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

Learn more at thermofisher.com/resdnaseq

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

Learn more at thermofisher.com/resdnaseq-plasmid

Product safety

Mycoplasma detection

The Applied Biosystems™ MycoSEQ™ Mycoplasma Detection Kit is a fully integrated solution for qPCR-based mycoplasma detection. It offers a reliable and efficient alternative to culture-based tests, delivering results in less than 5 hours.

- **Sensitive**—meets or exceeds regulatory guidance of 10 colony-forming units (CFU)/mL or 10 genome copies (GC)/mL
- **Specific**—no observed cross-reactivity to closely related non-mycoplasma bacterial species
- **Comprehensive**—multiplex assay screens for >200 species of mycoplasmas, including all key species listed in The International Pharmacopoeia

Learn more at **thermofisher.com/mycoseq**

Sterility testing

The Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit utilizes highly regarded and widely used TaqMan chemistry to help deliver a more efficient qPCR workflow and broader range of species detection—including more than 16,000 bacterial species and 2,600 species of fungi.

- **Fast**—provides actionable results in less than 5 hours
- **Specific**—primers/probes designed specifically for bacteria (16S rRNA) and fungi (18S rRNA)
- **Efficient**—minimizes use of sample material by simultaneously testing for bacteria and fungi, preserving precious cells for final product

Learn more at **thermofisher.com/steriseq**

Adventitious virus testing

Mouse minute virus (MMV) and vesivirus contamination are potential threats to mammalian cell culture manufacturing processes. The Applied Biosystems™ ViralSEQ™ Detection System provides an integrated, qPCR-based solution for rapid and sensitive detection of MMV or vesivirus from a wide range of sample types.

- **Specific**—no cross-reactivity with unrelated DNA
- **Reliable**—consistent performance kit to kit, lot to lot, and year to year

Learn more at **thermofisher.com/viralseq**

Product potency

Lentiviral vector titer determination

Lentiviral vector titers, both total/physical and infectious, as well as vector copy number (VCN) in transduced cells, are critical quality attributes (CQAs) in viral vector manufacturing. Applied Biosystems™ ViralSEQ™ Lentivirus titer kits are easy-to-use assays for lentivirus characterization that enable validation per industry expectations. They are available for both qPCR and dPCR technology platforms.

- **Robust**—long terminal repeat (LTR)-based assay design compatible with more than 200 transfer plasmids
- **Specific**—Applied Biosystems™ TaqMan™ Assay–based detection for specific quantitation
- **Linear**—broad dynamic range up to seven orders of magnitude

Learn more at **thermofisher.com/viralseq-viral-titer**

Adeno-associated virus (AAV) titer quantitation

AAV titer quantitation is a CQA in viral vector manufacturing for gene therapy development. The Applied Biosystems™ ViralSEQ™ dPCR AAV Titer Kit features a probe-based dPCR assay that delivers exceptional sensitivity and consistency, outperforming conventional DNA blotting or ELISA methods.

- **Specific**—quantitation of viral particles targeting inverted terminal repeat (ITR) and SV40 regions of the AAV vector
- **Robust**—assay design compatible with more than 80% of AAV transfer plasmids
- **Fast**—simple dPCR workflow delivers results in about 3 hours

Learn more at **thermofisher.com/viralseq-viral-titer**

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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

Learn more at **thermofisher.com/microseq**

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

Learn more at **thermofisher.com/prepseq**

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

Learn more at **thermofisher.com/accuseq**

Find out more at **fishersci.eu**

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