

BioPharma Product Testing

Abstract

As the pharmaceutical industry continually evolves, so do the products they produce. Viral Vectors, Cellular Therapies, and Gene Therapies are becoming increasingly predominant as they are a more naturally sourced treatment of illness and disease. However, these types of treatments can present challenges to pharmaceutical developers because of their unique make up, as most of these products are made for specific, individual patients, and sometimes originate from a patient's own body. Along with this, most of these products are integral, requiring short testing timelines, as they may be needed as soon as possible for critically ill patients. Most compendial methods aren't conducive to these tight timelines. In these instances, alternative methods may be the only option in getting these products to patients in dire need. A rapid contamination check may be an alternative option to compendial sterility testing to ensure that these products are administered to patients in time. There are important things to consider when evaluating alternative testing and outsourcing to ensure your product is going through appropriate GMP and compliant testing.

Introduction

Why we need sterility testing is simple: because it is in the name of the test. Products need to be free from the presence of viable organisms, ensuring they will not cause harm to patients, especially those who may be immunocompromised. It is required for all products and materials that claim to be sterile.



Learning Objectives

In this presentation, Eurofins BioPharma Product Testing will dive into key information needed as a third-party testing facility when effectively serving clients using a rapid contamination check and expanding on troubleshooting experiences when performing testing.

Alternatives to Sterility Testing of Cell and Gene Therapies

Challenges of Testing and Considerations

Alternative Methods

- Rapid Contamination Check
- Also referred to as Rapid Sterility
- Can provide results in as few as 7 days
- Half the time of compendial sterility test which requires 14 days of incubation
- Some outsourcing laboratories provide and report interim results during incubation
- Allows clients to weigh and make decisions for critically ill patients
- There are different methods for rapid sterility testing to consider based on your product:
- Respiration Detection-Based Methods
- i.e. BacT/ALERT
- ATP Detection-Based Methods
- i.e. Celsis

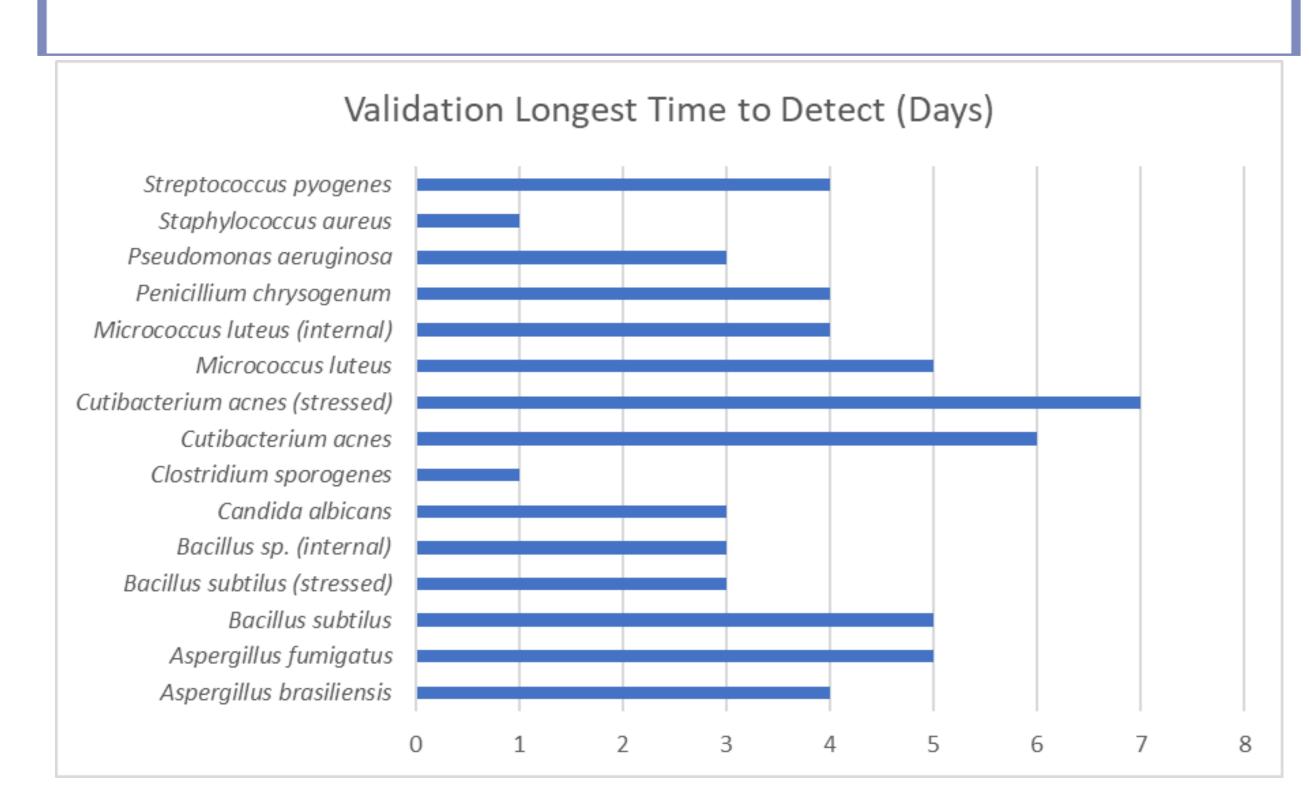
Organism	ATCC#
Streptococcus pyogenes	ATCC 19615
Staphylococcus aureus	ATCC 6538
Pseudomonas aeruginosa	ATCC 9027
Penicillium chrysogenum	In-House Isolate
Microccosus luteus	In-House Isolate
Micrococcus luteus	ATCC 700405
Cutibacterium acnes (stressed)	ATCC 6919
Cutibacterium acnes	ATCC 6919
Clostridium sporogenes	ATCC 11437
Candida albicans	ATCC 10231
Bacillus sp.	In-House Isolate
Bacillus subtilus (stressed)	ATCC 6633
Bacillus subtilus	ATCC 6633
Aspergillus fumigatus	In-House Isolate
Aspergillus brasiliensis	ATCC 16404

