BIOMÉRIEUX

BIOFIRE® MYCOPLASMA

1-hour Testing by Anyone, Anywhere, at Anytime

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

Reduce Costs and Maximize Efficiency with Automated, Rapid Testing.

Mycoplasma testing can be a challenge, but with BIOFIRE virtually anyone can rapidly test for contamination anywhere in the process, at any time.

With a small footprint, minimal hands-on time and fast time to result, BIOFIRE allows you to:

- Simplify training requirements
- Have a lower expertise to perform testing
- Minimize risk of human error
- Reduce costs of non-quality through early alert to contamination events
- Add flexibility to your testing planning with a 1-hour time to result
- Avoid costly outsourced testing

Easy in-Process and Reliable Release Testing

BIOFIRE makes it easy to quickly test at any point in the manufacturing process. The automated, multiplex PCR-based system meets pharmacopeia regulatory requirements for final product Mycoplasma release testing. Data integrity and traceability are assumed through 21 CFR Part 11 compliant software.

Anyone

- No PCR skills required
- Automated with easy-to-interpret results

Anywhere

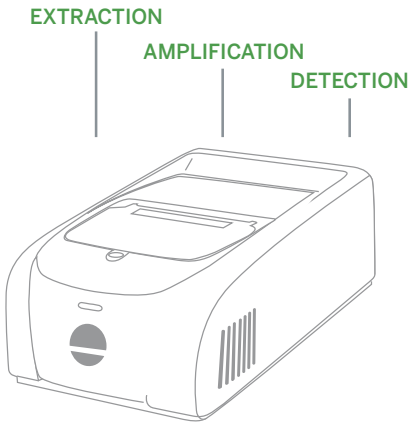
- No specialized lab necessary
- Can be performed near production line

Anytime

- Two minutes of hands-on time
- Results in less than an hour

Complex Testing Made Simple & Accessible

The BIOFIRE system consists of two components—the FILMARRAY instrument and the single-use "molecular lab in a pouch" disposable. With just two items, you have everything you need for fast, accurate *Mycoplasma* testing.

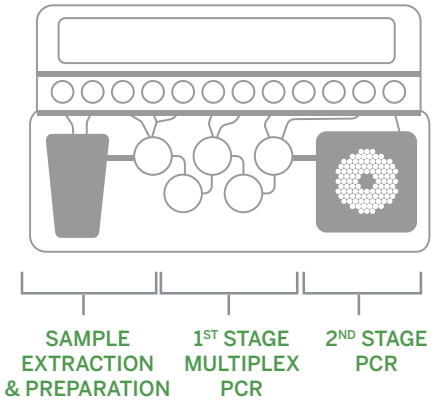


FILMARRAY®

The compact FILMARRAY instrument performs extraction, amplification, and detection in a single machine. Up to eight instruments can be connected for higher throughput.

MOLECULAR LAB IN A POUCH

The single-use pouch is a closed system containing internal controls and freeze-dried reagents and is neatly packaged with everything needed to run a single test. This, combined with room temperature storage, reduces waste and simplifies inventory management.



Rapid Testing in 3 Easy Steps

1. Inject hydration solution and unprocessed sample
2. Insert pouch into system and start run
3. Software reports whether or not Mycoplasma is detected

< 60 MINUTES

Confidently Meet Regulatory Requirements

BIOFIRE *Mycoplasma* provides simple, accurate, and rapid in-house *Mycoplasma* detection in raw materials, in-process and final product samples. bioMérieux offers validation services designed to meet regulatory requirements—from documentation to comprehensive on-site support.

- Assist with instrument qualification aligned with published industry guidance
- Validation guidance documents based on USP, EP and JP guidance
- BIOFIRE Master File (FDA CBER) and Drug Master File (FDA CDER) available to reference in regulatory submissions
- Primary Validation and Comparability study reports

Comparison of Mycoplasma Detection Methods

Testing Method	Regulation	Time To Result (TTR)	Hands-on Time	Level of Expertise Needed	Risk of Contamination	Reagent Storage Conditions	Testing Location	Sensitivity	Sample Size
BIOFIRE *Mycoplasma*	EP 9.0 <2.6.7> USP 39 <63> USP 39 <1223> JP 17 <G3>	< 60 Minutes (90 minutes if centrifugation step is required)	Minutes	Novice	Low	Room Temperature	Anywhere	≤10 CFU/ml	200µl – 10ml
Other PCR-based Methods		5 – 7 Hours	Hours	Expert	High	-20°C	Molecular Biology Lab		
Traditional Culture Methods		6 – 28 Days	Days	Expert	High	+4°C	Microbiology Lab with *Mycoplasma* Expertise		

BIOFIRE Mycoplasma

Easy

- Automated
- No PCR skills needed
- No PCR lab needed
- No precise measuring or pipetting
- Minimal data entry
- Simple standardized results

Rapid

- Two minutes of hands-on time
- Go from sample to result in < 60 minutes

Comprehensive

- Test raw materials, in-process and final product
- Detects > 130 strains of Mycoplasma and Mollicutes
- Full validation support
- 21 CFR Part 11 compliance features
- LIMS compatible

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