

resDNASEQ Quantitative Plasmid DNA— Kanamycin Resistance Gene Kit

qPCR system for quantitation of residual plasmid DNA

- Multiplex assay that targets all kanamycin resistance (KanR) gene alleles common in bioproduction
- Highly specific quantitation through innovative DNA-free master mix
- Highly sensitive quantitation using proven Applied Biosystems™ TaqMan® real-time PCR technology
- Reproducible results with manual and automated sample preparation, optimized for quantitative recovery from common gene therapy sample matrices
- Easy to use, with results in under 5 hours
- Integrated sample-to-results system with sample preparation kit, master mix, Applied Biosystems™ TaqMan® primer/probe mix, and plasmid DNA standard developed from plasmid carrying the KanR gene

The Applied Biosystems™ resDNASEQ™ Quantitative Plasmid DNA–Kanamycin Resistance Gene (pDNA-KanR) Kit utilizes a qPCR-based system for detection of residual plasmid DNA containing the kanamycin resistance gene. Residual DNA testing is an established method routinely used for assessment of product quality and safety in the development of gene therapies, vaccines, and similar biotherapeutics. The resDNASEQ system enables rapid, sensitive, and specific quantitation of plasmid DNA containing the kanamycin resistance gene (KanR) by targeting multiple KanR variants present on commonly used plasmids. This performance helps ensure a high degree of confidence in quantitation data obtained from a broad range of sample types—from in-process samples with different sample matrices, to bulk drug substances (Figure 1).



Table 1. Sensitive and reproducible quantitation of plasmid DNA containing the kanamycin resistance gene using the resDNASEQ Quantitative pDNA-KanR Kit.

Specification	
Accuracy	R ² >0.99
PCR efficiency	100% ± 10%
Precision	CV ≤10%
Limit of detection (LOD)	15 copies
Limit of quantitation (LOQ)	30 copies
Assay range	30–300,000 copies

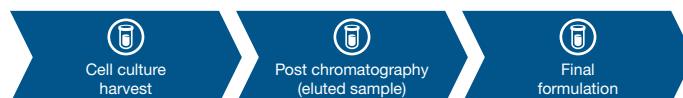


Figure 1. Sample extraction performance was tested on multiple matrices in the gene therapy workflow.

The broad linear range provided by TaqMan Assay technology allows testing of a wide range of plasmid DNA samples containing the KanR gene (Figures 2–3).

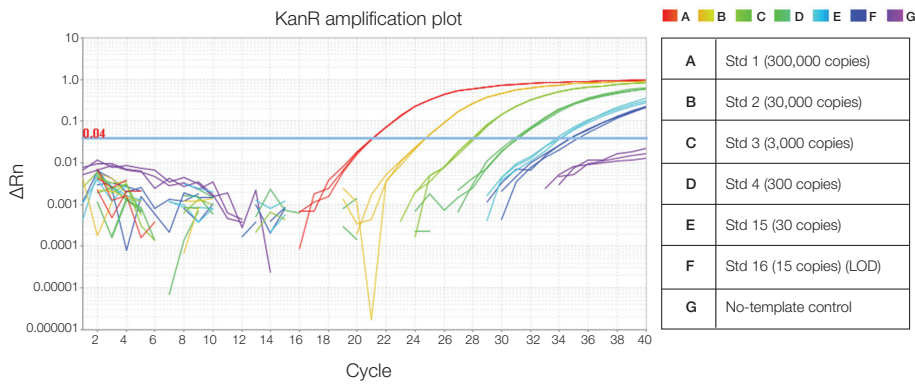


Figure 2. High sensitivity and broad dynamic range. The amplification plots were generated using serial dilutions of the KanR plasmid DNA positive control provided in the kit.

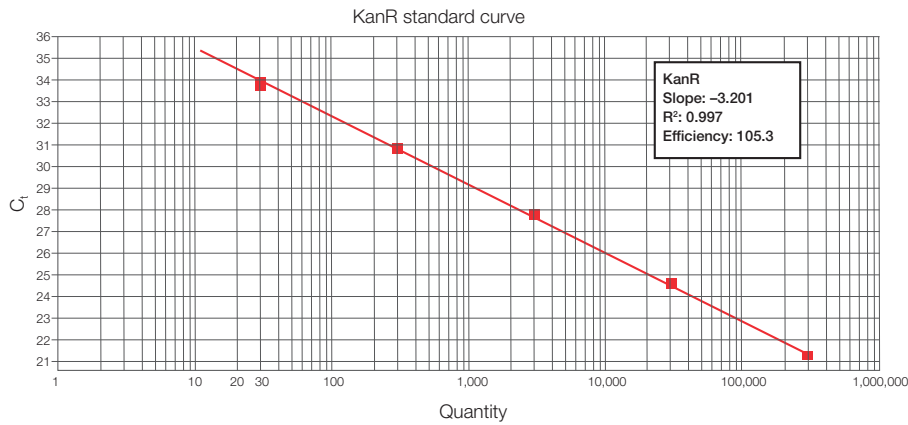


Figure 3. Standard curve (derived from amplification plot in Figure 2). The amplification plot was generated using a dilution series of the plasmid control provided in the kit; the standard curve demonstrates excellent accuracy and PCR efficiency.

resDNASEQ Quantitative Plasmid DNA Kit workflow



Figure 4. Integrated workflow solution to support process development. The resDNASEQ Quantitative Plasmid DNA–Kanamycin Resistance Gene Kit is part of an integrated workflow for impurity and contaminant testing during biopharmaceutical manufacturing. Use of the Thermo Scientific™ Pharma KingFisher™ Flex 96 Deep-Well Magnetic Particle Processor with the Applied Biosystems™ PrepSEQ™ Residual DNA Sample Preparation Kit ensures high recoveries of plasmid DNA containing the kanamycin resistance gene with decreased labor and less error. The Pharma KingFisher Flex 96 processor can process up to 24 samples in triplicate, compared to 3 samples in triplicate using the manual method. The resDNASEQ kit has been validated on the Applied Biosystems™ 7500 Fast Real-Time PCR System and QuantStudio™ 5 Real-Time PCR System. Data analysis is streamlined using Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software, which provides accurate quantitation as well as security, audit, and e-signature capabilities to help enable 21 CFR Part 11 compliance.

Ordering information

Product	Quantity	Cat. No.
resDNASEQ Quantitative Plasmid DNA–Kanamycin Resistance Gene Kit	100 reactions	A50337
resDNASEQ Quantitative Plasmid DNA–Kanamycin Resistance Gene Kit with PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	A50460
Sample preparation and automation		
PrepSEQ Nucleic Acid Sample Preparation Kit	100 reactions	A50485
Pharma KingFisher Flex 96 Deep-Well Magnetic Particle Processor	1 instrument	A31508
Real-time PCR system		
QuantStudio 5 Real-Time PCR System	1 instrument	A31672
Software		
AccuSEQ Real-Time PCR Detection Software	1 license	A48509
Service		
QuantStudio 5 IQ/OQ Service	1 service	A45613

To find out more, go to thermofisher.com/resdnaseq