

# The way forward in digital PCR

resDNASEQ dPCR HEK293 DNA Kit

Residual DNA quantitation

## Highly sensitive dPCR assay for quantitation of residual HEK293 host cell DNA

The Applied Biosystems™ resDNASEQ™ dPCR HEK293 DNA Kit is a powerful digital PCR (dPCR) solution for quantitating residual DNA from HEK293 expression systems, which are commonly utilized for the production of gene therapies, cell-based vaccines, and similar therapeutics. By harnessing the capabilities of high-performance Applied Biosystems™ TaqMan™ Assay chemistry, the resDNASEQ dPCR HEK293 DNA Kit offers a rapid and reliable approach for accurately quantifying residual HEK293 DNA (Tables 1–3). The resDNASEQ dPCR assay offers exceptional sensitivity and specificity, helping ensure that the quantitation data obtained from a range of sample types, including in-process samples with varying sample matrices and final product formulations, are reliable and consistent.

- Accurate, absolute quantitation of residual HEK293 DNA
- Easy-to-use, integrated sample-to-results system features Applied Biosystems™ Absolute Q™ DNA Digital PCR Master Mix and TaqMan™ primer/probe set
- Highly sensitive quantitation with ~90 minute dPCR run time
- Optional manual or automated sample preparation, optimized for quantitative recovery of samples from complex matrices

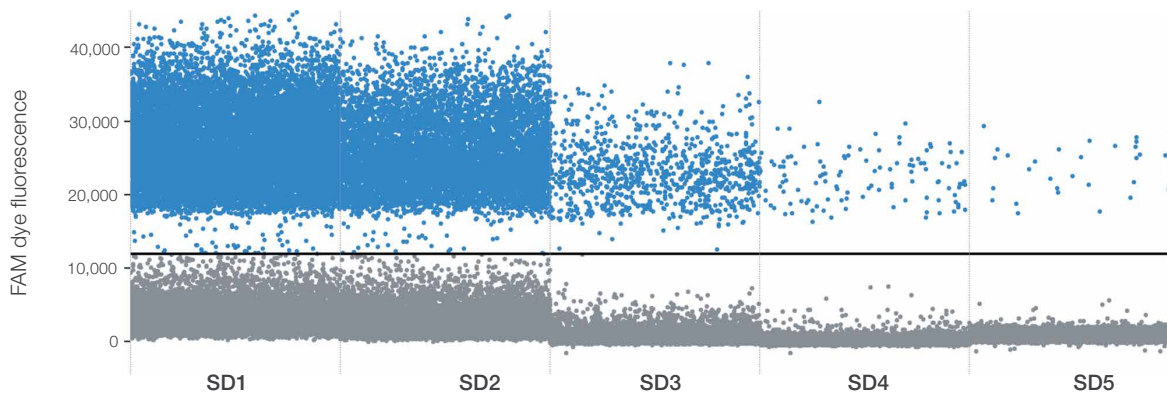


**Table 1. Sensitive and specific quantitation of HEK293 DNA using the resDNASEQ dPCR HEK293 DNA Kit.**

Specifications	
Linearity	$R^2 \geq 0.99$
Precision	CV <20%
Limit of detection (LOD)	2 copies/ $\mu$ L; 0.7 pg/reaction
Limit of quantitation (LOQ)	3 copies/ $\mu$ L; 1 pg/reaction
Slope	0.95–1.05

