



# BACT/ALERT® 3D DUAL-T

The complete solution for automated sterility testing.



PIONEERING DIAGNOSTICS

# Ensure patient safety with smart microbial testing.

The BACT/ALERT 3D DUAL-T offers advantages in every dimension. From its space-saving modular design to ease-of-use to flexible data management, it's a state-of-the-art solution for any size lab. And with dual-temperature incubation, the BACT/ALERT provides users with a reliable and objective alternative to the compendial method of sterility testing.

- Ready-to-use media bottles minimize handling and contamination
- Reagents with unique identification barcodes for traceability
- Automated, reliable, and objective results
- Continuous growth monitoring for real-time results
- Audit trail records, tracks, and reports on user actions
- 21 CFR Part 11 compliance-ready



## **ROBUST**

Detects bacteria, yeast, and mold



## **AUTOMATED**

Reduced labor and hands-on time



## **OBJECTIVE**

No manual interpretation required

## **FASTER STERILITY DETERMINATION WITH DUAL-TEMPERATURE TESTING.**

The BACT/ALERT 3D Low Temperature (LT) Module contains one BACT/ALERT 3D 240 incubator specifically designed and validated for incubation at 20-25°C. Each LT Module maintains its incubation temperature with a patented design that includes a built-in refrigeration unit.

- Validated for operation in normal lab environments
- Easily connects to BACT/ALERT Controller Module
- Easily upgrade your standard BACT/ALERT 3D to a DUAL-T system by adding the LT modules
- Extensive internal validation demonstrates ruggedness and robustness
- Validated for use with associated bioMérieux aerobic and anaerobic BACT/ALERT culture media bottles

## INTERNATIONALLY RECOGNIZED. PHARMACOPOEIA-COMPLIANT.

BACT/ALERT 3D DUAL-T is globally recognized by the industry and pharmacopoeias for use as a sterility testing method, according to:

- **EP 5.1.6:** Alternative methods for control of microbiological quality
- **USP 1223:** Validation of Alternative Microbiological Methods
- **EP 2.6.27:** "Microbiological examination of cell- based preparations
- **FDA Draft Guidance for Industry**
- **FDA 21 CFR 610.9:** Equivalent methods and processes.
- **PDA Technical report #33 :** Evaluation, Validation and Implementation of Alternative and Rapid Microbial Methods
- **USP 1071:** Rapid Microbial Tests for Release of Sterile Short Shelf Life Products: A Risk-based Approach

## BACT/ALERT 3D DUAL-T INCLUDES:



BACT/ALERT 3D 240 Incubator  
+ Controller Module  
• 30-35°C



BACT/ALERT 3D Low  
Temperature (LT) Module  
• 20-25°C

## TESTING IN THREE EASY STEPS.



INOCULATE



SCAN



LOAD



## EXPERT VALIDATION AND TECHNICAL SUPPORT FROM FELLOW SCIENTISTS.

To streamline the validation of BACT/ALERT 3D DUAL-T as a viable alternative to compendial testing, bioMérieux provides the BACT/ALERT Implementation Guide (BIG), which contains:

- Installation Qualification
- Operational Qualification
- Performance Qualification
- Validation Report

Don't have the resources for internal validation? A bioMérieux-approved partner can provide certified validation services to get your new BACT/ALERT system up and running without disrupting your current workload.

In addition, bioMérieux has a dedicated technical support team that works specifically with BACT/ALERT 3D DUAL-T for the industrial market. Our team can help conduct feasibility studies and provide protocol support, as well as continuous product support for BACT/ALERT customers around the globe.

