

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



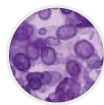
Thermo Fisher provides solutions for:



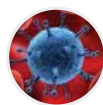
Bacterial identification



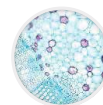
Fungal identification



Mycoplasma detection



Virus detection

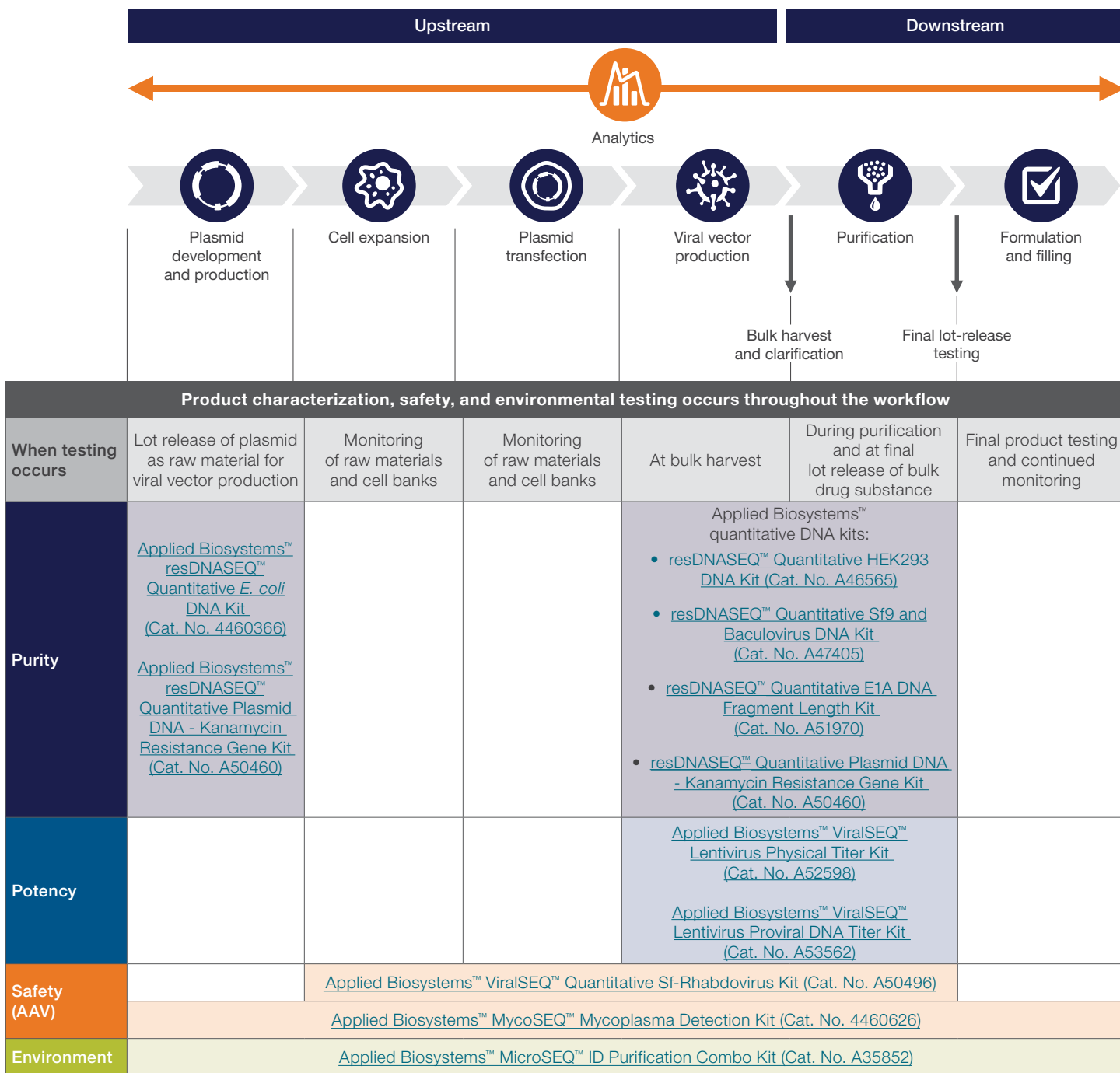


Viral vector titer assays



Residual DNA quantitation

Pharma analytics products for cell and gene therapy applications



Learn more at thermofisher.com/pharmaanalytics

applied biosystems