

# 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).



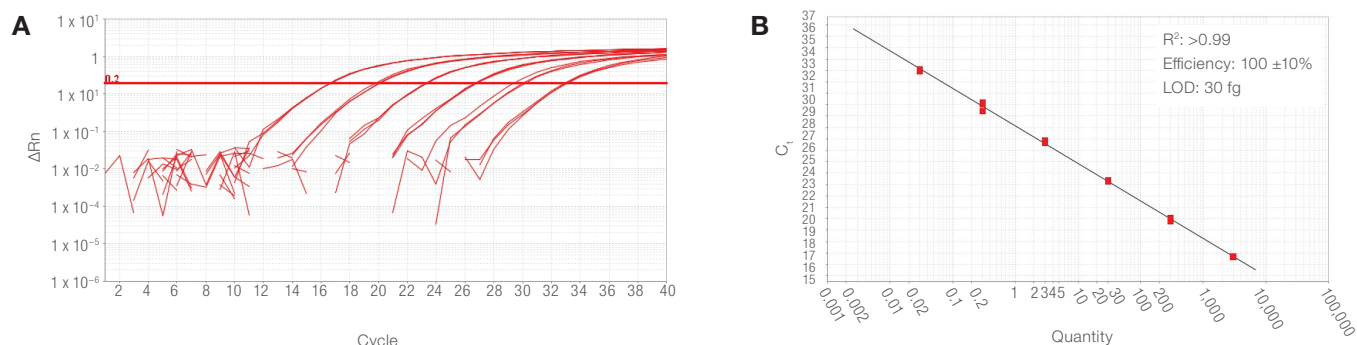
**Table 1. Sensitive and specific quantitation of HEK293 host-cell DNA using the resDNASEQ Quantitative HEK293 DNA Kit.**

Specification	
Accuracy	R <sup>2</sup> >0.99
PCR efficiency	100% ±10%
Precision	≤10% CV
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) The amplification plots were generated using 10-fold serial dilutions (ranging from 3 ng to 30 fg) of HEK293 gDNA, provided in the kit. (B) The 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. The 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 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.

## 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
<b>Sample preparation and automation</b>		
PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	4413686
Pharma KingFisher Flex 96 Deep-Well Magnetic Particle Processor	1 instrument	A31508
<b>System</b>		
QuantStudio 5 Real-Time PCR System	1 instrument	A31671
<b>Software</b>		
AccuSEQ Real-Time PCR Detection Software	1 license	A40303
<b>Service</b>		
QuantStudio 5 IQ/OQ Service	1 service	A45613

Find out more at [thermofisher.com/resdnaseq](https://thermofisher.com/resdnaseq)