Pharma analytics

SteriSEQ Rapid Sterility Testing Kit

Sterility testing for cell therapy bioproduction samples

Introduction

In cell therapy production, rapid sterility testing plays a critical role in helping to ensure the quality and safety of the final product. Given the fast-paced nature of the production process and the limited shelf life of cell therapy products, it is imperative to detect contamination as early as possible in the workflow. By implementing rapid sterility testing, potential sources of contamination can be uncovered and addressed promptly, helping to reduce the risk of product loss and unexpected production delays and outcomes. This not only enhances the overall efficiency of the workflow but also helps to maintain the integrity and efficacy of the cell therapy product.

SteriSEQ Rapid Sterility Testing Kit

The Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit is built around its robust, probe-based quantitative PCR (qPCR) assay. This assay, leveraging the high performance of widely used Applied Biosystems™ TaqMan™ qPCR chemistry, has the capability to detect over 16,000 bacterial species and 2,600 fungal species.* It can accurately detect cell densities of up to 10^6 cells, without any cross-reactivity to impurities resulting from in-process production methods (Tables 1 and 2). The multiplexed assay is designed to use 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, and includes discriminatory and internal positive controls that can help differentiate a control-based contamination versus a true positive sample.

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

* Based on *in silico* testing.

The SteriSEQ Rapid Sterility Testing Kit includes:

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

Table 1. Specifications of the SteriSEQ Rapid Sterility Testing Kit.

Sample types	Cells
Therapy types	Cell therapies
Detection chemistry	TaqMan probe-based qPCR
Sensitivity	5–25 genome copies per reaction
Number of species	16,000 bacterial species; 2,600 fungal species
Number of reactions per kit	50 or 100
Assay hours	Within 5 hours
Controls	Discriminatory positive control (DPC), internal positive control (IPC)
PCR inhibition	No inhibition observed in the presence of cell by-products
Cell line DNA	No cross-reactivity observed with production workflow components (e.g., CHO cells, HEK cells, adenovirus type 2, kanamycin and ampicillin resistance genes, baculovirus, and lentivirus)
Sample matrices	Jurkat cells

Table 2. Partial panel of species detected using the SteriSEQ Rapid Sterility Testing Kit.

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

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Integrated controls enable increased accuracy

The SteriSEQ Rapid Sterility Testing Kit includes a discriminatory positive control (DPC), as well as an internal positive control (IPC). The DPC uses a proprietary DNA sequence that enables risk-free spike control testing, reducing false positive calls caused by accidental cross-contamination. The IPC serves as a PCR inhibition control to provide confirmation of consistent performance across all reactions (Figure 1).

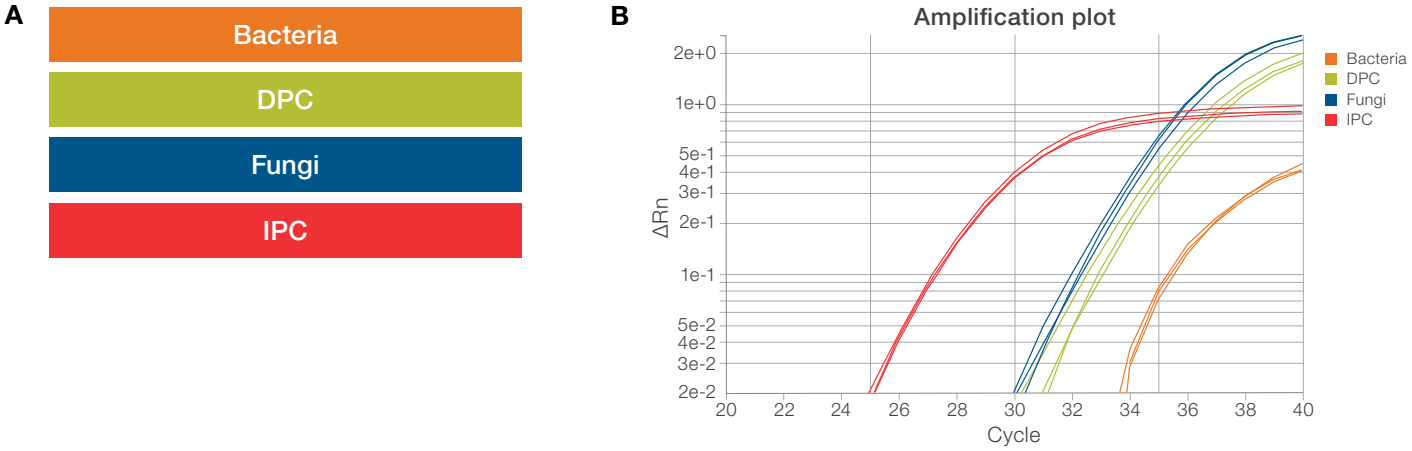

Figure 1. Confidence in performance. (A) Indicates the different targets. **(B)** A qPCR amplification plot obtained using a sample with simulated contamination (20 copies) to illustrate the different targets.

