ThermoFisher SCIENTIFIC

The way forward in rapid sterility testing.

Pharma analytics

SteriSEQ Rapid Sterility Testing System

2025 R&D 100 WINNER

applied biosystems

Confidently accelerate cell therapy manufacturing with simple, rapid sterility testing

In-process testing for bacterial and fungal contaminants

In the context of cell therapy production, rapid sterility testing plays a crucial role in enabling the quality and safety of the final product. The fast-paced nature of this production process, coupled with the limited shelf life of cell therapy products, necessitates the early detection and prevention of further contamination throughout the workflow. By implementing rapid sterility testing, potential sources of contamination can be uncovered and promptly addressed. This proactive approach helps mitigate the risk of product loss and unexpected production delays, ultimately enhancing workflow efficiency. Moreover, it preserves the integrity and efficacy of the cell therapy product, further bolstering its overall quality.

The Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing System is a real-time PCR (qPCR) solution designed specifically for rapid sterility testing of cell therapy products.

This integrated system combines a commercially available qPCR assay kit with widely used qPCR instruments and dedicated analytical software, enabling accurate and efficient contaminant detection while helping facilitate regulatory compliance.

- Actionable qPCR results in less than 5 hours
- A single-well, multiplexed assay that detects both bacterial and fungal contamination
- An efficient qPCR workflow solution, including security, audit, and e-signature (SAE)-compatible software
- A global network of regulatory and field application specialists for support, from method development and implementation to validation

The SteriSEQ Rapid Sterility Testing System provides actionable results in less than 5 hours, helping ensure product safety and quality.

SteriSEQ Rapid Sterility Testing System

Incorporated into the cell therapy bioproduction workflow, the SteriSEQ Rapid Sterility Testing System provides a valuable complement to the time-consuming culture-based test, enabling accurate and actionable results in less than 5 hours. Backed by technical and regulatory support, the SteriSEQ system can help accelerate and simplify sterility testing for both raw material and in-process testing.

Applied Biosystems™ AccuSEQ™ Real-Time PCR Software

Applied Biosystems™ QuantStudio™ 7 Pro, QuantStudio 5, or 7500 Fast Real-Time PCR System

Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit

Easy qPCR workflow delivers results in <5 hours

The SteriSEQ Rapid Sterility Testing System is a qPCR solution that simplifies the integration of sterility testing into your manufacturing process. It includes trusted Applied Biosystems™ qPCR systems, accompanied by dedicated analytical software that can help facilitate regulatory compliance. The SteriSEQ system workflow offers a straightforward and user-friendly approach to contaminant detection. To enable consistent functionality and system-wide integration, all components of the system are internally tested and validated to perform together.

Prepare sample	Set up reaction	Run qPCR	Analyze
	 SteriSEQ Rapid Sterility Testing Kit	 QuantStudio 7 Pro, QuantStudio 5, or 7500 Real-Time PCR System	 AccuSEQ Real-Time PCR Detection Software
~2.5 hours	Real-time PCR: ~1.5–2.5 hours		

Designed to help support recommended qualification guidelines

qPCR-based testing offers an additional level of scrutiny to standard growth-based sterility testing methods and can be applied as a rapid risk assessment tool in the measurement of bacterial and fungal DNA in test samples.

Able to provide quick results when time is critical, the SteriSEQ Rapid Sterility Testing Kit assays can offer early detection of potential contamination events when used for raw material or in-process testing.

The SteriSEQ system is designed to support recommended qualification guidelines from regulatory bodies:

- International Council for Harmonisation (ICH)
- United States Pharmacopeia (USP)
- European Pharmacopoeia (Ph. Eur.)
- Japanese Pharmacopoeia (JP)

Regulatory guidelines

USP <71>: This sterility testing is used to determine the absence of viable microorganisms in pharmaceutical products, medical devices, and other sterile products to ensure their safety and quality.

USP <1071>: It is widely recognized that the current growth-based sterility tests with an incubation period of at least 14 days are not suitable for products with a short shelf-life or for products prepared for immediate use, which are usually infused into patients before the completion of the test. These short-life products include … cell and gene therapies, which require a new generation of risk-based approaches that include rapid microbial tests. [1]

1. United States Pharmacopeia (2023). General Chapter, <1071> Rapid microbial tests for release of sterile short-life products: A risk-based approach. USP-NF. Rockville, MD: United States Pharmacopeia.

