

BIOMÉRIEUX

# BOOST CELL & GENE THERAPY PRODUCTION EFFICIENCY

With Advanced Quality Testing.



Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

# Rapid answers for your cell and gene therapy products.

Developing cell and gene therapies presents many challenges. Low-production volume, short shelf life, temperature sensitivity, complex raw materials, tracking and data integrity, scalability, and patient demands must all be taken into consideration.

Adding rapid and easy-to-use technologies to your operations bring overall efficiencies to the manufacturing process through both simplified workflows and accurate, actionable results to help ensure patient safety.

## Improve Chain of Custody and increase Patient Safety

The chain of custody required to ensure the right patient receives the right therapy can be challenging. Our solutions not only deliver rapid results but also reduce risk of human error with barcode scanning and traceability.

## Move Testing closer to Manufacturing

Our simple workflows with little hands-on time reduce the need for extensive expertise and training to get an objective, rapid, and accurate result. This allows you to decentralize your lab testing and move it closer to the manufacturing suite.

## Stay in Compliance

New regulations have been written specifically to support the use of rapid methods for use on products with short shelf lives such as advanced cell therapies. bioMérieux offers full validation support and technical staff to back you every step of the way.



### Simple

- Simplified workflows and automation bring standardization
- Simplified, objective results with full traceability



### Fast

- Simplified workflows reduce hands-on time
- Faster time to result supports timely decisions that help protect product safety



### Accurate

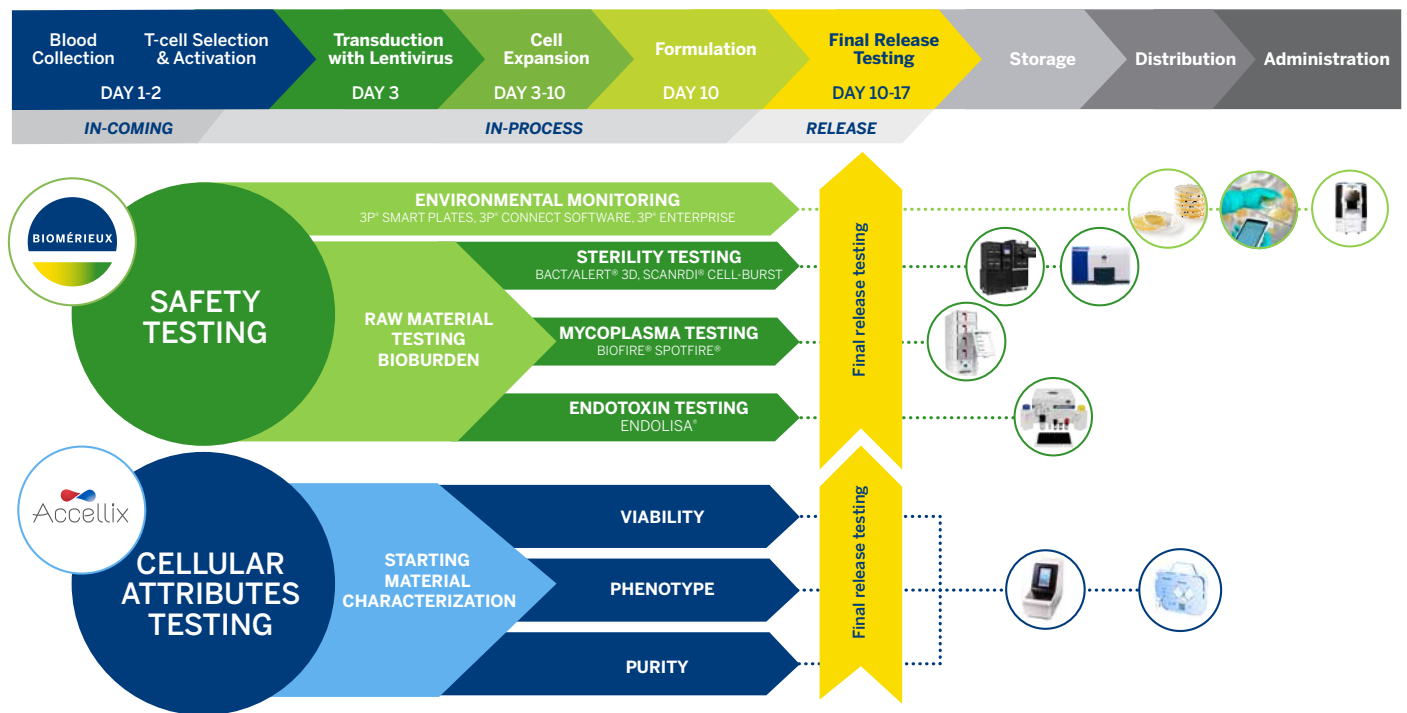
- State-of-the-art technologies provide objectivity and accuracy
- Increased data integrity helps ensure correct treatment is delivered to the right patient

