

Pharmaceutical analytics for cell and gene therapy development

Quickly evaluate and monitor your cell and gene therapy production processes

For cell and gene therapies, every minute counts, and any delay in production can directly affect the therapeutic outcome. Monitoring the purity, safety, and potency of pharmaceutical products during manufacturing is crucial, with testing accuracy and time-to-results being the cornerstones of a well-defined analytical strategy.

The portfolio of Applied Biosystems™ SEQ analytical testing solutions from Thermo Fisher Scientific 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
- Monitor the level of impurities, such as residual DNA or other residual host contaminants, and help ensure your product meets quality and regulatory requirements

Our products are based on rapid molecular methods, like real-time PCR (qPCR), digital PCR (dPCR), and DNA sequencing. They enable high sensitivity, fast results, and increased throughput—including the option to deploy an automated process for a large selection of tests.

Product safety:

- Mycoplasma testing
- Adventitious virus testing
- Sterility testing

Product potency:

- Viral titer quantitation

Environmental monitoring:

- Microbial detection and identification
- Sterility testing

PCR workflow for SEQ analytical testing solutions

Prepare sample

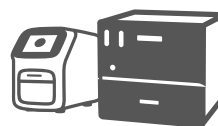


~2.5 hours

Set up reaction



Run instrument



Analyze data



Real-time PCR or digital PCR: <3 hours

Cell therapy solutions

Help swiftly and accurately safeguard your cell therapy products with our advanced testing solutions, providing trusted results in less than 5 hours.

Applied Biosystems™ MycoSEQ™ Plus Mycoplasma Detection Kit

- **Fast**—the qPCR-based workflow delivers actionable results in as little as 5 hours
- **Sensitive**—meets or exceeds the recommended regulatory guidance of 10 colony-forming units (CFU/mL) or 10 genome copies (GC/mL) for a variety of *Mycoplasma* species
- **Accurate**—a discriminatory positive control allows for differentiation between true mycoplasmas and accidental contamination



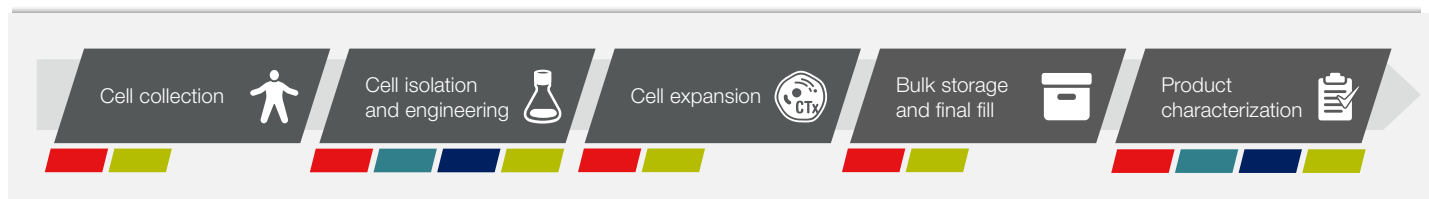
Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit

- **Fast**—delivers actionable results in as little as 5 hours, enabling quick detection of contaminants in raw materials and in-process byproducts
- **Efficient**—preserves precious sample material with single-well, multiplexed assay tests for bacterial and fungal contamination
- **Specific**—designed specifically for bacteria (16S rRNA) and fungi (18S rRNA), with no known cross-reactivity to in-process byproducts or sample matrix effects



Analytical solutions for your cell therapy workflow

Including experienced support from implementation through validation



Product safety Mycoplasma, viral, and microbial detection	Product quality Impurity analysis	Product potency Viral vector characterization	Environmental monitoring Microbial detection and ID
Mycoseq Plus Mycoplasma Detection Kit	resDNASEQ residual host cell DNA quantitation kits	ViralSEQ Lentivirus Physical Titer Kit	MicroSEQ Rapid Microbial Identification System
SteriSEQ Rapid Sterility Testing Kit*	resDNASEQ residual plasmid DNA quantitation kits	ViralSEQ Lentivirus Proviral Titer Kit	SteriSEQ Rapid Sterility Testing Kit*
ViralSEQ virus detection and quantitation kits		ViralSEQ dPCR AAV Titer Kit	

* The SteriSEQ Rapid Sterility Testing Kit is currently only recommended for in-process and raw material testing.

Gene therapy solutions

Maintain rigorous quality control in your gene therapy process without compromising on speed or precision. Our advanced testing solutions enable accurate results throughout the development workflow.

