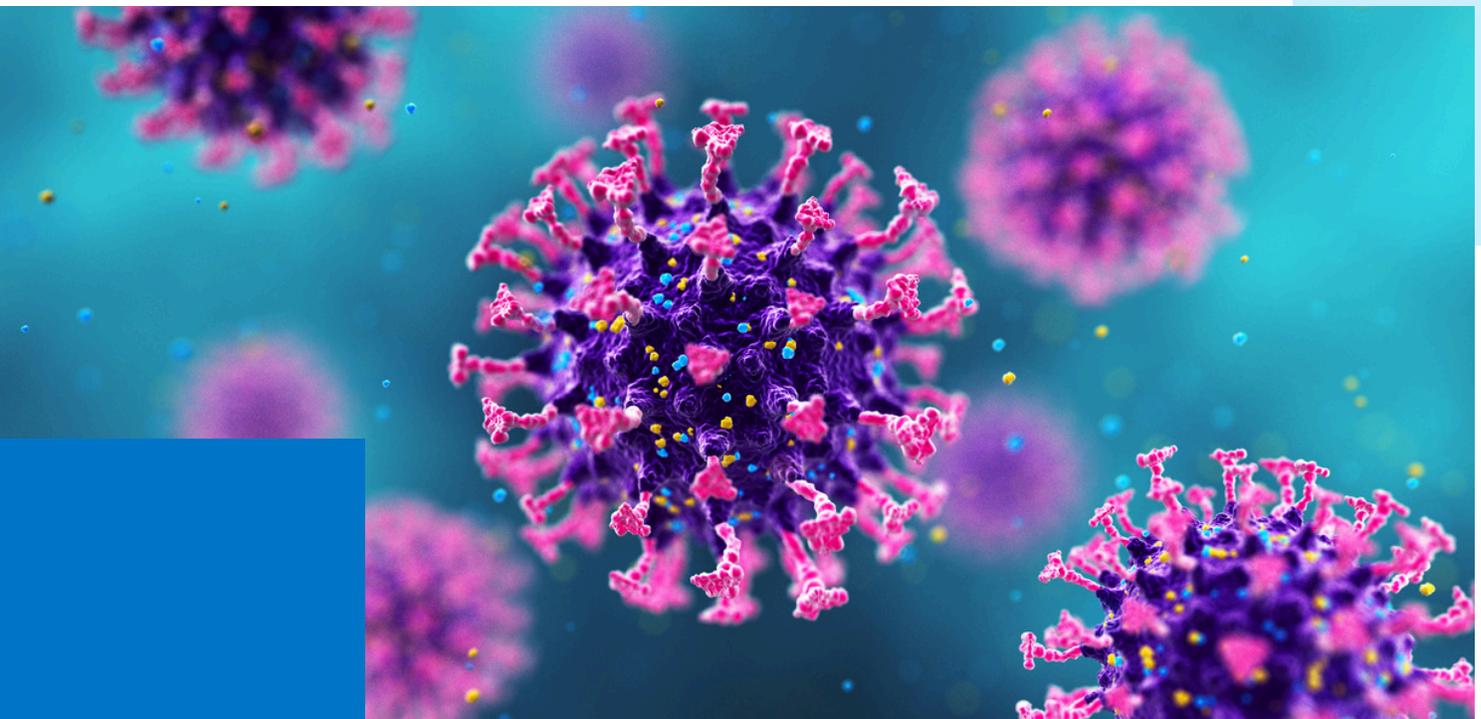




Adeno-Associated Virus (AAV) Vector

Lot Release Package

As of October, 2025



AAV Vector Lot Release

Below is our standard testing package for AAV Vector lot release. All testing is executed by Minaris Advanced Testing in full cGMP compliance to inform your downstream needs quickly.

Category	Assay Type
Vector-Specific Release Tests	Titer (genome, infectivity, particle)
	Potency assay
	Transgene sequencing
	Capsid identity
	Ratio of empty to full particles by AUC
Adventitious Agents	Sterility
	Bioburden
	Mycoplasma
	In vitro adventitious virus
	Replication competent Adenovirus
	Replication competent AAV
	Endotoxin
	Mycobacteria
	PCRs for specific viruses
	9CFR for bovine, porcine, or equine viruses
	Transmission electron microscopy (TEM)
Residuals	Residual plasmid DNA (E1a, 18s, kanamycin, SV40 large T, VSV-G)
	Residual host cell protein and DNA (including sizing)
	Process-related residuals (e.g. helper viruses, BSA)
General Characteristics	Color/appearance/sub-visible particles
	pH/residual moisture/aggregates
	Osmolality/extractable volume

Our team is also well versed in custom assay development, transfer and validation and can support your custom GOI PCR and titer assays to compliment this package.

ABOUT US

Enabling the Future of Medicine

With more than 40 years of bioanalytical testing experience, Minaris Advanced Testing has supported 140+Biologics and Advanced Therapy clients and understands the criticality of timely lot release testing.

We have provided consistent and reliable testing for biologics including more than 50 commercial lot release programs.

Dedicated, Modern, Testing Facility

Our expansive campus at the Navy Yard in Philadelphia, PA boasts a new 140,000 square foot facility which was designed for purpose and is completely dedicated to our testing business.

The facility, called Rouse 400 or R400, has proven regulatory success with the EMA, TGA, Health Canada and FDA.

Visit www.minaris.com to learn more or request a quote.



GET IN TOUCH WITH EXPERTS

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minaris-advanced-therapies

THANK YOU!

Our extensive team of customer-focused project managers and scientific experts look forward to supporting your lot release and serving your target patient population.

