

Rapid Mycoplasma Testing with BIOFIRE® 1



Flyer

Mycoplasma testing is a critical regulatory requirement for cell-based products and mandated by global health authorities including the FDA and EMA to ensure patient safety prior to product release. Compendial testing under USP <63>, EP 2.6.7, and JP <G3-14-170> relies on culture-based methods which require up to 28 days, specialized facilities, and highly trained personnel to execute. These methods are considered the gold standard and recommended and performed by Minaris when time is not a determining factor.

Minaris also offers a rapid PCR-based alternative that uses the MycoSEQ™ Plus platform from Thermo Fisher to reduce turnaround time. While this method achieves a significant reduction in turn-around time, it may not be sufficient for autologous cell therapies or other products with accelerated release timelines. Therefore, Minaris has also adopted the BIOFIRE® Mycoplasma, a fully integrated, closed-system PCR platform that enables an accelerated turn-around-time on release testing of 3-5 days.

Key Benefits

Accelerate Turnaround Time

Significantly reduces turn-around-time for release.

Ensure High Data Integrity

Use a closed, automated system with integrated analysis to minimize human interaction and generate consistent, traceable results.

Achieve High Sensitivity

Leverage nested multiplex PCR to detect low levels of mycoplasma DNA with sensitivity better than compendial methods.

Support Regulatory Confidence

Qualify assay performance using live mycoplasma to demonstrate real-world detection aligned with regulatory expectations.

Reduce Risk Through Automation

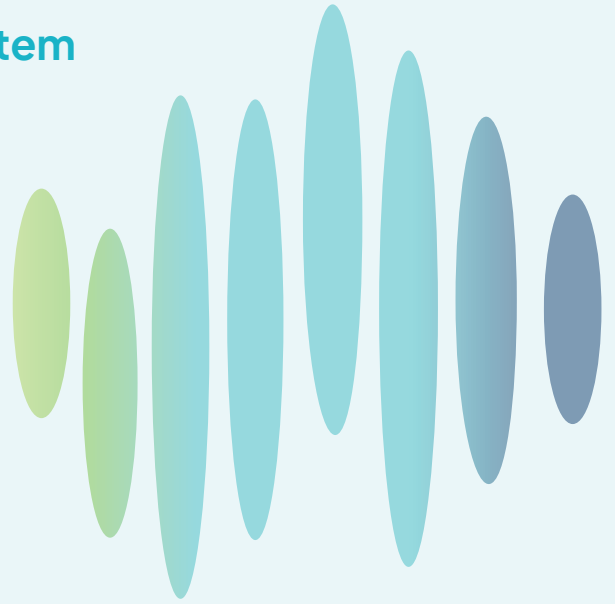
Automate extraction, amplification, and detection in a self-contained pouch to lower contamination risk and reduce operator variability.



¹BIOFIRE® is a registered trademark of bioMérieux, SA.

About the BIOFIRE® Mycoplasma System

The BIOFIRE® Mycoplasma offers a rapid closed system sample-to-answer test designed to detect over 130 mycoplasma species with minimal hands-on time. The platform utilizes a self-contained disposable pouch preloaded with lyophilized reagents and microfluidic channels that automate nucleic acid extraction, nested multiplex PCR amplification, and real-time detection all within a closed system that doesn't require any manual intervention. The test requires minimal operator training, and is compliant with the United States, European Union, and Japan pharmacopoeia (USP, EP, JP).



Typical Uses of Rapid Mycoplasma Testing with BIOFIRE® Mycoplasma



Final Product Release Testing

Rapid screening for lot release prior to patient administration.



Raw Material Testing

Screen critical raw materials before use in GMP manufacturing.



Autologous Cell Therapy Release

Support accelerated release decisions with patient specific products.



In Process Manufacturing Testing

Detect contamination early and prevent batch loss.



Investigational Tool

Rapidly assess suspected contamination to guide corrective actions.



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