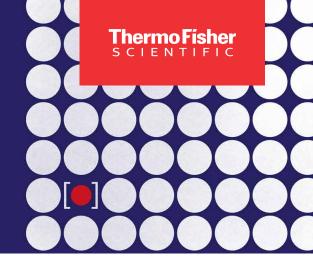
# Pharmaceutical analytics for cell and gene therapy development



## Quickly evaluate and monitor your lentivirus (LV) and adeno-associated virus (AAV) production processes

Monitoring the purity, safety, and potency of pharmaceutical products during manufacturing is crucial—testing accuracy and time-to-results are critical. For cell and gene therapies in particular, every minute counts, and any delay can directly affect the therapeutic outcome.

Thermo Fisher Scientific's portfolio of Applied Biosystems™ SEQ analytical testing solutions employs rapid, highly sensitive molecular methods to efficiently detect impurities, identify contaminants, and quantify titer. Delivering same-day results, often in less than 5 hours, our analytical solutions can help meet regulatory compliance for characterization and lot-release testing.

#### Benefits:

- Analyze your product throughout the development process to help ensure product safety and efficacy
- Leverage a fully integrated solution including kits, instruments, and software for analysis to save time, free up development resources, and provide more consistent results to help therapies get released quickly
- Helps ensure that the level of impurities, such as residual DNA or other residual host contaminants, meets quality and regulatory requirements
- Our products are based on rapid molecular methods (real-time PCR, digital PCR, and DNA sequencing), enabling high sensitivity, fast results, and increased throughput including the option to deploy an automated process for a large variety of tests

#### Product safety:

- Mycoplasma testing
- · Adventitious virus testing
- Environmental testing (cleanroom testing)

#### **Product purity:**

• Residual DNA quantitation

#### Product potency:

 Lentivirus quantitation and characterization



**DNA** sequencing

Real-time PCR



Thermo Fisher provides solutions for:



Bacterial identification



Fungal identification



Mycoplasma detection



Virus detection



Viral vector titer assays



Residual DNA quantitation



### Pharma analytics products for cell and gene therapy applications

	Upstream				Downstream		
	Analytics						
				- 11k			
	Plasmid development and production	Cell expansion	Plasmid transfection	Viral vector production	Purification	Formulation and filling	
						t-release sting	
Product characterization, safety, and environmental testing occurs throughout the workflow							
When testing occurs	Lot release of plasmid as raw material for viral vector production	Monitoring of raw materials and cell banks	Monitoring of raw materials and cell banks	At bulk harvest	During purification and at final lot release of bulk drug substance	Final product testing and continued monitoring	
Purity	Applied Biosystems™ resDNASEQ™ Quantitative E. coli DNA Kit (Cat. No. 4460366)  Applied Biosystems™ resDNASEQ™ Quantitative Plasmid DNA - Kanamycin Resistance Gene Kit (Cat. No. A50460)			quantitativ  • resDNASEQ™ Q DNA Kit (Ca  • resDNASEQ™ Q Baculovi (Cat. N  • resDNASEQ™ Qu Fragmen (Cat. N  • resDNASEQ™ Qua - Kanamycin Re	iosystems™ e DNA kits: uantitative HEK293 at. No. A46565) uantitative Sf9 and rus DNA Kit o. A47405) uantitative E1A DNA at Length Kit o. A51970) ntitative Plasmid DNA esistance Gene Kit o. A50460)		
Potency				Lentivirus Ph (Cat. No. Applied Biosyst Lentivirus Provi	ems™ ViralSEQ™ ysical Titer Kit . A52598) rems™ ViralSEQ™ ral DNA Titer Kit . A53562)		
Safety (AAV)	Applied Biosystems™ ViralSEQ™ Quantitative Sf-Rhabdovirus Kit (Cat. No. A50496)						
	Applied Biosystems <sup>™</sup> MycoSEQ <sup>™</sup> Mycoplasma Detection Kit (Cat. No. 4460626)						
Environment	Applied Biosystems <sup>™</sup> MicroSEQ <sup>™</sup> ID Purification Combo Kit (Cat. No. A35852)						