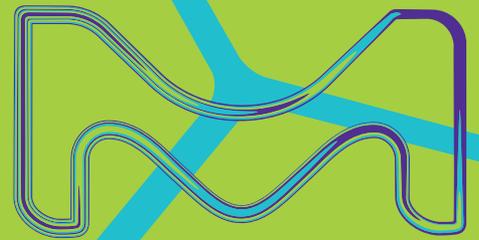
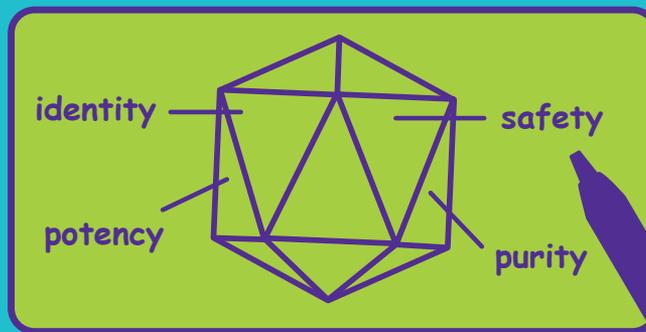
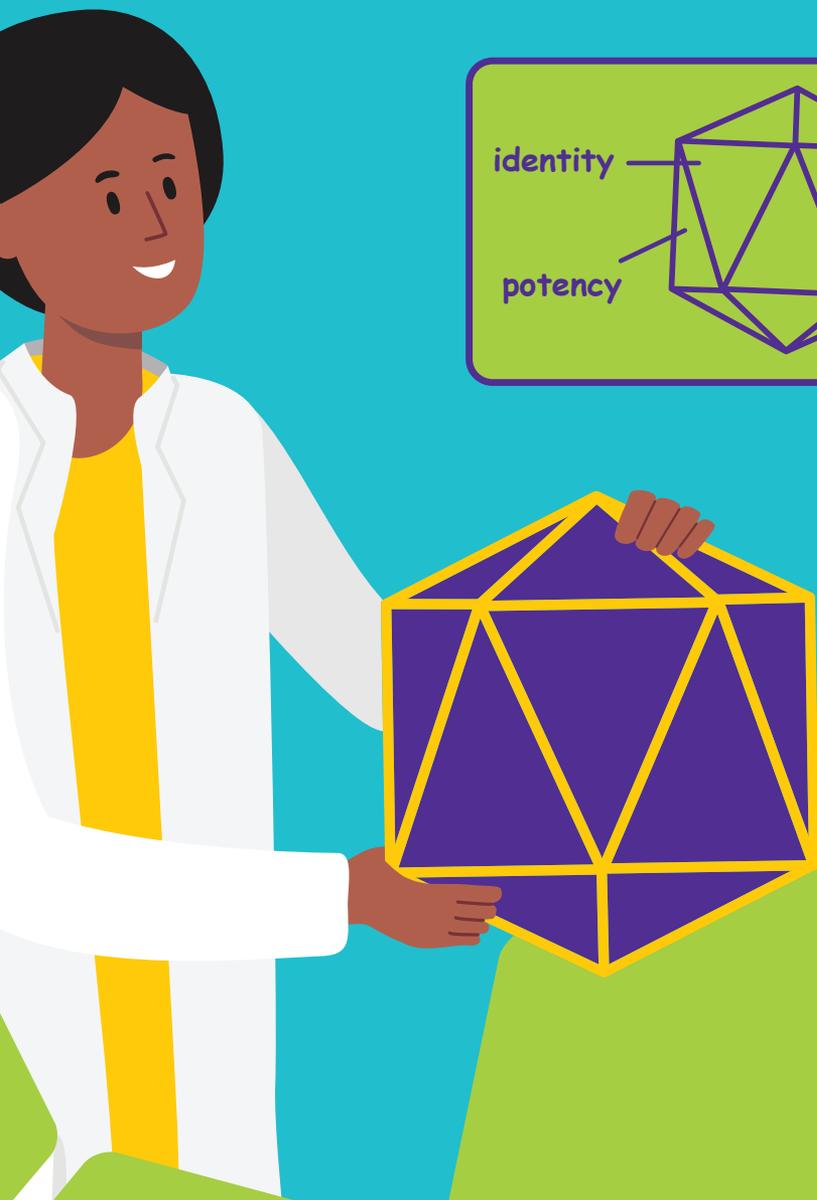


DRAW ON OUR EXPERIENCE

in biosafety testing and
characterization

Adeno-Associated Virus (AAV)



Adeno-Associated Virus (AAV) Biosafety Testing & Characterization

Cell & Gene Therapy Solutions

Biosafety testing and characterization for new products is essential as they emerge for clinical study. Both measures will help mitigate safety concerns and confirm product quality before these therapies are administered to patients. Our BioReliance® AAV testing services give you the confidence to get your products to market quickly and safely.

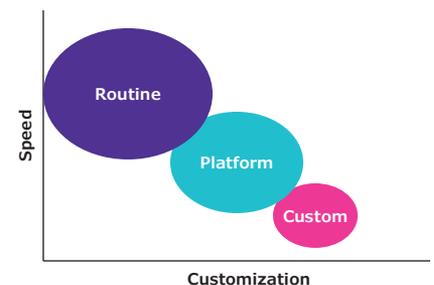
Balancing Speed and Customization

Many of the testing & characterization methods in existence today have been developed with traditional modalities and products in mind and don't always meet the needs of AAV developers. However, full method development and validation can add cost and extend timelines.

