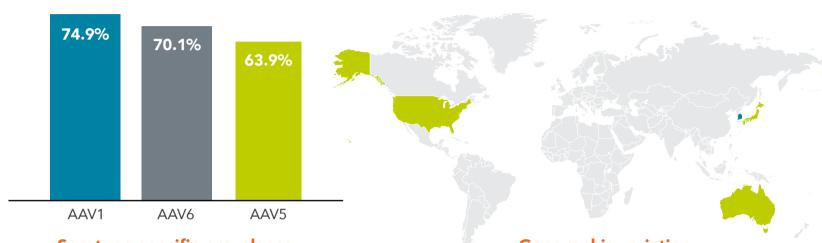
#### **Animal research**

Widespread prevalence in non-human primates makes preclinical research challenging.<sup>2</sup>



#### Age-related differences

Immunity starts at about 15% in infants, decreases during early infancy, and increases to 21% in older children and adolescents.3



#### Serotype-specific prevalance

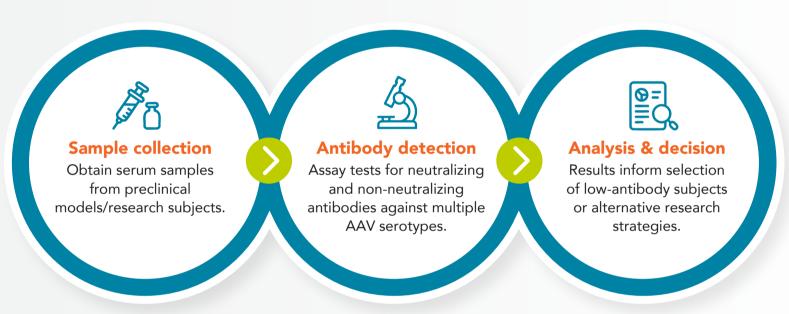
AAV1 has the highest prevalence, followed by AAV6 and AAV5.4

#### **Geographic variation**

Countries like South Korea report the highest prevalence across multiple serotypes, while Japan, Australia and the US exhibit lower rates.

These variations emphasize the need for robust pre-testing to prevent invalid models, wasted resources, and unreliable data, ultimately ensuring research accuracy and accelerating therapeutic progress.

# How AAV immunogenicity testing drives insights



Pre-testing detects immune barriers early, guiding model selection and strategy refinement. Identifying antibodies across serotypes reduces trial risks, accelerating therapeutic progress.

# The impact of undetected immunity

Failing to test for anti-AAV antibodies undermines research reliability, delays therapies and increases costs.



### **Invalid models**

Antibodies neutralize vectors, skewing results and compromising data reliability.



### **Resource waste**

Time, funding and biological materials are consumed with no actionable insights.

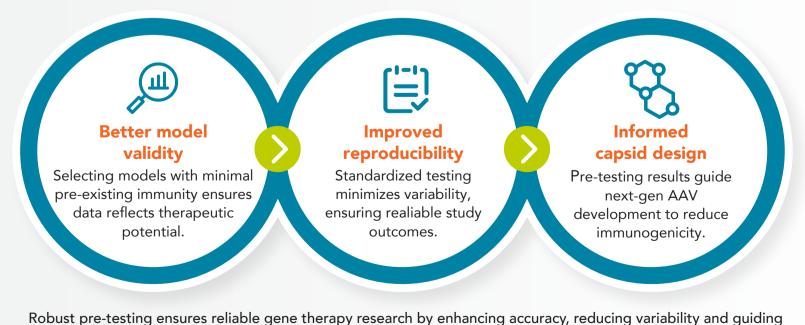


### **Delayed progress**

Inaccurate results cause rework, missed opportunities, and delayed development.

Each delay extends clinical trial timelines, increases costs, and slows patient access to life-changing treatments.

# Set the foundation for success



# capsid design. Addressing immunity early minimizes risks, optimizes resources, and accelerates therapeutic progress.

Pre-test with confidence. Explore tools to accelerate breakthroughs.

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peptide synthesis technologies provide high-quality peptides essential for research and development. Trusted by laboratories worldwide, we enable you from discovery through development to manufacture, driving progress in biotherapeutic drugs.

# References

- 1 https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2022.999021/
- 2 https://ashpublications.org/blood/article/134/Supplement\_1/3353/423771/Seroprevalence-of-Pre-Existing-Nabs-Against-AAV1-2?
- 3 https://journals.asm.org/doi/10.1128/cvi.05107-11?  ${\color{blue} 4 \ https://ashpublications.org/blood/article/140/Supplement \%201/10668/487952/Global-Seroprevalence-of-Neutralizing-Antibodies?}$

