The way forward in rapid sterility testing.

Pharma analytics

Rapid sterility testing to complement compendial testing

Protect your cell therapy with fast, actionable results

In cell therapy production, sterility testing is an essential step in ensuring the quality and safety of the final product. This is particularly crucial given the industry's trend toward faster production processes and the inherently limited shelf life of cell therapy products. Therefore, it is imperative to detect and prevent contamination promptly. Implementing rapid sterility testing facilitates the timely identification and resolution of potential contamination sources, thereby reducing the risk of product loss and unexpected production delays. This proactive approach not only enhances the overall efficiency of the workflow, but also maintains the integrity and effectiveness of the cell therapy product.

Compendial testing, while standardized and widely accepted, presents several challenges when applied to cell therapy products. Traditional compendial sterility tests can take 14 to 28 days to yield results, and even updated growth-based technologies can still take up to 7 days for results. This extended time frame is problematic for cell therapies, which often have short shelf lives and need to be administered to patients promptly. Finding contamination days into testing may endanger the release timeline, which is particularly critical to avoid costly deviations and potentially devastating batch failures. Any delay can negatively impact patient outcomes. You don't need to wait the 14 days that compendial testing requires to know if contamination is present. Incorporating rapid sterility testing into your workflow will give you answers while you wait for the results of growth-based methods to confirm lot release.

The Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit can complement compendial testing in several ways:

Accelerated results: The SteriSEQ kit offers faster time-to-results compared to traditional compendial and other growth-based methods. This can provide early indications of contamination, allowing for quicker decision-making and potentially reducing delays in the production process.

In-process monitoring: By using the SteriSEQ kit as an in-process control, manufacturers can detect contamination early in the production cycle. Early detection, as indicated by a rise in the level of contaminant DNA, helps in taking timely corrective actions before the final product undergoes compendial sterility testing.

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Enhanced quality assurance: The SteriSEQ Rapid Sterility Testing Kit can serve as an additional layer of quality assurance, complementing accepted compendial tests with microbial coverage based on *in silico* testing for over 16,000 bacterial species and 2,600 fungi species. This dual approach can enhance the overall reliability and robustness of sterility testing protocols.

Minimized risk of product loss: Fast sterility results from the SteriSEQ kit can help in identifying contamination issues sooner, thereby minimizing the risk of large-scale product loss and reducing the economic impact of such events.

Improved efficiency: The rapid results from the SteriSEQ kit can streamline various aspects of the production cycle, including storage and distribution, especially for products with short shelf lives. This can lead to better inventory management and reduced waste.

Regulatory compliance: While the SteriSEQ kit enables rapid results, it can be used alongside compendial testing to help ensure full compliance with regulatory standards. This dual approach can satisfy both the need for speed and adherence to established guidelines.

Better resource allocation: By identifying potential sterility issues earlier, the SteriSEQ kit can help you allocate resources more efficiently, address contamination problems, and improve overall production processes.

Enhanced investigations and corrective actions: Fast detection of contamination with the SteriSEQ kit enables more timely and effective investigations and implementation of corrective actions, helping ensure quicker recovery and less disruption to the production workflow.

The SteriSEQ kit can significantly enhance and complement compendial sterility testing strategies by enabling rapid, reliable results that help improve overall efficiency, quality assurance, and risk management in the production of cell therapy and other biopharmaceutical products.

Designed to help support recommended qualification guidelines

Supported by <USP> 1071, the SteriSEQ Rapid Sterility Testing Kit can be used as an in-process control before the final product release. With results in less than 5 hours, the SteriSEQ kit can enable early detection of gross contamination and assess the likelihood that a product may fail sterility.

Real-time PCR (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.

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 help 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 products with short shelf lives include cell and gene therapies, which require a new generation of risk-based approaches that include rapid microbial tests [1].

Easy qPCR workflow delivers results in <5 hours

The Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing System is a qPCR solution designed to streamline the integration of sterility testing into your manufacturing process. It incorporates reliable Applied Biosystems™ qPCR systems, paired with specialized analytical software to aid in regulatory compliance. The SteriSEQ system workflow provides a simple and user-friendly method for detecting contaminants. To help ensure seamless functionality and comprehensive system integration, all components are internally tested and validated to work cohesively.

Workflow for the SteriSEQ Rapid Sterility Testing System:

Prepare sample	Set up reaction	Run qPCR	Analyze
	 SteriSEQ Rapid Sterility Testing Kit	 Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System	 Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software
~2.5 hours	Real-time PCR: ~1.5–2.5 hours		

Ordering information

Product description	Cat. No.
Rapid sterility testing kits	
SteriSEQ Rapid Sterility Testing Kit (100 reactions)	A57185
SteriSEQ Rapid Sterility Testing Kit (50 reactions)	A57186
qPCR system	
Pharmaceutical Analytics QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL, desktop	A31672
Analysis software	
AccuSEQ Real-Time PCR Detection Software v3.2	A58643

References

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.

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