

SPOTFIRE® System and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/

Category:

Best Medical Technology

Company Name:

bioMérieux

Product/Solution Name:

BIOFIRE® SPOTFIRE® System and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel

Compound/Tech Name:

BIOFIRE® SPOTFIRE®

Trade Name:

BIOFIRE® SPOTFIRE® R/ST Panel

Corporate Name:

BIOFIRE® SPOTFIRE® R/ST Panel

Date of Approval:

2024-03-26

Indications:

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel is a multiplex polymerase chain reaction (PCR) test used with the BIOFIRE SPOTFIRE System to detect multiple respiratory viruses and bacteria. PCR is a powerful biochemistry method to exponentially amplify genetic signals from test materials. It is highly sensitive and specific. The BIOFIRE SPOTFIRE R/ST Panel is indicated to analyze:

- Nasopharyngeal swabs (NPS) from patients with respiratory symptoms (e.g., cough, fever, COVID-19).
- Throat swabs (TS) from patients with sore throat or suspected pharyngitis.

The test identifies nucleic acids from pathogens typically present during the acute phase of infection. It provides qualitative results (positive/negative) for each target organism.

Clinical Use

- Helps identify the presence of specific respiratory pathogens.
- Should be used alongside clinical evaluation, patient history, and other lab tests.
- Positive results indicate the presence of a pathogen but do not confirm it is the cause of illness.
- Negative results do not rule out infection, especially if symptoms persist or if the pathogen is not included in the panel.

Limitations

- May miss infections caused by pathogens not included in the test.
- Cannot determine disease severity or rule out coinfections.
- Additional testing (e.g., cultures, imaging) may be needed for a full diagnosis.

This panel is a valuable tool for rapid, broad-spectrum respiratory pathogen detection, but results must be interpreted in the full clinical context.

Therapeutic Areas:

Infectious diseases are illnesses caused by microorganisms such as bacteria, viruses, fungi, or parasites. These microorganisms can spread directly or indirectly from one person to another. Common symptoms vary depending on the organism and affected system, but typically include fever, fatigue, inflammation, and a range of localized signs. Effective management relies on accurate diagnosis and targeted treatment, such as antibiotics for bacterial infections or antivirals for certain viral infections.

A major category of infectious diseases includes respiratory tract infections, which are typically divided into upper and lower tract infections. Upper respiratory tract infections (URTIs) affect the nose, throat, pharynx, larynx, and sinuses. These infections are among the most common illnesses globally and are usually viral in origin, although some can be caused by bacteria. URTIs are generally self-limiting, with most cases resolving within a week to ten days without the need for antibiotics.

Pharyngitis refers specifically to inflammation of the pharynx, which is located at the back of the throat. It is most often referred to as a "sore throat." Pharyngitis can be caused by viruses or bacteria, with the most notable bacterial cause being *Streptococcus pyogenes* (group A streptococcus), which causes streptococcal pharyngitis or "strep throat." Viral pharyngitis is typically associated with cough, runny nose, hoarseness, and conjunctivitis, whereas bacterial pharyngitis often presents with sudden sore throat, fever, swollen lymph nodes, and absence of cough. Distinction of the causative agent is important because viral infections do not respond to antibiotics and should be managed with supportive care (e.g., hydration, pain relievers, throat lozenges), while bacterial infections require antibiotics to prevent complications such as rheumatic fever or peritonsillar abscess.

General Information File Document upload:

N/A

Background information and need for drug / device:

The COVID-19 pandemic underscored the critical need for fast, accurate, and accessible diagnostics. Upper-respiratory infections often present with non-specific symptoms, making it difficult to determine the appropriate treatment. Alarming, up to 50% of patients in ambulatory settings receive unnecessary antibiotics for viral infections, contributing to the growing threat of antimicrobial resistance(1,2).

In response, bioMérieux launched the BIOFIRE SPOTFIRE R/ST Panel in 2024-a groundbreaking, CLIA-waived diagnostic solution on the new SPOTFIRE system. This panel delivers highly accurate PCR results for up to 15 viral and bacterial pathogens in about 15 minutes, far surpassing the sensitivity and scope of traditional rapid-antigen tests.

Designed for near-patient use, the SPOTFIRE system empowers healthcare providers in urgent care centers, physician offices, and outpatient clinics to make faster, more informed treatment decisions. By enabling precise diagnosis at the point of care, it may improve patient outcomes and could potentially reduce inappropriate antibiotic prescriptions.

bioMérieux, a global leader in in vitro diagnostics, operates in 45 countries with 14,000 employees and serves customers in over 160 nations. In 2024, the company reported €3.98 billion in sales, with 45% from North America-the world's largest healthcare market(3).

Since its launch, the SPOTFIRE system has seen rapid adoption, with thousands of instruments and over one million tests sold across the U.S., Europe, and Asia. This innovation is reshaping respiratory care and reinforcing bioMérieux's commitment to advancing diagnostic excellence and global health.

Background File Document upload:

N/A

History of the development of the solution/product:

The BIOFIRE SPOTFIRE System is a fully automated molecular diagnostic platform designed to perform rapid, multiplexed nucleic acid testing. It integrates sample

preparation, nucleic acid extraction, reverse transcription, nested PCR amplification, and result analysis in a closed, self-contained system⁴. The system can deliver results in approximately 15 minutes with minimal user intervention^(5,6).