Applied Biosystems™ ViralSEQ™ lentivirus quantitation solutions

- **Sensitive**—designed against a conserved long terminal repeat (LTR) target for use across multiple stages of manufacturing
- **Specific**—seven-log dynamic range to titer yields across lots and batches without dilutions or optimizations
- **Quantitative**—allows measurement of viral particles and correlation of transducing activity (vector copy number and infectious viral titer) to help optimize your processes
- **Flexible**—available for both qPCR and dPCR



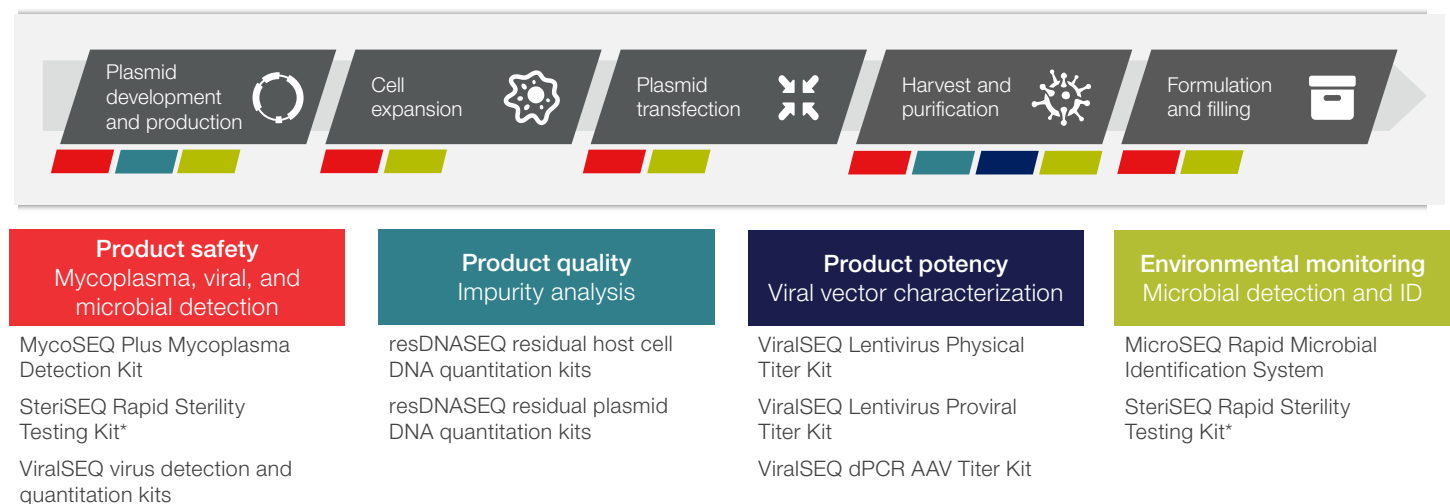
Applied Biosystems™ resDNASEQ™ Quantitative HEK293 DNA Kit

- **Rapid**—results in as little as 5 hours with optimized sample prep
- **Sensitive**—achieves a limit of quantitation as low as 0.3 pg for HEK293 DNA in your sample extract
- **Reliable**—designed to obtain results across multiple stages in the gene therapy manufacturing process
- **Flexible**—available for both qPCR and dPCR



Analytical solutions for your gene therapy workflow

Including experienced support from implementation through validation



* The SteriSEQ Rapid Sterility Testing Kit is currently only recommended for in-process and raw material testing.

Ordering information

Description	Cat. No.	
	qPCR	dPCR
MycoSEQ kit		
MycoSEQ Plus Mycoplasma Detection Kit	A55124	
SteriSEQ kit		
SteriSEQ Rapid Sterility Testing Kit	A57185	
ViralSEQ kits		
ViralSEQ Quantitative Sf-Rhabdovirus Kit	A50496	
ViralSEQ Lentivirus Physical Titer Kit	A52598	A59317
ViralSEQ Lentivirus Proviral Titer Kit	A53562	A59318
ViralSEQ dPCR AAV Titer Kit		A59364
resDNASEQ kits		
resDNASEQ Quantitative HEK293 DNA Kit	A46565	A59365
resDNASEQ Quantitative Sf9 and Baculovirus DNA Kit	A47405	A59319
resDNASEQ Quantitative E1A DNA Fragment Length Kit	A51970	A55852
resDNASEQ Quantitative Plasmid DNA - Kanamycin Resistance Gene Kit	A50460	
resDNASEQ dPCR <i>E. coli</i> DNA Kit		A57017
MicroSEQ PCR kits		
Fast MicroSEQ 500 16S rDNA PCR Kit, with protocol and quick reference card	4370489	
MicroSEQ Full Gene 16S rDNA PCR Kit, with protocol and quick reference card	4349155	
Fast MicroSEQ D2 Fungal rDNA PCR Kit, with protocol and quick reference card	4382397	
MicroSEQ sequencing kits		
MicroSEQ 500 16S rDNA Sequencing Kit, with protocol and quick reference card	4346480	
MicroSEQ Full Gene 16S rDNA Sequencing Kit, with protocol and quick reference card	4347484	
MicroSEQ D2 rDNA Fungal Sequencing Kit, with protocol and quick reference card	4347481	
Libraries and software		
MicroSEQ ID 16S rDNA 500 Microbial Library, v2019	A47134	
MicroSEQ ID 16S rDNA Full Gene Library v2.0	4371295	
MicroSEQ ID Fungal Gene Library, v2018	A47135	
MicroSEQ ID 16S rDNA 500 Supplemental Library, v2019	A47133	