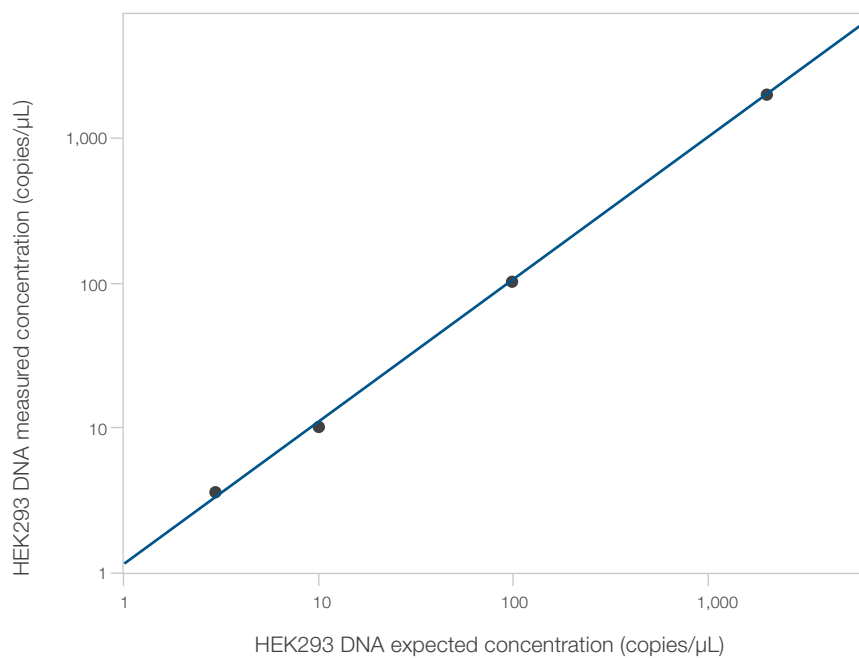
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A dPCR fluorescence plot illustrates the sensitivity of the assay down to very low quantities of residual HEK293 DNA (Figure 1).



**Figure 1. 1D dot plot of dPCR-based quantification of HEK293 DNA from serially diluted samples.** The fluorescence plot was generated using serial dilutions ranging from 10,000 copies/ $\mu$ L (SD1) to 3 copies/ $\mu$ L (SD5) of HEK293 DNA.

The linearity of TaqMan Assay technology allows testing of samples containing HEK293 DNA over a wide range of concentrations (Figure 2).



**Figure 2. High sensitivity and broad dynamic range.** A linear curve was generated using serial dilutions ranging from 10,000 copies/ $\mu$ L (SD1) to 3 copies/ $\mu$ L (SD5) of HEK293 DNA. Linearity:  $R^2 > 0.99$ ; slope = 1.01.

**Table 2. resDNASEQ dPCR HEK293 DNA Kit performance summary demonstrates assay accuracy and precision among triplicate reactions.**

Test item	Dilution	Expected concentration			Inter-plate precision					
		(copies/ $\mu$ L)	(pg/ $\mu$ L)	(pg/rxn)	Average concentration			Relative accuracy (%)	SD	CV
					(copies/ $\mu$ L)	(pg/ $\mu$ L)	(pg/rxn)			
HEK293 DNA	SD2 (ULOQ*)	2,000	76.9	692.3	1,952.3	75.1	675.8	97.6	17.3	<b>0.89%</b>
	SD3	100	3.8	34.6	99.7	3.8	34.5	99.7	2.4	<b>2.41%</b>
	SD4	10	0.4	3.5	10.1	0.4	3.5	101.0	0.5	<b>4.47%</b>
	SD5 (LOQ)	3	0.1	1.0	3.5	0.1	1.2	116.7	0.6	<b>16.87%</b>

\* ULOQ: upper limit of quantitation.