Accurate, fast contamination detection to help ensure product safety

The SteriSEQ system is centered around its robust, probe-based qPCR assay. The SteriSeq assay leverages the high performance of gold-standard Applied Biosystems™ TaqMan™ chemistry and has the capability to detect more than 16,000 bacterial species and 2,600 species of fungi.* It can accurately detect cell densities of up to 1 x 10^6 cells without any cross-reactivity to impurities resulting from in-process production. The multiplexed assay is designed to test for both bacteria and fungi in a single well, which offers several benefits, such as ease of use, improved workflow efficiency, and preservation of materials that can be used in the final product. Furthermore, the kit leverages multiple channels for detection, including a discriminatory positive control that can help differentiate a control-based contamination versus a true positive sample.

- **Fast**—delivers actionable results in less than 5 hours, enabling contamination detection of in-process and raw materials, which helps expedite the release of your cell therapy product
- **Sensitive**—detects bacterial and fungal species at 5–25 genome copies per reaction
- **Specific**—designed specifically for bacteria (16S rRNA) and fungi (18S rRNA) with no known cross-reactivity to in-process byproducts or sample matrix effects
- **Efficient**—minimizes use of sample material by simultaneously testing for bacteria and fungi, preserving precious cells for the final product
- **Accurate**—a discriminatory positive control helps eliminate false positives, and an internal positive control helps ensure PCR reaction consistency in the samples

Table 1. Partial panel of species detected by the SteriSEQ kit.

Aspergillus brasiliensis	*Staphylococcus aureus*	*Burkholderia cepacia*
Candida albicans	*Lactobacillus acidophilus*	*Ralstonia pickettii*
Bacillus subtilis	*Lactobacillus delbrueckii*	*Cryptococcus neoformans*
Clostridium sporogenes	*Niallia circulans*	*Komagataella pastoris*
Pseudomonas aeruginosa	*Afipia felis*	

The SteriSEQ Rapid Sterility Testing Kit includes:

- Applied Biosystems™ 2X Master Mix Plus
- Applied Biosystems™ SteriSEQ™ Assay Mix
- Applied Biosystems™ SteriSEQ™ Discriminatory Positive Control
- Applied Biosystems™ SteriSEQ™ DNA Dilution Buffer

* Based on *in silico* testing.

Simplicity, interactivity, and speed—choose your qPCR system

With more than 25 years of innovation behind their design, our qPCR systems deliver true value with excellent performance, reliability, and world-class support. The following instruments have been internally validated with both the SteriSEQ kit and AccuSEQ software, helping ensure a smoother pathway to process qualification and validation.

QuantStudio 7 Pro Real-Time PCR System

The QuantStudio 7 Pro system offers exceptional flexibility to support various applications and throughput needs. Designed with smart features to reduce contamination, it allows hands-free setup and remote scheduling and monitoring from your mobile device.

- Interchangeable blocks for increased throughput and enhanced convenience and adaptability—accommodating 96-well, 384-well, and TaqMan array cards
- Advanced SAE features, including SAE-specific archive and restore capabilities
- Automation compatibility to support 24/7 operation and increased productivity
- Lightweight Directory Access Protocol (LDAP) support for single sign-on and a single audit trail for both the instrument and the software
- Customizable user roles and permissions for enhanced security, workflow efficiency, and accountability and traceability
- System and email notifications to improve operational productivity and help optimize resource utilization

QuantStudio 5 Real-Time PCR System

The QuantStudio 5 system is factory-calibrated for rapid installation and immediate use. It can detect target quantity differences as small as 1.5-fold and supports remote monitoring. Enhanced functionality is provided through optional cloud-based Applied Biosystems analysis modules and data sharing.

- Applied Biosystems™ OptiFlex™ technology (6 decoupled channels and 21 filter combinations with white LED) for reliable results
- User account management, locked workflow, and pause features for greater control of experiment data
- Built-in software features to support compliance with 21 CFR Part 11 guidelines

- Simplified instrument software with interactive touchscreen for greater ease of use
- 96-well 0.2 mL or 96-well 0.1 mL formats

7500 Fast Real-Time PCR System

Sales of 7500 Fast systems will be discontinued as of October 31, 2025 and full service and support availability will be discontinued by October 31, 2030. If you're currently using a 7500 Fast system, you can leap forward to a smarter, faster, and more efficient testing experience by upgrading your qPCR system with our trade-in program.