Comprehensive qPCR workflow delivers results in hours, not days

The SteriSEQ Rapid Sterility Testing Kit is part of a comprehensive qPCR solution that greatly simplifies implementing sterility testing into your manufacturing process. Featuring trusted Applied Biosystems™ real-time PCR instruments with analytical software to help enable regulatory compliance, the SteriSEQ Rapid Sterility Testing Kit provides a simple, easy-to-implement approach to contaminant detection.

- Actionable qPCR results in less than 5 hours (Figure 2)
- Single-well multiplexed assay detects both bacterial and fungal contamination
- Efficient qPCR workflow solution, including security, audit, and e-signature (SAE)-compatible software
- Global network of regulatory and field application specialists for support from method development and implementation through validation

Workflow for the SteriSEQ Rapid Sterility Testing Kit

Figure 2. Workflow solution to support in-process and cell bank testing. The SteriSEQ kit is an integrated solution that includes analytical software reports for sterility testing during cell therapy manufacturing.

AccuSEQ Real-Time PCR Detection Software for automated data analysis

Automated reporting of presence or absence results from the SteriSEQ Rapid Sterility Testing Kit can be generated using Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software. Automated analysis tools enable one-click processing of SteriSEQ assay data, delivering presence or absence calls within seconds of data collection being completed.

For in-depth review of the data, 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. SAE capabilities included with AccuSEQ software help enable compliance with 21 CFR Part 11. AccuSEQ software is available for both Applied Biosystems™ QuantStudio™ 5 and 7500 Fast Real-Time PCR Systems (Figure 3).

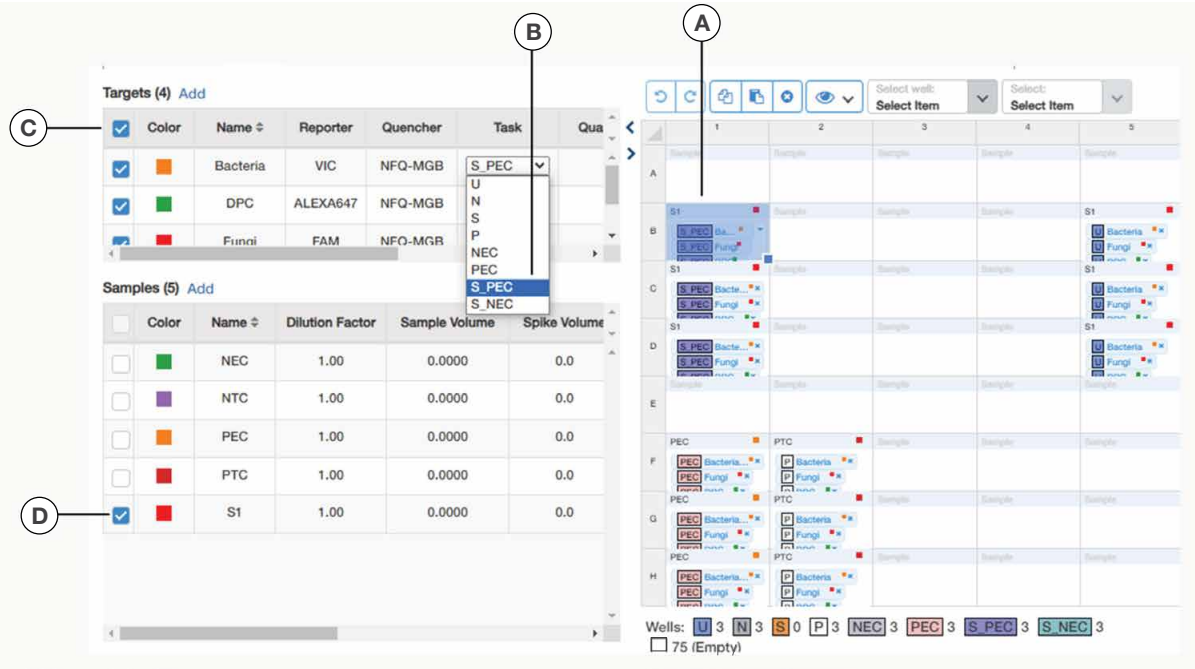

Figure 3. Example plate layout. (A) Selected well. **(B)** Selected task for each target for the well. **(C)** Selected targets for the well. **(D)** Selected sample or control for the well.

Ordering information

Product	Cat. No.
Rapid sterility testing kits	
SteriSEQ Rapid Sterility Testing Kit (100 reactions)	A57185
SteriSEQ Rapid Sterility Testing Kit (50 reactions)	A57186
Real-time PCR systems	
Pharmaceutical Analytics QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL, tower	A31672
7500 Fast Real-Time PCR System, tower, QST	4365463
Analysis software	
AccuSEQ Real-Time PCR Detection Software v3.2 (for QuantStudio 5 instrument)	A58643
AccuSEQ Real-Time PCR Detection Software v2.2 (for 7500 Fast instrument)	A58642

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