

# Rapid Contamination Check

Eurofins BioPharma Product Testing provides complete GMP rapid sterility testing in less time than the compendia method, including 3 day interim results with certificate of analysis. Utilizing the BioMerieux BacT/Alert 3D system, we can help you reduce product cycle times and improve overall production efficiency with our rapid sterility testing.

## Why Choose Eurofins BioPharma Product Testing?

With faster detection, we are able to help clients reduce the financial and operational impact of a contamination event by initiating investigations and corrective action early in the process.

We help bio/pharmaceutical companies manage the transition from the traditional compendial sterility method to a fully-validated rapid method.

We provide a 3 day Certificate of Analysis of interim test results.

We provide BacT/Alert culture bottles to our clients to allow for sampling during the manufacturing process, eliminating secondary transfers and potential sources of microbial contamination.

Our large and flexible Microbiology team of 80 microbiologists provides expansive capacity and over 40 years of experience serving the bio/pharmaceutical industry.

Our industry leading online data portal, LabAccess, provides customers access to our LIMS system, allowing 24 hour access to data.

## About the BacT/Alert 3D Technology

BioMerieux developed the BacT/Alert 3D microbial detection system as a fully automated system built on their patented colorimetric technology that detects microorganisms' growth by tracking CO<sub>2</sub> production. The system incubates, agitates, and with solid-state reflectometers, continuously monitors the status of each culture bottle for microbial growth.



If microorganisms are present in the test sample, CO<sub>2</sub> is produced as the microorganisms metabolize the substrate found in the culture medium. When growth of the microorganism produces CO<sub>2</sub>, the color of the sensor located in the bottom of each culture bottle changes from dark to light. A light emitting diode (LED) projects light onto the sensor, which is then reflected and measured by a photodetector.

There are several advantages to this technology including the testing timeline. Timelines for releasing sample results are <7 days, compared to the 14 day incubation required for compendial sterility. In addition, turbidity that may occur in the sample due to the presence of cellular components or debris does not have an impact on the results of the system. This makes the system suitable for testing a wide range of products.

The BacT/Alert 3D system accommodates varying sample types, sample sizes, enrichment broths, and volumes, and is generally accepted as an alternative method for testing short shelf-life products. With faster micro screening and shorter production cycle times, this method delivers significant cost savings and efficiencies.

The Rapid Sterility Test performed by Eurofins BioPharma Product Testing is referred to as BacT Test and is intended to serve as a Rapid Contamination Check with a method that was validated in accordance with USP <1223>. While the BacT test was determined to be non-inferior to the USP <71> test, it is not a replacement for the USP <71> test.

### Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing  
Cell Banking Services • Virology Services • Facility & Process Validation  
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
Stability Testing & Storage • Primary & Secondary Package Testing

### Flexible Service Models

Fee For Service (FFS)  
Full-Time-Equivalent (FTE)  
PSS Insourcing Solutions®

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