To get started and request a quote, visit thermofisher.com/qpcrtradein

Table 2. Comparing qPCR systems.

	QuantStudio 7 Pro Real-Time PCR System	QuantStudio 5 Real-Time PCR System	7500 Fast Real-Time PCR System
Format	96-well; 0.1 mL, 0.2 mL, and 384-well	96-well; 0.1 mL	96-well; 0.1 mL
Sample ramp rate	3.66°C/sec.	3.66°C/sec.	± 2.2°C/sec.
Sensitivity	1 copy detection, 1.5-fold differences in target quantity (singleplex reaction)		
Dynamic range	10 logarithmic units	10 logarithmic units	9 logarithmic units
Optical detection/multiplexing	6 decoupled filters, up to 6 targets/well	6 decoupled filters, up to 6 targets/well	5 excitation filters, up to 5 targets/well
SAE package	Included with enhanced functionality (not compatible with QuantStudio 5)	Included	Optional
Dimensions (H x W x D)	54.7 x 33.8 x 52.5 cm	40 x 27 x 50 cm	49 x 34 x 45 cm
Display	12-in. capacitive touchscreen with real-time application viewing	Touchscreen	None
Connectivity	WiFi enabled, Thermo Fisher Connect Platform (cloud) enabled	Wi-Fi enabled	None
Automation compatibility	Yes	No	No

Take control of your data with one powerful software solution

AccuSEQ Real-Time PCR Software offers rapid and straightforward data interpretation for contaminant and impurity testing. As a crucial part of a comprehensive solution, it delivers actionable insights essential for biopharmaceutical manufacturing. AccuSEQ software integrates with a validated workflow, encompassing real-time PCR, data analysis, and report generation for precise contaminant and impurity assessment.

AccuSEQ software offers an efficient, cost-effective approach to real-time PCR data analysis by helping you establish processes suited to your specific requirements, take advantage of advanced QuantStudio qPCR instrumentation, and strengthen data protection and regulatory compliance.

- Optimized and validated for SteriSEQ assays
- An integrated, easy-to-use interface to enable consistency across multiple data applications, reducing the time needed to train your team
- SAE capabilities support 21 CFR Part 11 compliance and include username and password restrictions, audit trails tracked through the SAE module, and a range of e-signature modes and actions
- Flexible throughput of 10–500 samples per week
- Traceability with assay-specific output, helping eliminate manual calculations
- Comprehensive data management and reporting features
- Advanced database storage and rapid recovery capabilities to protect data even in the face of catastrophic computer loss

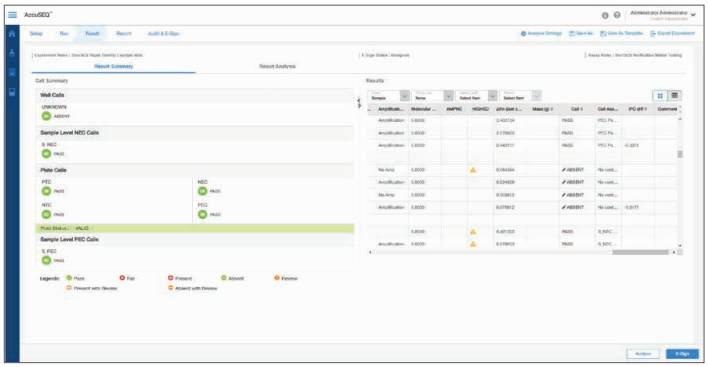

Figure 1. Example of automated presence and absence calls.

Sterility testing using AccuSEQ software

- **Automated analysis**—advanced algorithms for automated calling were developed using data interpretation guidelines for SteriSEQ assays; automated analysis tools enable one-click processing of SteriSEQ assay data, helping deliver presence or absence calls within seconds of data collection being completed (Figure 1)
- **In-depth data review**—AccuSEQ software offers easy-to-use manual review tools, including a complete table of C_t values as well as amplification, multicomponent, and raw data plots (Figure 2)
- **Regulatory compliance**—SAE capabilities included with AccuSEQ software help enable 21 CFR Part 11 compliance

Amplification plot (ΔRn vs. cycle)