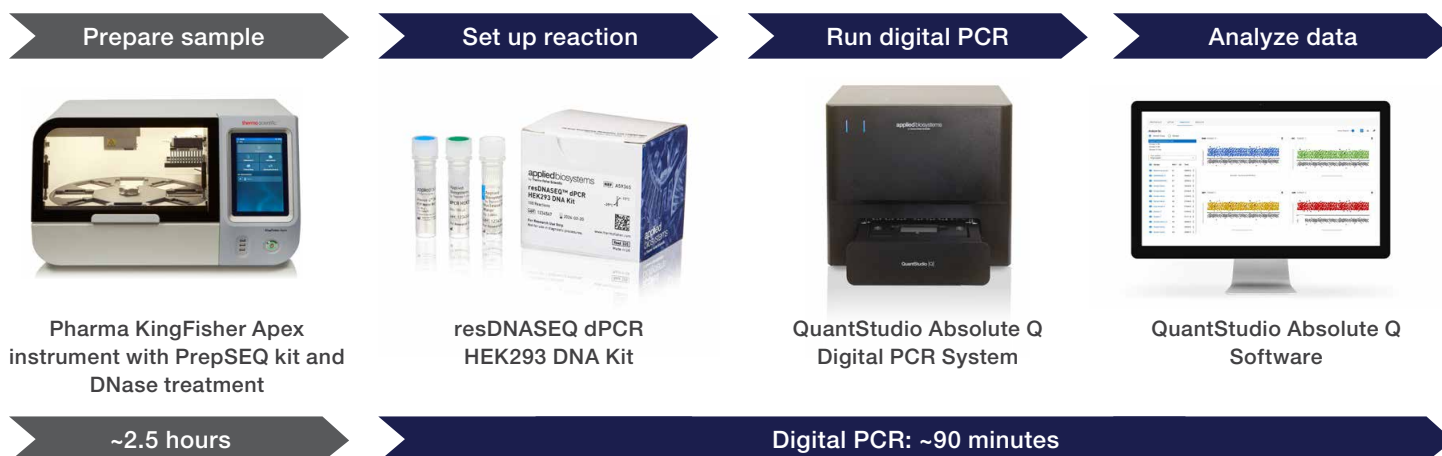
**Table 3. Summary of assay LOD for the resDNASEQ dPCR HEK293 DNA Kit.**

Test item	Expected conc. of LOD (copies/ $\mu$ L)	Average conc. of LOD (copies/ $\mu$ L)	Average conc. of NTC (copies/ $\mu$ L)	3 SD of NTC (copies/ $\mu$ L)	Conc. of NTC + 3 SD (copies/ $\mu$ L)
HEK293 DNA	2.00	<b>1.96</b>	0.13	0.38	<b>0.51</b>

### Digital PCR workflow

The resDNASEQ dPCR HEK293 DNA Kit is part of an integrated digital PCR workflow for impurity testing during biopharmaceutical manufacturing (Figure 3). Optional use of the Thermo Scientific™ Pharma KingFisher™ Apex 96 Deep-Well Magnetic Particle Processor with the Applied Biosystems™ PrepSEQ™ Residual DNA Sample Preparation Kit helps ensure high recovery of residual DNA with less labor and error than with manual processing. The Pharma KingFisher Apex instrument can process up to 24 samples in triplicate, as compared to 3 samples in triplicate using a manual method.

To help ensure performance that meets or exceeds regulatory compliance, the resDNASEQ kit has been internally validated on the Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System. Data analysis is streamlined using QuantStudio Absolute Q Software, which includes accurate quantitation and security, audit, and e-signature (SAE) capabilities to help enable 21 CFR Part 11 compliance.



**Figure 3. An integrated workflow solution to support process development and a good manufacturing practice (GMP) environment.**



### Powerfully simple digital PCR

The QuantStudio Absolute Q Digital PCR System offers a simple workflow, delivering results from DNA samples with a ~90 minute dPCR run time. Moreover, there is no steep learning curve, as the workflow is nearly identical to that of real-time PCR.

- **Simple**—streamlined workflow integrates all dPCR steps on 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 HEK293 DNA Kit	100 reactions	A59365
<b>Sample preparation and automation</b>		
PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	4413686
Pharma KingFisher Apex 96 Deep-Well Magnetic Particle Processor	1 instrument	A57715
<b>Systems</b>		
QuantStudio Absolute Q Digital PCR System	1 instrument	A52864
Absolute Q DNA Digital PCR Master Mix (5X)	200 reactions	A52490
QuantStudio Absolute Q MAP16 Plate Kit	1 kit	A52865
<b>Services</b>		
QuantStudio Absolute Q IQ/OQ Service		A53878
QuantStudio Absolute Q CSV Service		A55623
Pharma KingFisher Apex IQ/OQ Service		A31532

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

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