

applied biosystems

The way
forward in
biotherapeutic
analytics.

Pharma analytics

Rapid analytical solutions for environmental monitoring, critical materials testing, in-process testing, and lot-release quality control testing

Ensuring the quality of pharmaceutical products is crucial during manufacturing, which is why accurate and fast testing is essential. Applied Biosystems™ SEQ analytical testing solutions utilize rapid and highly sensitive molecular methods to efficiently detect impurities, detect and identify contaminants, and measure potency. With our products, you can obtain same-day results, typically in less than 5 hours, which can help you mitigate production risks and meet regulatory guidelines for final product release.



Product quality

Residual host cell DNA quantitation

The removal of host cell impurities is a critical step in the purification of biopharmaceutical products. The Applied Biosystems™ resDNASEQ™ host cell residual DNA quantitation system is a fully integrated system available for both qPCR and digital PCR (dPCR) technology platforms. This system is a trusted solution and is routinely used by major biopharma companies.

- **Sensitive**—meets or exceeds regulatory guidance of 10 ng per therapeutic dose (World Health Organization, US Food and Drug Administration)
- **Expansive**—assays for most commonly used cell lines (CHO, HEK293, Human, *E. coli*, Vero, MDCK, *Pichia pastoris*, Sf9/baculovirus, and NS0), as well as E1A DNA fragment sizing

Residual plasmid DNA quantitation

Measuring residual plasmid DNA is essential for both regulatory compliance and the design and optimization of manufacturing processes. The Applied Biosystems™ resDNASEQ™ Quantitative Plasmid DNA Kit utilizes highly sensitive Applied Biosystems™ TaqMan™ chemistry to deliver rapid and specific real-time PCR (qPCR)-based quantitation of residual plasmid DNA containing kanamycin resistance genes.

- **Reliable**—reproducible quantitative results for common gene therapy sample matrices
- **Comprehensive**—multiplex assay targets all kanamycin resistance gene alleles common in bioproduction

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Environmental monitoring

Microbial identification

Bacterial and fungal contamination in raw materials and production facilities can have a detrimental effect on product quality and safety. To prevent issues like delayed product releases, back orders, and recalls, a genetic approach for microbial detection is highly effective. By targeting the 16S rRNA gene for bacteria and the D2 region of the large subunit ribosomal DNA for fungi, the Applied Biosystems™ MicroSEQ™ Microbial Identification System can quickly identify thousands of bacterial and fungal species in less than 5 hours.

- **Accurate**—a phylogenetic approach delivers high discrimination power
- **Compliant**—complies with approaches recommended by regulatory agencies such as ICH, USP, EUP, and JP, for accurate contamination identification
- **Comprehensive**—offers a robust, validated *in silico* database, containing more than 12,000 strain types

Complete the workflow

Sample preparation

The success of a quality control analytical test is critically dependent on the sample preparation used to remove PCR interferants. We offer a range of Applied Biosystems™ PrepSEQ™ sample preparation kits in both manual and automated formats to enable exceptional recovery efficiency for applications where consistent, absolute quantitation and the highest sensitivity of detection are required.

- **Efficient**—reproducible recovery of DNA from complex samples
- **Extensive**—universal sample prep for nucleic acid extraction for residual host cell DNA, mycoplasmas, MMVs, and vesiviruses
- **Adaptable**—manual and automated solutions enable flexible throughput and workflow options

qPCR detection software

Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software supports the unique needs of analytical testing for contaminants and impurities during the biopharmaceutical manufacturing process. AccuSEQ software is part of the integrated workflow for mycoplasma detection, residual DNA quantitation, and rapid sterility testing.

- **Efficient**—single software platform for multiple qPCR assays for SEQ analytical testing solutions
- **Proven**—supported and fully tested for the Microsoft™ Windows™ 10 operating system
- **Compliant**—helps enable 21 CFR Part 11 compliance

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