

CITATIONS

BACT/ALERT®

1. "How a Top 5 Pharma Company Protects Production and Increases Productivity Using BACT/ALERT® 3D". Available on <https://www.biomerieux.com/us/en/education/resource-hub/case-studies/pharmaceutical-qc-case-studies/how-a-top-5-pharma-company-protects-production-an-increases-productivity-using-bact-alert-3d-media-statement.html>

ENDOZYME® II GO

2. "Comparison of bacterial endotoxin testing methods in purified pharmaceutical water matrices". Available on <https://www.sciencedirect.com/science/article/pii/S1045105620300774?via%3Dihub>

3P® ENTERPRISE

3. "Environmental Monitoring: Expert Discussion on the Benefits of a Single Incubation Temperature". Available on <https://www.biomerieux.com/corp/en/education/resource-hub/webinars/pharmaceutical-qc-on-demand-webinars/Environmental-Monitoring--Expert-Discussion-on-the-Benefits-of-a-Single-Incubation-Temperature.html>

CREATING VALUE BY HARVESTING THE FULL POTENTIAL OF YOUR BIOPROCESSING TESTING



Your Ally in Advancing Quality

BY YOUR SIDE TO INCREASE EFFICIENCY THROUGHOUT THE VALUE CHAIN OF VACCINES AND RECOMBINANT PROTEINS

Today’s pharmaceutical landscape is more vibrant than ever; and while new modalities such as mRNA and an ever-increasing number of biosimilars help make critical vaccines and therapies available to more patients in need, they also put pressure on manufacturers to control costs to deliver these drugs safely while remaining profitable.

While there is no single solution to **increasing operational efficiencies and reducing costs of non-quality**, industry experts agree that **automating routine analytical testing brings value by reducing costly errors; providing reliable, actionable and traceable data faster; and increasing throughput to reduce bottlenecks.**



INCREASED LAB EFFICIENCY

Automation & digitalization

- Reduce human error
- Reduce retesting
- Reduce subjectivity
- Increase standardization and facilitate training
- Optimize workflows
- Improve data integrity and traceability
- Increase throughput to reduce outsourcing

Decentralized testing

- Move in-process testing closer to production



OPTIMIZED PRODUCTION COSTS

Reduce cost of non quality through rapid in-process controls and digitalization

- Reduce scrap
- Facilitate investigations
- Reduce downtime
- Optimize human resource utilization

Reduce working capital

- Release product to market faster with rapid methods

The people of bioMérieux are proud to be Your Ally in Advancing Quality by providing the most comprehensive portfolio of microbiology Quality Control solutions to monitor your products, process and environment.

CRITICAL QUALITY ATTRIBUTES TESTING	ENVIRONMENTAL MONITORING	MICROBIAL IDENTIFICATION	SERVICES AND IT
Rapid Sterility BACT/ALERT® SCANRDI®	Automated EM 3P® ENTERPRISE 3P® SMART PLATES	 VITEK® MS PRIME	 FEASIBILITY & VALIDATION
Rapid Mycoplasma BIOFIRE®	 3P® CONNECT SOFTWARE	 VITEK® 2 COMPACT	 INSTRUMENT AND APPLICATION SUPPORT
Rapid Endotoxin ENDONEXT™	 3P® STATION	STANDARDIZED STRAINS	 ENDOXPerts™
	Active Air Monitoring AIRIDEAL®	 BIOBALL®	 VITEK® EXPRESS*
	Surface Monitoring APP LOCKSURE3P™ QUANTISWAB		

*Available in some countries.
For more information,
contact your bioMérieux
representative.

CRITICAL QUALITY ATTRIBUTES TESTING

With hundreds of steps required to manufacture a biologic, monitoring your product and process at key points gives you the confidence that your batch quality is secure.

Rapid and automated technologies for both **in-process** and **release testing** increase the **efficiency of your operations through standardization—reducing the cost of non-quality by cutting costs** from scrap, investigations, downtime, decontamination, and additional human resources.

