

resDNASEQ[®] *E. coli* Residual DNA Quantitation System

Integrated sample preparation and real-time PCR assay for the quantitation of *E. coli* host cell DNA

- Highly sensitive quantitation using proven TaqMan[®] real-time qPCR technology (Figure 1)
- Manual and automated sample preparation, optimized for quantitative recovery from complex sample matrices (Table 1)
- Enables consistent performance across the expected range of DNA fragment sizes (Figure 2)
- Integrated system from sample to results with sample preparation, master mix, TaqMan[®] primer/probe mix, and genomic DNA standard

The resDNASEQ® *E. coli* Residual DNA Quantitation System is a quantitative PCR (qPCR)-based system for the detection of host cell DNA from *E. coli*, an expression system commonly used for the production of recombinant proteins. Reliable and rapid, the system enables sensitive (LOQ = 15 pg DNA/mL test sample, Figure 1) and specific (Figures 2 and 3) quantitation of *E. coli* DNA typically in less than four hours. This performance helps <complex-block>

ensure a high degree of confidence in quantitation data obtained from a broad range of sample types—from in-process samples to bulk drug substance—whether the sample contains high molecular weight or sheared DNA (Figure 3). Table 1. DNA recovery using the manual **PrepSEQ®** sample preparation protocol. Assay performance data using 10 pg *E. coli* genomic DNA spike per sample, 3 analysts, and 9 test samples.

50 mg/mL protein sample		
	Mean recovery	Mean %CV
E. coli	83%	5.04%

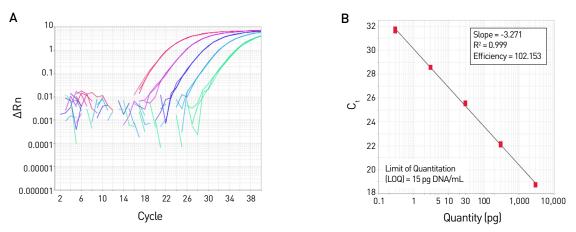


Figure 1. High sensitivity and broad dynamic range using the resDNASEQ[®] *E. coli* Residual DNA Quantitation System. The amplification plot (A) was generated using a 10-fold serial dilution of *E. coli* genomic DNA, provided in the kit. Concentrations range from 3 ng to 300 fg. The standard curve (B) of the 10-fold dilution series. Data were analyzed using AccuSEQ[®] Real-Time Detection Software.

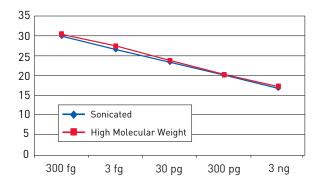


Figure 2. Consistent quantitation across a broad range of fragment sizes. Standard curves were generated using a 10-fold serial dilution of high molecular weight (red) and fragmented (blue) DNA from 3 ng to 300 fg. Fragmented DNA was generated by sonicating total *E. coli* genomic DNA. Fragmentation of the DNA was confirmed by agarose gel analysis.

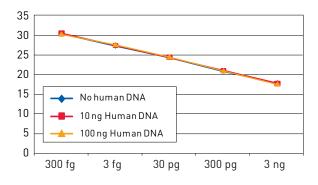


Figure 3. Assay specificity. Standard curves generated using 10-fold serial dilution (3 ng to 300 fg) of *E. coli* genomic DNA (included in the kit) in the presence of 100 ng human DNA (yellow), 10 ng human DNA (red), and no human DNA (blue).

Ordering information

Description	Part no.
resDNASEQ [®] E. coli Residual DNA Quantitation System	
resDNASEQ® Quantitative E. coli DNA Kit, 100 rxns, without Protocol and Quick Reference Card	4458435
resDNASEQ® Quantitative E. coli DNA Kit and PrepSEQ® Residual DNA Sample Preparation Kit,	
100 rxns, without Protocol and Quick Reference Card	4460366
PrepSEQ® Residual DNA Sample Preparation Kits	
PrepSEQ® Residual DNA Sample Preparation Kit, 100 rxns, with Protocol and Quick Reference Card	4415414
PrepSEQ® Residual DNA Sample Preparation Kit, 100 rxns, without Protocol and Quick Reference Card	4413686
AccuSEQ [®] Real-Time PCR Software	
AccuSEQ® Real-Time PCR Software v1.0	4443420

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