ThermoFisher SCIENTIFIC

Powerfully simple digital PCR

resDNASEQ dPCR *E. coli* DNA Kit

Residual DNA quantitation

Quantification of residual *E. coli* host-cell DNA

The Applied Biosystems™ resDNASEQ™ dPCR *E. coli* DNA Kit is a digital PCR (dPCR)-based solution to detect residual DNA from *E. coli* expression systems, which are commonly used for production of recombinant proteins and plasmids. The rapid and reliable assay enables sensitive and specific quantification of *E. coli* DNA (Table 1). This helps ensure a high degree of confidence in quantitation data obtained from a broad range of sample types—from in-process samples of different sample matrices to final product formulations.

- Accurate, absolute quantitation of residual *E. coli* DNA
- Highly sensitive quantitation using proven Applied Biosystems™ TaqMan™ Assays, with results in under 3 hours
- Highly characterized *E. coli* DNA control that can be leveraged during qualification and verification
- Easy-to-use, integrated sample-to-results kit consisting of Applied Biosystems™ Absolute Q™ DNA Digital PCR Master Mix, TaqMan™ *E. coli* assay mix, well-characterized DNA positive control, and DNA dilution buffer
- Manual or automated sample preparation, optimized for quantitative recovery of samples from complex matrices

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

Specification	
Linearity	R^2 >0.99
Precision	CV ≤30%
Limit of detection (LOD)	1 copy/µL
Limit of quantitation (LOQ)	3 copies/µL
Assay range	1–10,000 copies/µL
Assay accuracy	50–150%
Slope	0.95-1.05

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The linear range provided by TaqMan Assay technology allows testing of a wide range of samples containing *E. coli* DNA (Figure 1).

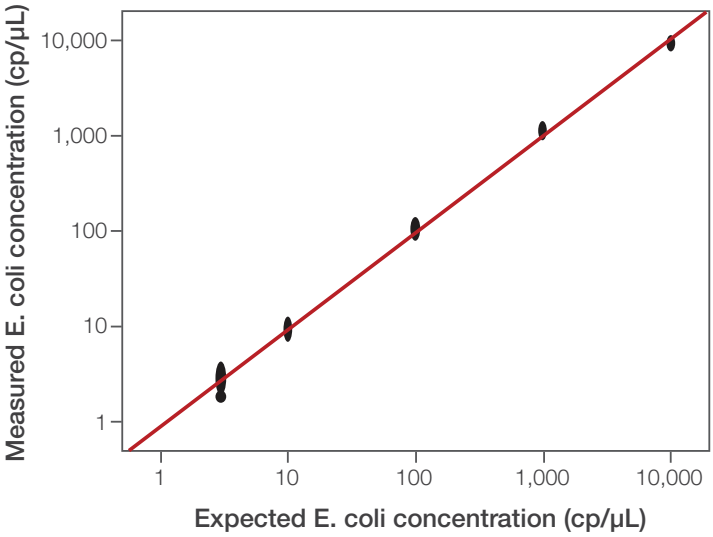

Figure 1. High sensitivity and broad dynamic range. Amplification plots were generated using serial dilutions ranging from 10,000 copies/µL (cp/µL) (SD1) to 3 copies/µL (SD5) of *E. coli* DNA provided in the kit. Linearity: R^2 >0.99; slope = 1.01.

Table 2. Summary of assay accuracy and precision of the resDNASEQ dPCR *E. coli* DNA Kit. The copy number output can be converted to mass using a conversion factor. NTC: no-template control.

Sample	Expected concentration (cp/µL)	Mean of measured concentration (cp/µL)	Mean of measured concentration (pg/µL)	Assay accuracy (measured/expected, %)	CV (%)
SD1	10,000	8,669.62	84.17	87	2.00
SD2	1,000	1,027.43	9.98	103	3.25
SD3	100	98.67	0.96	99	5.54
SD4	10	8.84	0.09	88	3.74
SD5	3	2.57	0.02	86	13.83
NTC	0	0	0	NA	NA

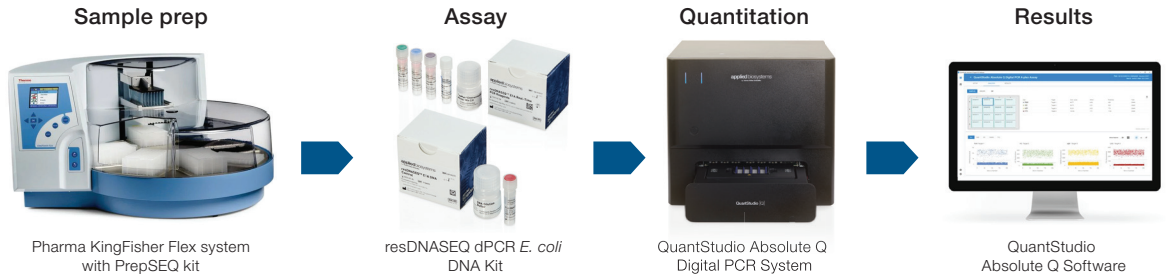

Figure 2. Integrated workflow solution to support process development and a GMP environment. The resDNASEQ dPCR *E. coli* DNA Kit is part of an integrated workflow for impurity testing during biopharmaceutical manufacturing. Optional use of the Thermo Scientific™ Pharma KingFisher™ Flex 96 Deep-Well Magnetic Particle Processor with the Applied Biosystems™ PrepSEQ™ Residual DNA Sample Preparation Kit ensures high recoveries of residual *E. coli* DNA, with decreased labor and less error from 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 (SAE) capabilities to enable 21 CFR Part 11 compliance.

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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 *E. coli* DNA Kit	100 reactions	A57017
Options	**Quantity**	**Cat. No.**
Sample preparation and automation		
PrepSEQ Residual DNA Sample Preparation Kit	100 preps	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-dpcr**