# Continuous monitoring for continuous cell and gene therapy production.

Integrating quality management and manufacturing allows for continuous production. However, carefully managing and maintaining the supply chain becomes even more vital when scaling products.

bioMérieux's easy-to-use detection solutions allow labs to test for contamination at every stage of the production process, giving you confidence the therapy the patient receives will be as safe as possible.

Accellix\* platform automates sample preparation, flow cytometry, and data analysis to deliver rapid, standardized results on cell phenotype, enumeration, viability, identity, and purity - enhancing blood starting material optimization and simplifying incoming, in-process, and release testing across the entire cell therapy workflow.



## Bring Quality Testing Closer to Production with Easy-to-Use Rapid Methods

<p><b>3P® ENTERPRISE</b> Full digitalization and automation for environmental monitoring</p> <ul style="list-style-type: none"> <li>• 3P® SMART PLATES: Clear design performance culture media</li> <li>• 3P® CONNECT SOFTWARE: Digitalization of the EM process</li> <li>• 3P® STATION: Automation of Incubation &amp; Reading</li> </ul>	<p><b>BACT/ALERT® 3D DUAL-T</b> Automated, compendial rapid sterility testing results in days</p> <ul style="list-style-type: none"> <li>• Inoculate, load and go workflow</li> <li>• Allows testing closer to production</li> <li>• Barcode scanning and 21 CFR traceability increase data integrity</li> </ul>	<p><b>SCANRDI® CELL-BURST</b> Same-shift ultra-rapid sterility testing</p> <ul style="list-style-type: none"> <li>• Enables same-shift sterility results to accelerate product release</li> <li>• Proven, compendial-aligned method supporting current and future cell-based therapies</li> <li>• Automated solid-phase cytometry with 21 CFR compliance to ensure data integrity</li> </ul>	<p><b>BIOFIRE® SPOTFIRE®</b> Automated Mycoplasma detection with results in less than an hour</p> <ul style="list-style-type: none"> <li>• Two minutes of hands on time</li> <li>• Can be performed by virtually anyone, anywhere, anytime</li> <li>• Barcode scanning and 21 CFR traceability increase data integrity</li> </ul>	<p><b>ACCELLIX™</b> Automated &amp; Standardized Flow Cytometer</p> <ul style="list-style-type: none"> <li>• Automated sample preparation in single-use microfluidic cartridge</li> <li>• Results within ~30 minutes</li> <li>• Fully automated algorithm-based data analysis and auto-classification process</li> </ul>

\*In January 2026, bioMérieux acquired Accellix, strengthening its Pharmaceutical Quality Control portfolio with innovative flow cytometry solutions.



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**There's no time to lose when a patient relies on your product. Streamlined QC testing specific to cell and gene therapies yields safe, rapid, and efficient results.**

## The People

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With more than 60 years' experience in microbiological diagnostics, the people of bioMérieux understand the challenges manufacturers face when it comes to ensuring product safety and quality. Our development, scientific affairs, customer service, and support teams work hand in hand with our clients to create and implement groundbreaking solutions to everyday problems.

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## The Products

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The bioMérieux portfolio is dedicated to providing comprehensive solutions. As a leader in microbiology, we understand what it takes to enable fast accurate testing, optimize lab workflow, boost productivity, and improve financial performance.

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## The Science

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Innovation is one of the pillars of bioMérieux's longstanding scientific tradition. We innovate to drive progress in pathogen detection and identification. True to our pioneering spirit, our R&D teams combine their knowledge of medicine and emerging techniques and technologies to create solutions for pharmaceutical labs.