Rapid Sterility



Rapid Mycoplasma



Endotoxins



Our user-friendly platforms will not only help **make your lab workflow more efficient** and improve your team's work environment, but also **reduces risk of error and increases data integrity**. Collectively, these improvements **increase efficiency of each technician** which can **reduce reliance on costly outsourcing of testing**.

CRITICAL QUALITY ATTRIBUTES TESTING SOLUTIONS RAPID MYCOPLASMA

BIOFIRE® MYCOPLASMA

1-HOUR MYCOPLASMA TESTING BY ANYONE, ANYWHERE, ANYTIME

While Mycoplasma contamination is infrequent in a GMP environment, testing for Mycoplasma is necessary for both regulatory compliance and business continuity. bioMérieux has revolutionized the complex process of Mycoplasma testing with BIOFIRE® Mycoplasma; with just two minutes of hands-on time, BIOFIRE® provides sample to results in less than one hour.



ANYONE

- Easy to learn with no PCR skills required
- Automated with simple presence/absence results

ANYWHERE

- No specialized lab required
- Can be performed near production line

ANYTIME

- Sample to results in less than an hour
- On-demand testing provides scheduling flexibility



RAPID STERILITY & BIOBURDEN

BACT/ALERT® 3D DUAL-T

THE METHOD OF CHOICE FOR RAPID STERILITY TESTING

BACT/ALERT® 3D DUAL-T simplifies sterility testing of cell-based matrices. The “load and go” system cuts the time of traditional growth-based methods in half; automatically monitoring your sample and alerting you in real-time if contamination is present.



SCANRDI®

WHEN YOU NEED TO KNOW NOW

If you need sterility or bioburden results within the same shift, SCANRDI® gives you the answers you need within 4 hours; making it a powerful tool for troubleshooting or facilitating investigations.



“By implementing the BACT/ALERT® 3D DUAL-T, we save **€150,000 per year.**”

— Top Vaccine Manufacturer¹



“We have **reduced our cycle time 50 to 75%** by using BACT/ALERT®.”

— Top Vaccine Manufacturer¹

ULTRA-RAPID

- Same-shift results (<4 hours)
- Release your products faster

BROAD SPECIFICITY

- Universal labeling detects bacteria, yeasts and molds
- Proven compatibility with >200 drug products*

COMPLIANT

- Full validation support—URS completion guide, primary validation report, suitability guide and Drug Master File (DMF)

**non exhaustive list*

SIMPLE

- Minutes of hands-on time
- Automated continuous reading
- Objective, standardized results improves data integrity

FLEXIBLE

- Dual- temperature incubation
- Modular system to meet throughput needs
- Random-access loading for scheduling flexibility
- Release final product or get and early alert for inprocess controls

PROVEN

- Validated protocols and Master File (MF) with US FDA
- More than 1,400 industrial microbiology systems worldwide



BACTERIAL ENDOTOXIN TESTING

ENDOZYME® II GO

EMBRACE rFC FOR LAB TRANSFORMATION

Streamlined endotoxin testing is a key factor in driving efficiency. Our recombinant ENDOZYME® II GO, with pre-coated standards not only reduces errors, hands-on time and variability of your bacterial endotoxin testing, it also offers flexible throughput options ranging from single sample testing to full automation to enhance traceability.



EFFICIENT

- Throughput options ranging from single-test strips to 120 water samples per hour with fully-automated TECAN® Fluent handles up to 120 water samples per hour
- Simplified reaction requiring only one reagent, reducing complexity and potential errors

ROBUST

- 100% endotoxin specificity—no false positives from β -Glucan
- Recombinant production provides high lot-to-lot consistency
- Fewer invalid results reduces costly retesting

SUSTAINABLE

- Supports 3Rs principle (Replace, Reduce, and Refine) as Recombinant Factor C does not use horseshoe crab blood
- Increases supply chain security by limiting dependency on a natural resource
- Reduces use of plastics compared to cartridge-based testing



“The ENDOZYME® II GO assay had the **lowest sample CVs**, showed **very low variability**,...presented the **best correlation for the standard curves**, and had the **lowest rate of invalid results**.”

