



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 viable alternative to compendial 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- **FDA Draft Guidance for Industry**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



MYLA®, AN INTEGRATED DATA MANAGEMENT SOFTWARE

When speed and accurate test results are critical for both in-process quality control testing and release product testing, put time on your side with insightful data. MYLA provides a dashboard view of your instrument status and testing, consolidated results and helps you anticipate corrective actions with real-time alerts of positive bottles.

- Monitor instruments & results locally and remotely
- Easy to generate real-time and on-demand reports
- Data Integrity & cybersecurity
- 21 CFR part 11 compliance ready
- Un-editable results & indefinite data storage
- Remote support via VILINK remote support tool



Leverage VILINK for rapid, remote support service – all within the safety of your IT network. VILINK is your one-touch access to bioMérieux technical support and helping you be productive.

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. We can help conduct **feasibility studies** and provide protocol support, as well as continuous product support for BACT/ALERT customers around the globe.

