# Rapid Sterility Webinar Questions and Answers

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

## Q&A Session

1. **Given the limitation on detectable organisms, can any CO2 detection methods be used as a single method to satisfy USP <71> requirement?**

   No rapid sterility test will satisfy USP <71> testing requirements. USP <71> requires a specific incubation time (14 days) and conditions. Therefore, any alternative test method which offers reduced incubation times cannot accurately claim to be compliant with USP <71>.

   It is possible that rapid sterility methods, which utilize CO2 detection, may not detect all microorganisms that a traditional sterility test would detect. It is important that a thorough validation protocol address any potential limitations of a rapid sterility system.

2. **Because the BactiAlert uses CO2 production as its detection method, does that mean it may not catch all the organisms that a USP <71> will catch?**

   The BacT/ALERT 3D system has demonstrated the ability to detect the six USP <71> compendial microorganisms, and many others. Its ability to detect every microorganism in a USP <71> sterility test is more difficult to determine. It is important that a thorough validation protocol address any potential limitations of a rapid sterility system.

3. **Why are including stressed organisms important during the method validation?**

   Recovery of stressed / injured microorganisms are important because they are representative of potential contaminants present in pharmaceutical preparations.

4. **Do growth-based rapid sterility tests utilize a 2-3 day incubation period?**

   Yes, there are some growth-based rapid sterility test methods which utilize a 2-3-day incubation period. The incubation time required varies based on detection method and should be concluded based on the method validation results. Using the Celsis Advance, ARL validation testing results indicated that 5-6 days of incubation is required to detect all stressed / injured microorganisms.

5. **How many organisms are required for method suit and is this the same number of organisms required for USP <71>?**

   A reasonable method suitability protocol should include the 6 microorganisms in USP <71>. There is the option of including additional challenge microorganisms based on a firm's specific requirements.

6. **Will a method-suitability "library" be available to customers. For example, a solution of morphine 20 mg/ml in saline is a simple, but frequently prepared sterile preparation. Will ARL require my specific solution to be tested for suitability, or will a library of method suit studies be used?**

   At this time, no library will be available to perform full method suitability references. Partial references, or verifications, will be offered for similar products at a reduced cost. Please contact ARL directly for more information.

7. **Does ARL recommend sampling per USP <71> for rapid methods? What if the method cannot handle that large of a volume?**

   While ARL does not cite USP <71> as the test method, we suggest submitting the full USP <71> required test volume. These recommendations are made based on statistical likelihoods of detecting a contaminant in a batch, should one be present.

# Rapid Sterility Webinar Questions and Answers

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

## Q&A Session (continued)

**8. Can you compare Celsis Rapid System method with that of ScanRDI?**

The Celsis Rapid Sterility Method is a growth-based sterility test, which detects microbial contamination based on the presence of microbial Adenosine triphosphate (ATP) in a sample. Since it is a growth-based test, it is more readily compared to the compendial USP <71> test. Additionally, when comparing to other competing technologies, the Celsis Rapid Sterility test allows for the processing of multiple sample types (solutions, oils, suspensions, etc.). If a test failure occurs, the Celsis system also allows for microbial identification since it does not require an additional filtration of the test media.

**9. What kind of out of spec investigation can occur if there is no sample?**

Certain rapid sterility systems allow for the exact test sample and media to be investigated in the case of a suspected contamination. This is a strength of non destructive tests. Other rapid sterility systems do not allow for investigations, which may require a second sample to be assessed for contamination. This can be problematic if microbial contamination is not uniform. Since a representative contaminant ID may not be ascertained, it would be more difficult to perform a complete investigation.

**10. Can you comment on the cost of initial setup and routine analysis?**

Standard tests costs are a one-time $1,500 charge for Method Suitability, and $250 for a rapid sterility test of the same formulation.

**11. Can you confirm that rapid sterility methods are not allowed in California? Is CA for prescriptions, outsourcing or just not accepting it at all?**

As of January 31, 2020, the California State Board of Pharmacy had no plans to address rapid microbiological methods or any compounding regulations until after the USP appeals had been completed. As of today, 21CCR section 1751.7(e)(1) will not allow any non-USP 71 test for end product release testing.

Follow California State Board of Pharmacy Compounding Committee for updates: https://www.pharmacy.ca.gov/about/meetings.shtml

Click here to access Rapid Sterility Webinar On Demand.
Click here to access additional information on Rapid Sterility Testing.