NovaScan™: A Proof-of-Concept for Rapid Detection of Anti-AAV Neutralizing Antibodies

Accelerating patient screening and vector selection in AAV gene therapy

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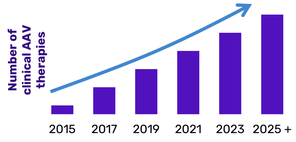
1 WHY AAV GENE THERAPY NEEDS BETTER SCREENING

AAV vector delivers a therapeutic gene → Target cell expression

AAVs are among the leading vectors used in gene therapy due to their safety profile and tissue tropism.

AAV-BASED THERAPIES ARE EXPANDING ACROSS MULTIPLE INDICATIONS

STRONG AND GROWING PIPELINE OF AAV THERAPIES



KEY CHALLENGES

Pre-existing anti-AAV antibodies can block vector delivery and reduce therapeutic efficacy.

2 WHY ANTI-AAV NAbS MATTER

NO NEUTRALIZING ANTIBODIES

AAV binds to the target cell and delivers the therapeutic gene

Successful transduction

WITH NEUTRALIZING ANTIBODIES

Antibodies bind to AAV and prevent cell entry and transduction

Blocked transduction

ANTI-AAV NEUTRALIZING ANTIBODIES MAY

- Prevent efficient transduction
- Reduce therapeutic efficacy
- Exclude patients from treatment
- Complicate vector re-administration

CLINICAL RELEVANCE

Even low levels of neutralizing antibodies may impact AAV transduction efficiency,

A significant proportion of the population carries pre-existing immunity against common AAV serotypes.[1]

1. Source: Various publications report seroprevalence rates ranging from 30% to >70% depending on AAV serotype and population.

3 CURRENT LIMITATIONS IN NAb DETECTION

CURRENT METHODS	KEY LIMITATIONS
Cell-based neutralization assays	• Time-consuming (2-5 days) • Require cell culture and specialized facilities
Reporter gene assays	• Complex workflow • Variability between labs
ELISA-based assays	• Limits functional relevance • Do not measure neutralization
Centralized testing	• Limited scalability • Logistical constraints and delays

UNMET NEED

There is a growing need for rapid, scalable and biologically relevant anti-AAV neutralization assays,

4 NOVASCAN™ TECHNOLOGY

Designed as ready-to-use kit format (reagents & multi-well plate), NovaScan™ simplifies neutralization assays. By replacing living cells with luminescent cell-like particles (CLPs) displaying targeted receptors, NovaScan™ recreates native AAV–cell interactions, bridging the gap between existing analytical methods.

1 AAV Particles

Native serotype or your engineered AAV particles.

2 Serum/AAV Incubation

Patient serum is incubated with AAV particles.

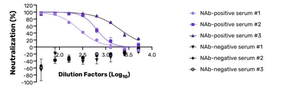
3 Interaction with CLPs - AAV Particles

Neutralization events → No Luminescent Signal

Low/No neutralization → Luminescent Signal

Neutralizing antibodies reduce the interaction and modulate the measurable signal.

4 Wash and Read



Quantitative neutralization results are obtained in a rapid and streamlined workflow.

~ 4 HOURS Total assay time | < 1 HOURS Hands-on time | HIGH THROUGHPUT Screening capacity | CELL-FREE & BIORELEVANT

5 FEATURES, ADVANTAGES & APPLICATIONS

Main Features

- **Native-like capsid presentation** — Reproduces authentic AAV surface architecture
- **Functional neutralization readout** — Measures the ability of antibodies to inhibit AAV-cell interaction
- **Simplified workflow** — No cell culture, rapid and easy to standardize
- **Potential adaptability** — Designed for multiple AAV serotypes and future expansion

NovaScan™ Vision: A Next-Generation Solution

Conventional Assays	NovaScan™ Vision
Multi-day workflow (2-5 days)	Rapid workflow (~4 hours)
Cell culture required	Simplified, cell-free workflow
High operational complexity	Automation friendly format
Variable reproducibility	Standardized and reproducible
Limited scalability	Scalable assay concept

Potential Applications

- **Patient screening** — Assess pre-existing immunity before AAV therapy.
- **Serotype selection** — Guide the choice of the most suitable AAV serotype.
- **Preclinical vector evaluation** — Support candidate selection and optimization
- **Translational research** — Enable studies in complex biological matrices.
- **Assay standardization** — Toward harmonized and reproducible testing.
- **Gene therapy development** — Accelerate and de-risk therapeutic programs.

NOVASCAN™: BRIDGING THE GAP

Combining the biological relevance of cell-based assays with the speed, simplicity and scalability needed for the next generation of AAV therapeutics.

RAPID | RELEVANT | SCALABLE

6 DEVELOPMENT ROADMAP

- **Phase 1** — Proof-of-concept assay design: Establish AAV-mimetic and targeted cell-mimetic systems and functional readout.
- **Phase 2** — Signal optimization & workflow refinement: Optimize assay conditions, increase robustness and streamline workflow.
- **Phase 3** — Validation with characterized sera: Test with well-characterized Nab-positive and Nab-negative serum samples.
- **Phase 4** — Multi-serotype expansion: Expand assay capabilities to additional AAV serotypes.
- **Phase 5** — Comparison evaluation: Compare performance with gold-standard cell-based neutralization assays and ELISAs.
- **Phase 6** — Beta testing with external partners: Evaluate usability, robustness and integration in partner workflows.
- **Phase 7** — Automation & translational deployment: Finalize automation, documentation and prepare for broader deployment.

7 SEEKING COLLABORATORS AND EARLY PARTNERS

ACADEMIC COLLABORATORS
For assay validation and translational studies

ACCESS TO CHARACTERIZED SERUM SAMPLES
Across diverse AAV serotypes and populations

BETA TESTING PARTNERS
To evaluate workflow integration and usability

GENE THERAPY DEVELOPERS
Interested in next-generation neutralization testing

CRO & TRANSLATIONAL PARTNERS
For comparative assay evaluation and standardization initiatives

Let's accelerate the future of AAV gene therapy.

Interested in partnering with us?

Scan the QR code to start the conversation!

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