

# Powerfully simple digital PCR

## resDNASEQ dPCR E1A DNA Fragment Length Kit

### Residual DNA quantitation

### Quantitation of different fragments of the *E1A* gene from residual HEK293 host-cell DNA

The Applied Biosystems™ resDNASEQ™ dPCR E1A DNA Fragment Length Kit is a digital PCR (dPCR)-based system for the quantitation of host-cell DNA from the HEK293 system or other cell lines transformed with the *E1A* oncogene. The kit is designed for cell lines used in the development of gene therapies, cell-based vaccines, and similar biotherapeutics. Reliable and rapid, the resDNASEQ kit enables sensitive and specific quantitation of *E1A* DNA fragments (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.

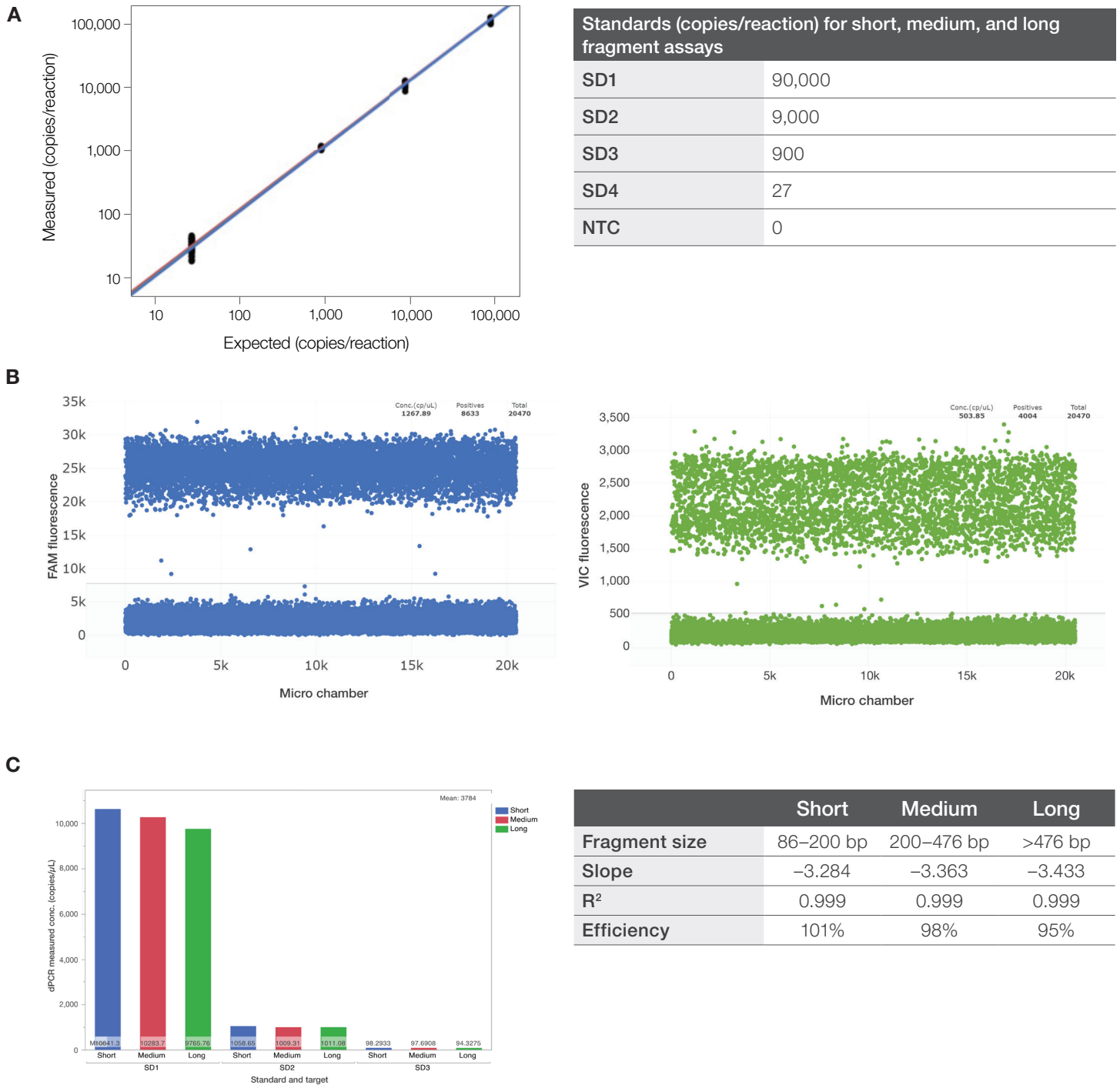
- Accurate absolute quantitation of residual DNA fragments by targeting the *E1A* oncogene, inherent in HEK293 cell lines and other cell lines transformed with *E1A*
- Highly sensitive quantitation using proven Applied Biosystems™ TaqMan™ Assays, with results in under 3 hours
- Highly characterized *E1A* DNA standard that can be leveraged during qualification and verification
- Easy-to-use, integrated sample-to-results system consisting of a sample preparation kit, master mix, TaqMan primer/probe sets, and well-characterized DNA standard
- Manual or automated sample preparation, optimized for quantitative recovery from complex sample matrices

