BIOMÉRIEUX

BIOFIRE® *Mycoplasma*

Rapid testing by anyone, anywhere, anytime.

PIONEERING DIAGNOSTICS

Easy, rapid at-line testing on demand.

Mycoplasma testing has always been a challenge—until now. BIOFIRE® *Mycoplasma* is the fastest, easiest, and simplest *Mycoplasma* testing method available.

You no longer have to send out testing, wait 28 days for traditional analysis, or require a molecular biologist and specialized lab for a rapid result.

BIOFIRE allows you to be assured your manufacturing process is on track by allowing nearly anyone to test for *Mycoplasma* anywhere in the facility at any time.

EASY IN-PROCESS TESTING

With a small footprint, minimal hands on-time, and fast time-to-result, BIOFIRE makes it easy to quickly test at any point in the manufacturing process.

ANYONE

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

ANYWHERE

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

ANYTIME

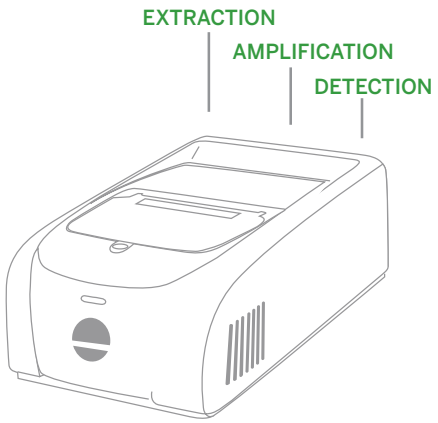
- Two minutes of hands-on time
- Results in less than an hour

RELIABLE RELEASE TESTING

BIOFIRE's automated, multiplex PCR-based system meets the regulatory requirements of all major pharmacopoeias for final product *Mycoplasma* release testing. Data integrity and traceability are assured through 21 CFR Part 11 compliant software.

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.

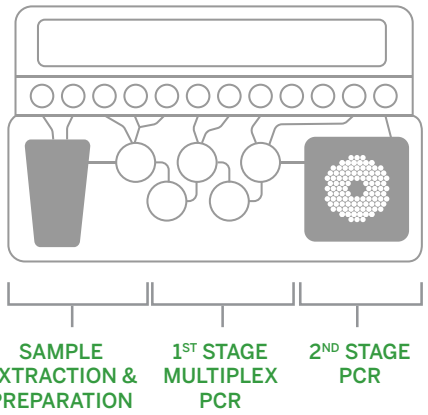


FILMARRAY®

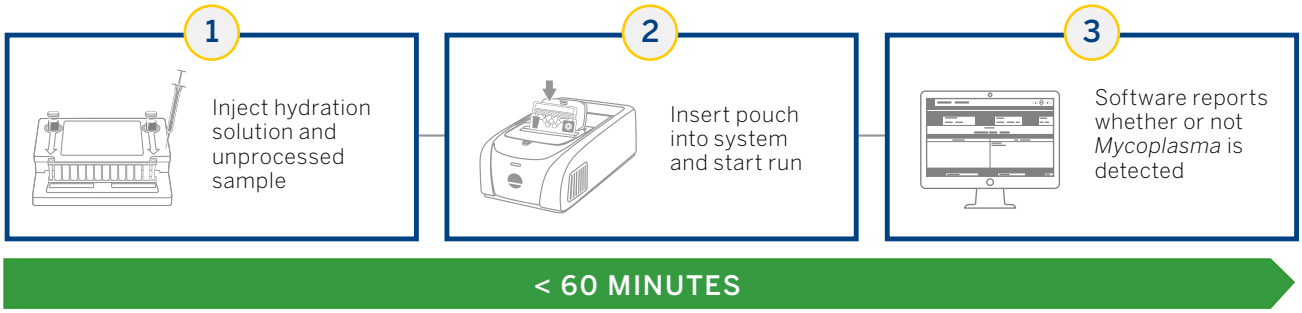
The compact FilmArray instrument performs extraction, amplification, and detection in a single machine. Up to eight instruments can be connected for higher throughput.

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



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.

Testing Method	Regulation	Time To Result (TTR)	Hands-on Time	Level of Expertise Needed	Risk of Contam-ination	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 > 120 strains of *Mycoplasma* and *Mollicutes*
- Full validation support
- 21 CFR Part 11 compliant software

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