

# CREATE VALUE BY HARVESTING THE FULL POTENTIAL OF YOUR BIOPROCESSING TESTING



Your Ally in Advancing Quality

# BY YOUR SIDE TO INCREASE EFFICIENCY IN THE VALUE CHAIN OF VACCINES AND THERAPIES

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

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

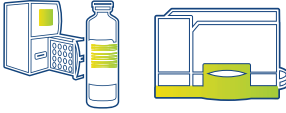





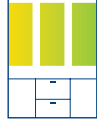









- Reduce scrap
- Facilitate investigations
- Reduce downtime
- Optimize human resource utilization

### Reduced working capital

- Release product to market faster with rapid methods

# EFFICIENCY THROUGHOUT THE AND RECOMBINANT PROTEINS

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
<p><b>Rapid Sterility</b></p>  <p>BACT/ALERT® SCANRD1®</p>	<p><b>Automated EM 3P® ENTERPRISE</b></p>  <p>3P® SMART PLATES</p>	 <p>VITEK® MS PRIME</p>	 <p>FEASIBILITY &amp; VALIDATION</p>
<p><b>Rapid Mycoplasma</b></p>  <p>BIOFIRE®</p>	 <p>3P® CONNECT SOFTWARE</p>  <p>3P® STATION</p>	 <p>VITEK® 2 COMPACT</p> <p><b>STANDARDIZED STRAINS</b></p>	 <p>INSTRUMENT AND APPLICATION SUPPORT</p>  <p>ENDOEXPERTS™</p>
<p><b>Rapid Endotoxin</b></p>  <p>ENDONEXT™</p>	<p><b>Active Air Monitoring</b></p>  <p>AIRIDEAL®</p> <p><b>Surface Monitoring</b></p>  <p>APP LOCKSURE3P™</p>  <p>QUANTISWAB</p>	 <p>BIOBALL®</p>	 <p>VITEK® EXPRESS*</p>

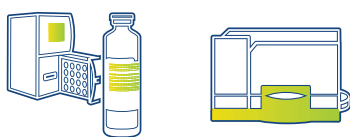
\*Available in some countries. For more information, contact your bioMérieux representative.

# 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



BACT/ALERT®

SCANRD®

## Rapid Mycoplasma



BIOFIRE®

## Endotoxins



ENDONEXT™

ENDOXPERTS™

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**.



# 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

### STERILITY TESTING SIMPLIFIED

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.



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

— Top Vaccine Manufacturer<sup>1</sup>



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

— Top Vaccine Manufacturer<sup>1</sup>

### 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



## 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.



### 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*



# 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  $\beta$ -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.<sup>2</sup>  
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 ENDOXPERS™ 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<sup>®</sup> EM suite of solutions is designed to **improve and secure efficiency through standardization and digitalization.**

## 3P<sup>®</sup> SMART PLATES



Digitalization

## 3P<sup>®</sup> CONNECT



Full automation

## 3P<sup>®</sup> ENTERPRISE



**3P<sup>®</sup> 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<sup>®</sup>

### Automated Microbial Identification



VITEK<sup>®</sup> MS PRIME



VITEK<sup>®</sup> 2 COMPACT



By adding **BIOBALL<sup>®</sup>** for your growth promotion testing and the **VITEK<sup>®</sup> 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 Bonnevey<sup>3</sup>  
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 Bonnevey<sup>3</sup>  
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.



### 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

## 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.



#### 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



## 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>