Using our platform assays allows AAV-based therapies to move through development and release testing faster. These assays are developed and validated to allow for customizing predefined components, e.g. positive control or target region, permitting a streamlined approach to validation.

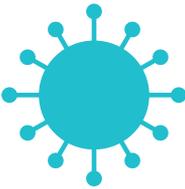
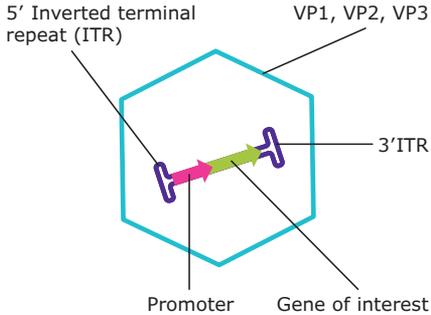
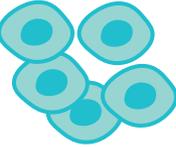
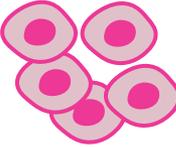
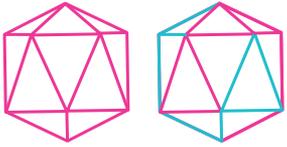
Our team of experts will consult with you to develop your specific testing program from our wide array of routine and platform assays to fully characterize and analyze your AAV vector's safety, identity, quality, purity, potency, and stability.

Employing a mix of routine and platform assays reduces time required for customization, accelerating your release testing.



The Unique Nature of AAV

A testing program can quickly become complex with the different AAV vector production systems. Draw on our experience with in-depth guidance on regulatory expectations to help guide your approach.

Production Systems				Vector Constructs	
Transient Transfection	Stable	Helper Virus	Baculovirus		
					
Plasmid	HeLa Cell Line	HSV			
					
HEK293 Cell Line			SF9 Cell Line	Serotypes (incl. hybrid/novel)	

Characterize and release your therapy with confidence

BioReliance® AAV Testing Services

GMP Testing of Starting Materials



Raw Materials

- Sterility
- Endotoxin
- Mycoplasma
- Adventitious viruses



Plasmids

- *E coli* cell bank characterization
- Plasmid characterization
 - Plasmid supercoiling
 - Concentration
 - Identity



Cell Lines & Virus Seeds

- Production
- Characterization
- Storage & Stability

GMP Release Testing

Biosafety Testing

- Bioburden
- Mycoplasma
- Mycobacterium
- Adventitious viruses*

Bulk Harvest

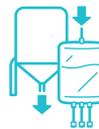


Characterization

- Identity*
- Infectious Titer*
- Empty/full capsid analysis

- Sterility
- Endotoxin
- Mycoplasma
- Replication competent AAV (rcAAV)
- Process & product-related impurities
 - Plasmids
 - Cell lines
 - Process reagents
 - Encapsidated contaminants

Drug Substance



- Identity*
- Variant & sub-population detection
- Infectious, genomic & capsid titer*
- Potency: expressed protein, function
- Purity of capsid proteins
- Empty/full capsid analysis

- Sterility
- Endotoxin

Drug Product



- Identity*
- Variant & sub-population detection
- Infectious & genomic titer*
- Potency: expressed protein, function
- Aggregation
- Physico-chemical characteristics
- Capsid protein characterization

*Platform Methods

Stability Testing & Storage



Custom designed programs that meet ICH guidelines, and help you understand the affects of environmental conditions - temperature, humidity, light, and container interactions - on your therapy.

Viral Clearance Studies



It is important to the overall viral safety of the AAV product to demonstrate the manufacturing process' capacity to inactivate or remove potential contaminating viruses through a viral clearance study. We will work closely with you to design a custom study that evaluates the clearance potential of specific purification steps unique to the manufacturing process of your AAV vector.

BioReliance®

Pharma & Biopharma
Manufacturing &
Testing Services

14920 Broschart Rd
Rockville, MD 20850 USA

[EMDMillipore.com/BioReliance](https://www.emdmillipore.com/BioReliance)

Draw on our Experience



Acceleration

The **optimal balance between speed and customization** will give you the confidence to get products to market quickly and safely



Expertise

Our R&D team is **continuously innovating** to optimize existing assays and establish new platform assays that can be tailored to meet your needs



Flexible Approach

Client-specific testing programs utilize a unique set of pre-developed assays, customizable to your specifications, and will help you **meet your critical development timelines**



Proven Results

Our cell and gene therapy assays have been included in regulatory filings with various agencies worldwide

Learn more about our testing solutions for cell & gene therapy programs:

[emdmillipore.com/gene-therapy-testing](https://www.emdmillipore.com/gene-therapy-testing)

or contact one of our experts to get started today:

info@bioreliance.com

© 2020 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. MilliporeSigma, the vibrant M, and BioReliance are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

MS_BR6869EN Ver. 0.0
30798
11/2020