

resDNASEQ Quantitative Sf9 and Baculovirus DNA Kit

Duplex quantitative qPCR system for the detection of residual Sf9 and baculovirus 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 Sf9 cell line (Gibco™ ExpiSf9™ Cells, Cat. No. A35243) and linearized baculovirus DNA from the Invitrogen™ BaculoDirect™ Baculovirus Expression System

The Applied Biosystems™ resDNASEQ™ Quantitative Sf9 and Baculovirus DNA Kit is a duplex quantitative PCR (qPCR)-based system for the detection of residual DNA from the Sf9 baculovirus platform 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 Sf9 host cell DNA and baculovirus DNA. This performance helps ensure a high degree of confidence in quantitation data obtained from a broad 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 residual Sf9 and baculovirus DNA using the resDNASEQ Quantitative Sf9 and Baculovirus DNA Kit.

| Specification | |
|-----------------------------|----------------------|
| Accuracy | R ² >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 Sf9 and baculovirus DNA samples (Figures 2–4).

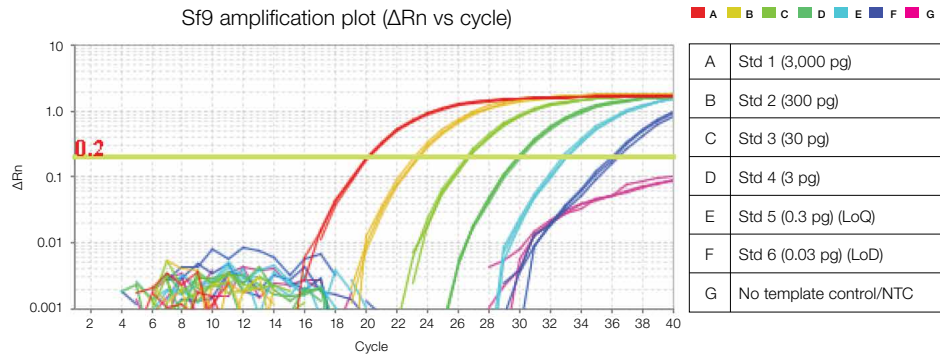


Figure 2. High sensitivity and broad dynamic range. The amplification plots were generated using 10-fold serial dilutions (ranging from 3 ng to 30 fg) of Sf9 gDNA, provided in the kit.

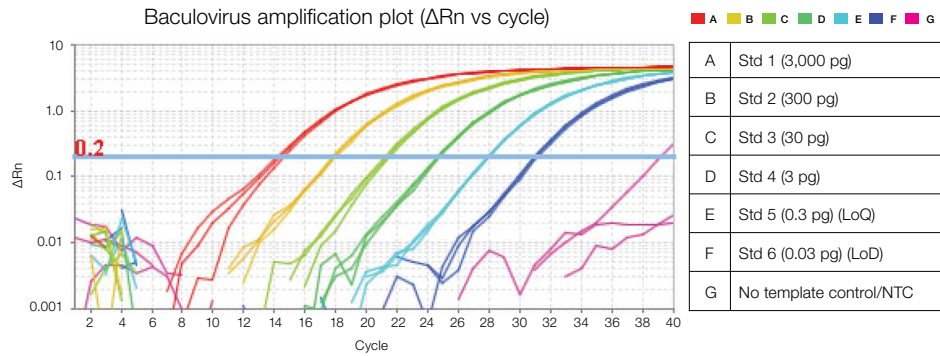


Figure 3. High sensitivity and broad dynamic range. The amplification plots were generated using 10-fold serial dilutions (ranging from 3 ng to 30 fg) of baculovirus gDNA, provided in the kit.

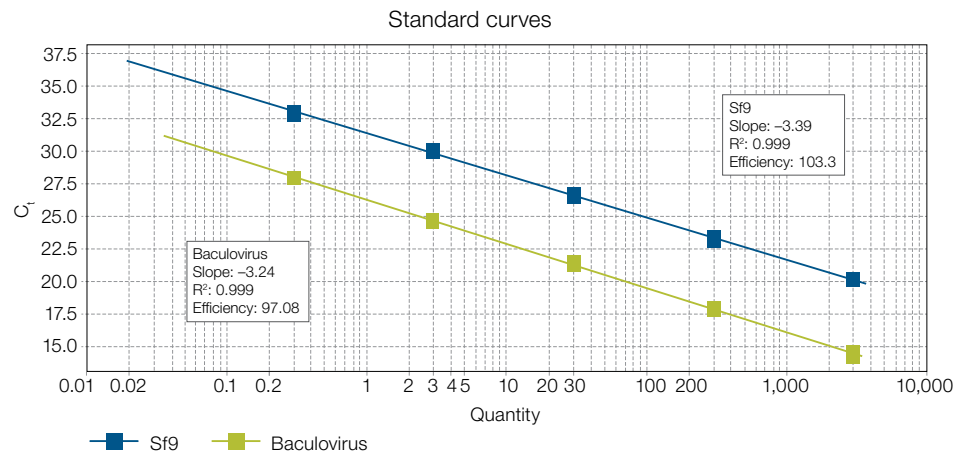


Figure 4. Standard curves (derived from amplification plots of Figures 2 and 3). Both of the standard curves meet criteria for accuracy and PCR efficiency.

resDNASEQ Quantitative Sf9 and Baculovirus DNA Kit workflow



Figure 5. Integrated workflow solution to support process development and GMP environment. The resDNASEQ Quantitative Sf9 and Baculovirus 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 Sf9 and baculovirus 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 Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System. Data analysis is streamlined using Applied Biosystems™ AccuSEQ™ Real-Time PCR 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 Sf9 and Baculovirus DNA Kit | 100 reactions | A46066 |
| resDNASEQ Quantitative Sf9 and Baculovirus DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit | 100 reactions | A47405 |
| 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 5 Real-Time PCR System | 1 instrument | A31672 |
| Software | | |
| AccuSEQ Real-Time PCR Detection Software | 1 license | A48509 |
| Service | | |
| QuantStudio 5 IQ/OQ Service | 1 service | A45613 |

To find out more, go to thermofisher.com/resdnaseq