



## Adeno-Associated Virus (AAV) Testing

Adeno-Associated Virus (AAV) vectors play a crucial role in gene therapy due to their efficient gene delivery, versatility, long-term expression, low immunogenicity, and safety. Avance Biosciences supports AAV manufacturers by performing essential characterization assays for identity, purity, potency, and more.

Critical Quality Attributes	Assay	Description
Identity	Sequence Confirmation	Verify the sequence of AAV genome by Sanger Sequencing or NGS
	Capsid Identity	Confirm the identity of the AAV capsid serotype using ELISA or Jess or CE-SDS
	Long Read NGS	Sequence AAV genome by long read Nanopore sequencing
Purity	Capsid content (empty/full ratio)	Measure the percent of full to empty capsids by CE-SDS
	Capsid purity Analysis	Assess the purity of AAV capsid proteins using CE-SDS or Jess
	Residual Plasmid DNA	Quantify residual plasmid DNA using qPCR or ddPCR
	Residual host cell DNA	Quantify residual host cell DNA using qPCR or ddPCR
	Residual Host Cell Protein	Determine presence and quantitate residual host cell proteins by ELISA
Potency	Vector Genome Titer	Quantify the number of vector genomes using qPCR or ddPCR
	Cell-based assay	Develop cell-based assay for evaluating post-transduction endpoint (mRNA expression, protein production)
Genetic Integrity	Vector Genome Integrity	Confirm the integrity of the vector genome using QPCR/ddPCR or Bioanalyzer or CE

Critical Quality Attributes	Assay	Description
Safety	Endotoxin	USP <85>
	Bioburden	USP <61>
	Sterility	USP <71>
Other	pH	USP <790>
	Osmolality	USP <791>

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