Method Suitability

- Also known as Bacteriostasis/Fungistasis
- This is one of the biggest hurdles to complete, as it ensures microbial contamination present will be recovered when performing the sterility test
- Helps address any possible inhibitory factors in the product and prevent false negative results

Sample Volume Requirements

- There is no compendial driven volume requirement for Rapid Sterility, and because of this, significantly less sample can be used than compendial tests
- Method Suitability Testing:
- Dependent on method, different media types, organisms tested, and controls
- The more medias and organisms tested requires more product
- However, this can lead to a better panel of results, and shorter testing times
- Amount tested during method suitability impacts routine testing volume needed
- Routine Testing
- Can be performed on as little as 1mL per media type
- i.e. BacT/ALERT can utilize three medias: iNST, iAST, and iLYM



Sample Submission

- Can differ depending on outsourcing laboratory
- Some facilities only accept samples inoculated at the client facility
- If this occurs, does your laboratory offer QC released media or do you have to procure it?
- Other facilities will inoculate within their sterility isolator

Outsourcing Considerations: Capacity

- Can the outsourcing laboratory appropriately handle your project?
- Project Management
- Communication bridge to help support your project
- Technical Support
- Most data is reported through electronic systems, can they provide support?
- Quality Assurance
- Well trained staff overlooking release of results

Outsourcing Considerations: Staff

- Do they have multiple shifts that have 7 day a week coverage?
- Is the staff well trained and competent?



Outsourcing Considerations: Redundancy

- Are there multiple pieces of functioning equipment, as issues and maintenance occur?
- If one system fails, does it completely halt testing operations?

Outsourcing Considerations: Environmental Monitoring

- Is there appropriate environmental monitoring?
- Plays an integral role in the event of a positive result

Author: Zachary Beck, B.S.

Keys to Success

- Start the conversation with your third-party laboratory as soon as possible
- Share as much information about your product as possible
- Establish Timelines
- When can they expect submissions?
- What is the drop-dead timeline related to your product?



Disclaimer: Evaluation of the use of alternative methods should be done through risk assessments and in collaboration with regulatory agencies.