Each test is performed using a BIOFIRE SPOTFIRE Panel reagent pouch, a disposable unit that contains all necessary reagents in freeze-dried form. The pouch is divided into compartments (blisters) where different chemical processes occur. After sample collection, the user mixes the specimen with a denaturing buffer to inactivate nucleases, injects it into the pouch, selects the specimen type (nasopharyngeal or throat swab), and loads the pouch into the instrument.

Once inside the instrument, the system automates the following steps:

- 1. Cell Lysis: Mechanical agitation with zirconia-silica beads disrupts cells.
- 2. Nucleic Acid Extraction: Magnetic beads bind nucleic acids, which are then washed and eluted.
- 3. First-Stage RT-PCR: Reverse transcription and initial amplification occur.
- 4. Second-Stage Nested PCR: Amplified products are further amplified using nested primers in a multiplexed array.

The second-stage PCR includes a fluorescent dye (LC Green Plus) that binds to double-stranded DNA. As the temperature increases, the dye fluoresces until the DNA melts, causing a drop in fluorescence. This melt curve analysis identifies each target based on its unique melting temperature (T_m).

Each analyte is tested in triplicate. A result is considered positive if at least two of the three wells produce a product with a T_m within the expected range. Otherwise, the result is negative. Internal controls ensure the validity of each test run.

The system is modular, allowing up to four testing modules to be connected to a single SPOTFIRE Control Station. Each module operates independently, enabling random access testing and high throughput.

The following organism types and subtypes are identified and differentiated using the SPOTFIRE R/ST Panel:

Respiratory Menu	Sore Throat Menu
Viruses	Viruses
Adenovirus	Adenovirus
Coronavirus SARS-CoV-2	Coronavirus (seasonal)
Coronavirus (seasonal)	Human metapneumovirus
Human metapneumovirus	Human rhinovirus/enterovirus
Human rhinovirus/enterovirus	Influenza A virus
Influenza A virus	Influenza A virus/H1-2009
Influenza A virus/H1-2009	Influenza A virus/H3

Influenza A virus/H3
Influenza B virus
Parainfluenza virus
Respiratory syncytial virus

Influenza B virus
Parainfluenza virus
Respiratory syncytial virus

Bacteria
Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Bacteria
Chlamydia pneumoniae
Mycoplasma pneumoniae
Streptococcus dysgalactiae (Group C/G Strep)
Streptococcus pyogenes (Group A Strep)

The clinical performance of the BIOFIRE SPOTFIRE R/ST Panel was evaluated using a combination of prospectively collected, archived and contrived specimens. Positive Percent Agreement (PPA) ranged from 96.3-100% for prospectively collected specimens and from 96.0-100% for archived specimens, depending on the analyte, whereas Negative Percent Agreement (NPA) ranged from 90.6-100% for prospectively collected specimens and from 96.7-100% for archived specimens. Overall, the BIOFIRE SPOTFIRE R/ST Panel exhibited substantially equivalent PPA and NPA in comparison to other FDA-cleared methods for the detection of the targeted analytes in nasopharyngeal or throat swab specimens(7).

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The BIOFIRE SPOTFIRE System is the first platform to bring comprehensive, multiplex PCR testing to the near-patient setting, offering lab-quality results in about 15 minutes. Developed by bioMérieux, this system builds on the company's legacy of syndromic testing, which began in 2011 with FDA-cleared BIOFIRE panels for hospital use(3). These panels test for up to 45 pathogens across various syndromes-respiratory, bloodstream, gastrointestinal, central nervous system, lower respiratory, and joint infections-delivering results in about an hour. Their use has been shown to reduce time to diagnosis(8), support earlier discharges9, improve antimicrobial stewardship(9,10), and lower mortality(10).

To meet the needs of point-of-care environments, the SPOTFIRE System was engineered for speed, simplicity, and accuracy. Achieving a ~15-minute turnaround required the development of a new thermocycler capable of faster cycling than any commercial system before it, along with optimized PCR chemistry to support rapid

thermal transitions(11).

The system is designed for ease-of-use, requiring no laboratory training. Starting a new test takes about two minutes and involves just six simple steps.

Looking ahead, bioMérieux plans to expand the SPOTFIRE test menu to include panels for sexually transmitted infections, gastrointestinal pathogens, and women's reproductive tract infections, continuing its mission to deliver rapid, reliable, and easy-to-use diagnostics at the point of care.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

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8. Real-life diagnostic performance and clinical impact of the BIOFIRE Joint Infection Panel in joint infections. S Kaoual, H Ernandes, R Rezgui, Y Ben Lamine, H Aouel, Y Chaaba, S Sallem, A Bellaaj, I Kooli, S Bouhalila Besbes. Eur Rev Med Pharmacol Sci. 2025 Apr;29(4):199-210.

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11. Extreme PCR: efficient and specific DNA amplification in 15-60 seconds. Jared S Farrar, Carl T Wittwer. Clin Chem. 2015 Jan;61(1):145-53.

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