**Table 1. Sensitive and specific quantitation of three different fragments of the *E1A* gene from HEK293 host-cell DNA using the resDNASEQ dPCR E1A DNA Fragment Length Kit.**

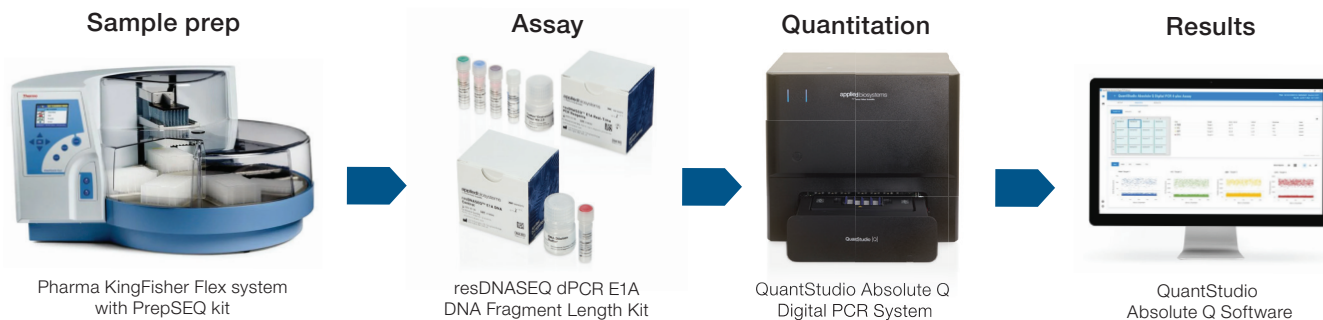
Specification	
Linearity	$R^2 > 0.99$
PCR efficiency	100% ± 10%
Precision	CV ≤ 20%
Limit of detection (LOD)	9 copies
Limit of quantitation (LOQ)	27 copies
Assay range	10 to 90,000 copies
Slope	0.95–1.05



The linear range provided by TaqMan Assay technology allows testing of a wide range of samples containing *E1A* DNA, most commonly HEK293 DNA (Figure 1).



**Figure 1. High sensitivity and broad dynamic range.** (A) Amplification plots were generated using serial dilutions (ranging from 90,000 copies/reaction (SD1) to 27 copies/reaction (SD4)) of *E1A* DNA provided in the kit. (B) With automatic threshold applied, clear separation between positive and negative droplets is observed in both the FAM™ dye channel for targets and the VIC™ dye channel for an internal positive control (IPC). (C) Equal quantification is observed for short, medium, and long fragments, with good slope, linearity (R<sup>2</sup>), and efficiency.



**Figure 2. Integrated workflow solution to support process development and a GMP environment.** The resDNASEQ dPCR E1A DNA Fragment Length Kit is part of an integrated workflow for impurity testing during biopharmaceutical manufacturing. Optional use of the Applied Biosystems™ 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 in even the most complex sample matrices. Data analysis is streamlined using Applied Biosystems™ QuantStudio™ Absolute Q™ Software, which provides accurate quantitation and security, audit, and e-signature capabilities to help enable 21 CFR Part 11 compliance.



### Powerfully simple digital PCR

Simplify your workflow by combining resDNASEQ dPCR assays with the Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System. Results can be obtained from DNA samples in <3 hours with minimal hands-on time. Moreover, there is no steep learning curve, as the workflow is identical to that for real-time PCR.

- **Simple**—streamlined workflow integrates all dPCR steps into a single instrument
- **Fast**—the QuantStudio Absolute Q system requires only one hands-on step that takes <5 minutes to complete with minimal technical skill

### Ordering information

Product	Quantity	Cat. No.
resDNASEQ dPCR E1A DNA Fragment Length Kit	3 x 100 reactions	A55852
Options	Quantity	Cat. No.
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 Absolute Q Digital PCR System	1 instrument	A52864
Absolute Q DNA Digital PCR Master Mix (5X)	200 reactions	A52490
Service		
QuantStudio Absolute Q IQ/OQ Service	1 service	A53878
QuantStudio Absolute Q CSV Service	1 service	A55623
Pharma KingFisher Flex IQ/OQ Service	1 service	A31532

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

**applied biosystems**