

Residual DNA quantitation

resDNASEQ Quantitative HEK293 DNA Kit

Integrated sample preparation and real-time PCR assay for the quantitation of HEK293 host-cell DNA

- Highly sensitive quantitation using proven Applied Biosystems™ TaqMan® real-time PCR technology
- 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 genomic DNA (gDNA) standard developed from established HEK293 cell line (Gibco™ Viral Production Cells, Cat. No. A35827)



The Applied Biosystems™ resDNASEQ™ Quantitative HEK293 DNA Kit is a quantitative PCR (qPCR)-based system for the detection of host-cell DNA from HEK293 cell lines used in the development of gene therapies, cell-based vaccines, and similar biotherapeutics. Reliable and rapid, the resDNASEQ system enables sensitive and specific quantitation of residual HEK293 host-cell DNA (Table 1). This performance helps ensure a high degree of confidence in quantitation data obtained from a wide range of sample types—from in-process samples with different sample matrices to purified final product (Figure 1).

Table 1. Sensitive and specific quantitation of HEK293 host-cell DNA using the resDNASEQ Quantitative HEK293 DNA Kit.

Specification	
Accuracy	$R^2 > 0.99$
PCR efficiency	$100 \pm 10\%$
Precision	$CV \leq 10\%$
Limit of detection (LOD)	30 fg
Limit of quantitation (LOQ)	300 fg
Assay range	300 fg–3 ng

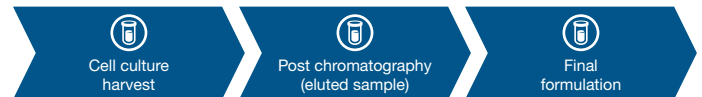


Figure 1. Sample extraction performance was tested on multiple matrices in the gene therapy workflow.

The broad linear range provided by the TaqMan technology allows testing of a wide range of HEK293 DNA samples (Figure 2).

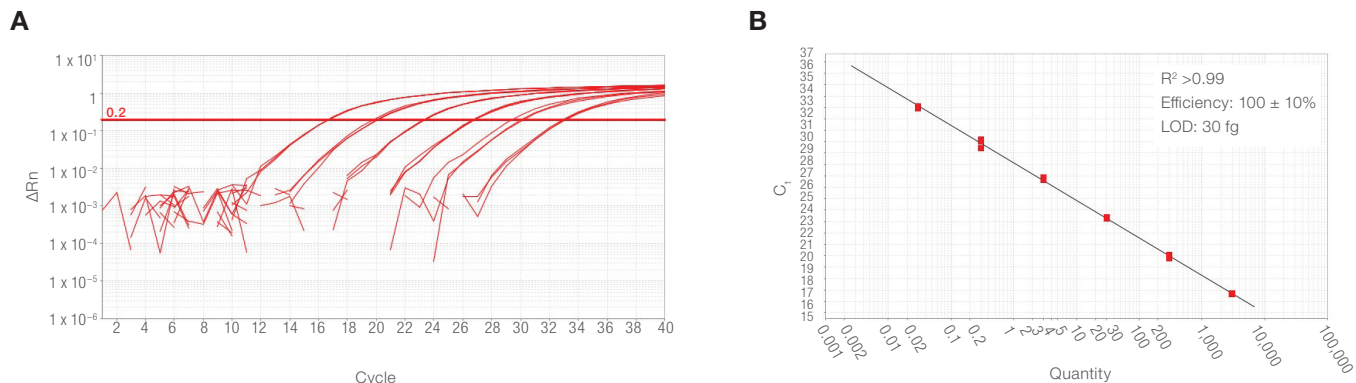
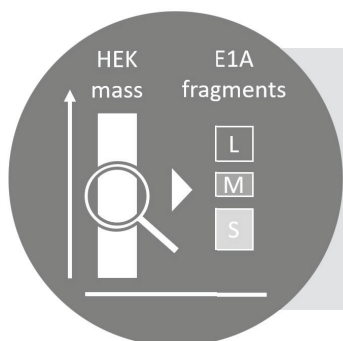


Figure 2. High sensitivity and broad dynamic range. (A) Amplification plots were generated using 10-fold serial dilutions (ranging from 3 ng to 30 fg) of HEK293 gDNA, provided in the kit. (B) Standard curve of the 10-fold dilution series.



Figure 3. Integrated workflow solution to support process development and GMP environment. The resDNASEQ Quantitative HEK293 DNA 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 helps ensure high recoveries of HEK293 residual DNA with decreased labor and less error. The Pharma KingFisher Flex 96 Deep-Well Magnetic Particle 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 the QuantStudio™ 5 Real-Time PCR System. Data analysis is streamlined using Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software that provides accurate quantitation and security, audit, and e-signature capabilities to help enable 21 CFR Part 11 compliance.



The Applied Biosystems™ resDNASEQ™ Quantitative E1A DNA Fragment Length Kit can be used in combination with the resDNASEQ Quantitative HEK293 DNA Kit to measure the length of residual *E1A* DNA fragments that are transformed into the HEK293 cell line. The workflow can use the same sample as for the resDNASEQ Quantitative HEK293 DNA Kit.

Ordering information

Product	Quantity	Cat. No.
resDNASEQ Quantitative HEK293 DNA Kit	100 reactions	A46014
resDNASEQ Quantitative HEK293 DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	A46565
Sample preparation and automation		
PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	4413686
Pharma KingFisher Flex 96 Deep-Well Magnetic Particle Processor	1 instrument	A31508
System		
QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL	1 instrument	A31671
7500 Fast Real-Time PCR System with Dell Tower	1 instrument	A4365463
Software		
AccuSEQ Real-Time PCR Detection Software	1 license	A40303
Service		
QuantStudio 5 IQ/OQ Service	1 service	A45613
Pharma KingFisher Flex IQ/OQ Service	1 service	A31532
Related products		
resDNASEQ Quantitative E1A DNA Fragment Length Kit	100 reactions	A51969
resDNASEQ Quantitative E1A DNA Fragment Length Kit with PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	A51970
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

 Learn more at thermofisher.com/resdnaseq

applied biosystems