— Marius et al.²
Sanofi Pasteur

ENDOXPERTS™ Services for Low Endotoxin Recovery (LER)

Regulatory bodies such as the US FDA require Hold Time Studies as part of new Biological License Applications to prove there is no masking of endotoxins by the product. Our ENDOXPERTS™ can not only perform these studies for you, but also develop a “de-masking” protocol to overcome LER, if present.



ENVIRONMENTAL MONITORING SOLUTIONS

Environmental Monitoring (EM) data is perhaps the best overall indicator of the overall health of your biomanufacturing process, so it is critical that the data are collected, processed, and trended accurately to drive informed decisions.

Each of our 3P® EM suite of solutions is designed to **improve and secure efficiency through standardization and digitalization**.

3P® SMART PLATES



Digitalization

3P® CONNECT



Full automation

3P® ENTERPRISE



3P® ENTERPRISE simplifies and secures your microbial EM activities **from sample preparation to data approval**.

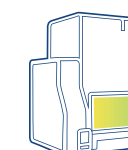
Make your EM analysis even more powerful with **standardized counting results and automated reading**. **Early alerts for Out-of-Specification results facilitate faster corrective actions**.

Standardized Strains



BIOBALL®

Automated Microbial Identification



VITEK® MS PRIME



VITEK® 2 COMPACT



By adding **BIOBALL®** for your growth promotion testing and the **VITEK® MS PRIME** for automated microbial identification of colonies, you can bring even **more efficiency and data integrity** to your EM program.

DIGITALIZED AND AUTOMATED ENVIRONMENTAL MONITORING

PHARMACEUTICAL PROVEN PERFORMANCE (3P®) SOLUTIONS

Our 3P® solutions for environmental monitoring are **fully integrated** and designed to **optimize and secure** operations of your biomanufacturing process.

3P® SMART PLATES are thoughtfully designed with **GS1 barcoding and clear design to enhance the reliability of your data. Tracking is continuous throughout the entire EM workflow** through the user-friendly **3P® CONNECT SOFTWARE**.

Combined with the **3P® STATION**, a system that **automates the incubation and reading** of standard Petri dishes, you reach **end-to-end maximum efficiency and improve compliance**.



“By combining kinetic technology with single temperature incubation, **we’ve been able to provide early results.**”

— Thierry Bonnevey³
Sanofi Pasteur



“**We’re saving a lot of time** with kinetic reading and early indications of out-of-specifications, so that **we can act on issues earlier.**”

— Thierry Bonnevey³
Sanofi Pasteur

3P® SMART PLATES EM-BRACE TRACEABILITY

3P® SMART PLATES are the cornerstone of the EM process when it comes to data accuracy and traceability. Specifically designed to deliver Pharmaceutical Proven Performance, you can rest assured that your sampling is secured.



3P® CONNECT EM-BODY CONNECTIVITY

3P® CONNECT empowers you to plan and execute your EM sampling workflow knowing you can trust the data collected. Full traceability and trending ensure reliable decision making and process efficiency.



STREAMLINED

- Intuitive software centralizes data capture and storage, eliminating paper
- Integrated sampling plan with map or list user navigation guidance
- Real-time conformity checks and user alerts

AUTOMATED

- Real-time capture and tracking of data, events, and actions
- Fully integrated trending and reporting tools

IT READY

- Full connectivity with seamless integration into IT infrastructures
- Cybersecurity by design
- 21 CFR Part 11 compliance

3P® STATION EM-POWER THE FUTURE

Bring full automation and digitalization to your EM process with 3P® STATION. This highly-flexible workhorse not only delivers standardized counting results and automated reading but early alerts of out-of-specification sample alerts for faster corrective actions.



