

BIOMÉRIEUX

# BACT/ALERT® 3D DUAL-T

THE COMPLETE SOLUTION  
FOR AUTOMATED STERILITY TESTING.



Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS



# Sterility Testing Made Simple and Accessible with BACT/ALERT® 3D DUAL-T

For more than 15 years, the BACT/ALERT has delivered **simplicity** and **flexibility** to sterility testing with automated contamination detection in a wide range of industrial\* samples.



## Anyone

- No advanced skills required
- Automated and easy-to-interpret results



## Anywhere

- No specialized lab required
- Testing can be moved closer to production



## Anytime

- Minimal hands-on-time
- On-demand testing for scheduling flexibility

## Simple Workflow, Fast Results

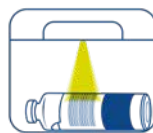
Not only does BACT/ALERT **decrease the time of traditional sterility testing results by half\*\***, it also minimizes your hands-on-time with a **three-step workflow**:

1



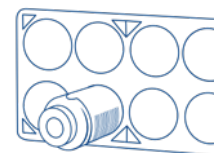
INOCULATE

2



SCAN

3



LOAD

**Continuous monitoring provides real-time alerts** allowing you to take corrective actions sooner. Connect your BACT/ALERT to our data management software, **MYLA**® to consolidate your data and optimize traceability and data integrity.

\* Industrial: pharmaceutical & food samples.

\*\* Timeframe must be validated by customer.

## Incredibly Flexible



- **Compatible with a broad range of matrices to meet your needs**
  - Cell-based products
  - Non-filterable, viscous or turbid products



- **Dual-temperature incubation ensures recovery of aerobic and anaerobic strains**
  - High temperature module: 30-37°C
  - Low temperature module: 20-25°C



- **Scalable so you can adapt your system size to your throughput**
  - 120 to 1440 bottles per system



- **On-demand testing and automated reading brings flexibility to your testing schedule**
  - Add samples at anytime
  - 24/7 remote alerts through MYLA

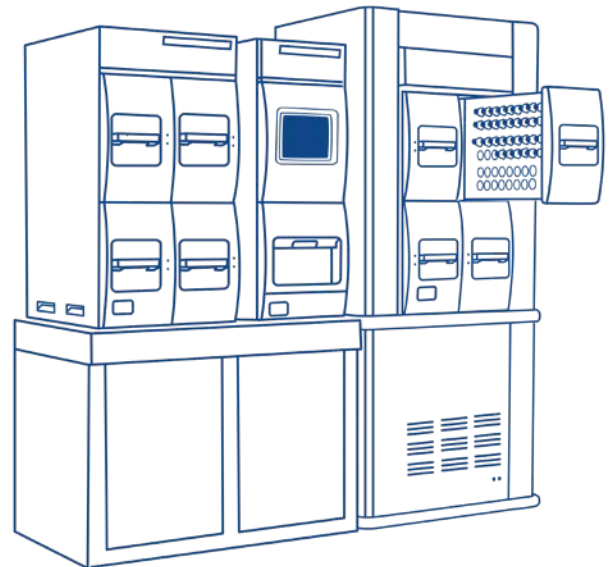
## Rely on a Proven Solution

- **Accepted by regulatory bodies**

- BACT/ALERT has been validated by numerous customers for product release and accepted by US Food and Drug Administration, European Medicines Agency & others.
- Accepted as a compendial method for designated products:
  - > Chinese pharmacopeia and , EP 2.6.27 for cellular products
  - > USP 72 for short shelf-life products

- **Widely used in industry\***

- More than 700 Industry users worldwide.
- More than 80% of top 20 pharma companies\*\*\* are BACT/ALERT users.



## 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:

- **URS completion guide**
- **IOPQ guide**
- **Primary validation report**
- **Suitability testing**
- **Feasibility studies**

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.

\*\*\* As defined by FiercePharma & IQVIA - <https://www.fiercepharma.com/pharma/top-20-pharma-companies-2022-revenue>

\*\*\*\*Check with your sales representative for availability in your area.



## Enjoy a Wide Range of Media to Answer your Needs

Specifically developed and qualified for industrial microbiology applications, the BACT/ALERT Culture Media Bottles portfolio can address a wide range of needs such as the recovery of aerobic and anaerobic microorganisms as well as the neutralization of residual antimicrobials in matrices.

Best practice is to use a set of aerobic and anaerobic bottles when culturing samples for optimized overall recovery. Each bottle comes in packages of 100.

NAME	REFERENCE NUMBER	FORMULATION	CAP COLOR
<b>iAST</b> Standard (Aerobic)	<b>259786</b>	40ml Supplemented Tryptic Soy Broth (TSB); CO2 in oxygen	Blue 
<b>iNST</b> Standard (Anaerobic)	<b>259785</b>	40mL Supplemented TSB; Nitrogen	Purple 
<b>iFA PLUS Resin</b> For antimicrobial neutralization (Aerobic)	<b>412990</b>	30 mL Supplemented TSB; CO2, N2, and oxygen with adsorbent polymeric beads neutralizer	Light Green 
<b>iFN PLUS Resin</b> For antimicrobial neutralization (Anaerobic)	<b>412991</b>	40 mL Supplemented TSB; Nitrogen and CO2 with adsorbent polymeric beads neutralizer	Orange 
<b>iLYM</b> For Lactic, Yeast, & Mold (Anaerobic)	<b>259788</b>	20mL Supplemented Carbohydrate Medium; Nitrogen	Green 