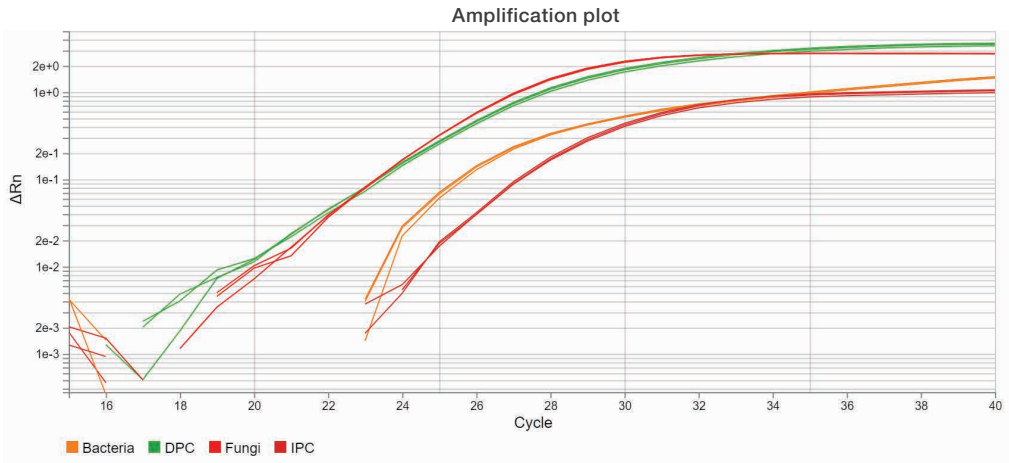

Figure 2. Example of manual review tools.

Take control of your timeline

By your side from evaluation to validation

Releasing your product safely, rapidly, and cost-effectively is your top priority—and we're here to help. Thermo Fisher Scientific services can help maximize the utility and effectiveness of your SteriSEQ system. Whether it's setting up instruments and equipment, installing and fine-tuning software, optimizing your lab or site, or training your staff, we can get you up and running quickly and efficiently.

Design and implementation

Save time and money by getting your lab designed and set up efficiently the first time.

- Laboratory workflow consultation and setup assistance based on good molecular biology lab practices
- Introduction to the basics of DNA-based vs. traditional culture methods
- Multiple visits by a specialist over a six-month period
- Guidance in establishing data acceptance criteria and interpretation
- Detailed analysis of the data collection to identification process
- Workflow design to maximize efficiency for variable sample throughput
- Software training and routine system maintenance

Installation and operation qualification (IQ/OQ)

Get your lab up and running in record time so you can validate your system and reach routine use.

- Determine training needs, system installation, and validation timelines and plans
- System hardware and software installation and operation
- Software security and audit trail verification
- IQ protocol and service: as fast as 2 days
- OQ protocol and service: as fast as 3 days
- Performance qualification (PQ) recommended guidelines

Computer system validation (CSV)

If it isn't documented, then it can't be proven—but CSV offers the evidence you need.

- Documentation that a computer system meets a set of defined requirements
- Documentation of user requirements for the software
- Verification that electronic record-keeping systems are performing to specifications
- Audit-style template documentation for development and flexibility
- Validation of each system's ability to identify altered or invalid records

Comprehensive training

Train your team quickly with our one- or two-day training options.

- Online learning delivered by specialists, right at your desktop
- On-site instruction from factory trained professionals
- Courses at one of our global training and demo centers

Benefit from worldwide implementation and support

Our distribution and service network, composed of highly trained support and application personnel, reaches 150 countries on 6 continents.

Ordering information

Description	Cat. No.
SteriSEQ Rapid Sterility Testing Kits	
SteriSEQ Rapid Sterility Testing Kit (100 reactions)	A57185
SteriSEQ Rapid Sterility Testing Kit (50 reactions)	A57186
qPCR systems	
QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL, w/laptop (Pharmaceutical Analytics)	A31671
QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL, w/tower (Pharmaceutical Analytics)	A31672
QuantStudio 7 Pro Real-Time PCR System, 96-well, 0.1 mL, w/laptop (Pharmaceutical Analytics)	A40006420
QuantStudio 7 Pro Real-Time PCR System, 96-well, 0.1 mL, w/tower (Pharmaceutical Analytics)	A40006426
Data analysis	
AccuSEQ Real-Time PCR Detection Software v4.0	A40005162
AccuSEQ Real-Time PCR Detection Software v4.0 (upgrade license)	A40005161
AccuSEQ Real-Time PCR Detection Software v4.0 (seat license)	A40005163

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

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