PERFORMANT

- Long shelf-life, large batch sizes
- Monolot delivery with flexible storage conditions (2-25°C)
- Validated for use in isolators

SECURE

- Patented LOCKSURE® locking mechanism
- Dual manufacturing in France/USA for continuous supply

CLEARLY TRACEABLE

- “Clear design” plates ensure 99.9% of surface visibility
- GS1 compliant barcode with unique ID number

STANDARDIZED

- Automated incubation and Kinetic reading
- Hourly image capture allows time lapse review of colony growth with full traceability
- Performant algorithm able to detect 1 CFU

FLEXIBLE

- Single or double temperature incubation
- Batch or continuous loading options
- Modular system with 300 plate capacity

COMPLIANT

- Barcode reader for plate identification
- Tracking of user actions and events

ENVIRONMENTAL MONITORING SOLUTIONS

STANDARDIZED STRAINS

BIOBALL®
TAKE CONTROL OF YOUR MICROBIOLOGICAL QC

BIOBALL® standardized strains are Certified Reference Material (CRM) delivering accurate and precise CFU per inoculum batch after batch, thereby significantly reducing risk of failed QC during culture media growth promotion testing and method validation.



AUTOMATED MICROBIAL IDENTIFICATION

VITEK® MS PRIME
GET SPECIES LEVEL IDENTIFICATION & MAXIMIZE YOUR LAB EFFICIENCY

Built on a solid foundation of microbiology expertise, VITEK® MS PRIME is a true evolution of the MALDI-TOF (Matrix Assisted Laser Desorption Ionization-Time of Flight) technology for microbial identification to deliver accuracy and efficiency.



ACCURATE AND PRECISE

- Patented technology delivers unprecedented accuracy
- Consistent CFU counts batch after batch, with a very low standard deviation

OPTIMIZED WORKFLOW

- No pre-incubation or standardization required with as few as 4 steps
- Test on demand – any day, anytime
- Easy cross-training between operators

ROBUST & EVOLVING

- Species-level identification of >1500 bacteria and fungi species including pharmaceutical contaminants
- More than 15,000 total strains tested to include intra-species diversity
- Strains collected from pharmaceutical customers, culture collections (ATCC®*) and internal strains across different geographies

OPTIMIZED

- Fast and easy sample preparation for bacteria and fungi
- Automated, continuous load & go
- Urgent slide prioritization for critical samples
- Automated fine-tuning

INTEGRATED

- Review results from anywhere on your network or remotely via web access
- Seamless connectivity to your LIMS
- 21 CFR Part 11 compliance with full reagent traceability

* The ATCC trademark and trade name and any and all ATCC catalog numbers are trademarks of the American Type Culture Collection.



SERVICES AND IT

SERVICES

BIOMÉRIEUX ON YOUR SIDE

We have developed a best in class range of services to accompany our customers in their search for efficiency and productivity. Every step of the way, our team of experts are your trusted partners to help you get the most out of your investment.



IT & CONNECTIVITY

DATA INTEGRITY, COMPLIANCE AND CYBERSECURITY ON YOUR TERMS

Designed to maintain the accuracy and consistency of data, our software solutions provide end-to-end cybersecurity support, and integrate seamlessly into your Information Technology (IT) environment, while ensuring compliance with regulations such as 21 CFR part 11 (ALCOA+) / Annex 11 / GMP / GAMP.



IMPLEMENTATION

- Benefit from a seamless integration of instruments in your ecosystem: lab consultancy, installation, connectivity, training

QUALITY

- Be confident in your investment with our feasibility service
- Accelerate time to routine with limited resources involvement thanks to our Qualification (IOPQ) & Method Validation offer

LIFECYCLE

- Maximize the system uptime with our instrument service
- Maintain quality and reliability through flexible service contracts program
- Ease your procurement with the supply chain services

COMPLIANCE READY

- Result revision and validation with e-signature*
- User management and access control
- Full traceability with audit trail and time stamps
- Integrated tools for digital archive and backup

CYBER SECURE

- Continuous software surveillance with cybersecurity bulletins delivered on demand**
- Vulnerabilities are assessed and corrected in patches**
- Penetration tests cybersecurity whitepapers delivered before every software release**

INTEGRATED

- Installation of your anti-virus or anti-malware***
- Integration in your domain***
- LIMS Compatibility***
- Deployment on your PC or Virtual Machine for solutions like 3P® CONNECT, MYLA®, and the VITEK® Product Range

* NA for BIOFIRE® and MYLA®

** Differences applicable for solutions like BIOFIRE® and VITEK® 2

*** Prerequisites applicable

