



# BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Solution

## BIOFIRE SPOTFIRE Respiratory / Sore Throat (R/ST) Panel Mini

1 PCR Test. Up to 5 Targets. ~ 15 Minutes.

Based on the sample type collected, users can select either the Respiratory or Sore Throat menu.

FDA CLEARED  
CLIA WAIVED

### RESPIRATORY | 5 TARGETS

#### VIRUSES

Coronavirus SARS-CoV-2  
Human rhinovirus  
Influenza A virus  
Influenza B virus  
Respiratory syncytial virus

#### Overall Respiratory Performance†

(NPS specimens):  
PPA: 98.7% | NPA: 98.4%  
(ANS specimens):  
PPA: 95.6% | NPA: 99.1%

Sample Type: Nasopharyngeal swab or anterior nasal swab in 3 mL of transport media.

### SORE THROAT | 5 TARGETS

#### VIRUSES

Human rhinovirus  
Influenza A virus  
Influenza B virus  
Respiratory syncytial virus

#### BACTERIA

*Streptococcus pyogenes*  
(group A Strep)

#### Overall Sore Throat Performance†

(TS specimens):  
PPA: 96.2% | NPA: 97.9%

Sample Type: Throat swab in 1 mL of transport media.

## BIOFIRE SPOTFIRE Respiratory / Sore Throat (R/ST) Panel

1 PCR Test. Up to 15 Targets. ~ 15 Minutes.

Based on the sample type collected, users can select either the Respiratory or Sore Throat menu.

FDA CLEARED  
CLIA WAIVED

### RESPIRATORY | 5 TARGETS

#### VIRUSES

Adenovirus  
Coronavirus SARS-CoV-2  
Coronavirus (seasonal)  
Human metapneumovirus  
Human rhinovirus/enterovirus  
Influenza A virus  
    Influenza A virus A/H1-2009  
    Influenza A virus A/H3  
Influenza B virus  
Parainfluenza virus  
Respiratory syncytial virus

#### BACTERIA

*Bordetella parapertussis*  
*Bordetella pertussis*  
*Chlamydia pneumoniae*  
*Mycoplasma pneumoniae*

#### Overall Respiratory Performance†

(NPS specimens):  
PPA: 98.5% | NPA: 99.1%

Sample Type: Nasopharyngeal swab in 3 mL of transport media.

### SORE THROAT | 5 TARGETS

#### VIRUSES

Adenovirus  
Coronavirus (seasonal)  
Human metapneumovirus  
Human rhinovirus/enterovirus  
Influenza A virus  
    Influenza A virus A/H1-2009  
    Influenza A virus A/H3  
Influenza B virus  
Parainfluenza virus  
Respiratory syncytial virus

#### BACTERIA

*Chlamydia pneumoniae*  
*Mycoplasma pneumoniae*  
*Streptococcus dysgalactiae*  
(group C/G Strep)  
*Streptococcus pyogenes*  
(group A Strep)

#### Overall Sore Throat Performance†

(TS specimens):  
PPA: 95.9% | NPA: 99.0%

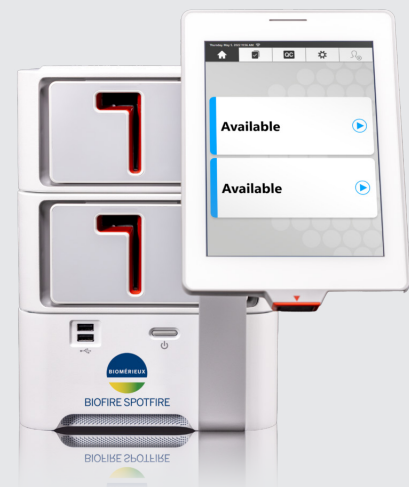
Sample Type: Throat swab in 1 mL of transport media.



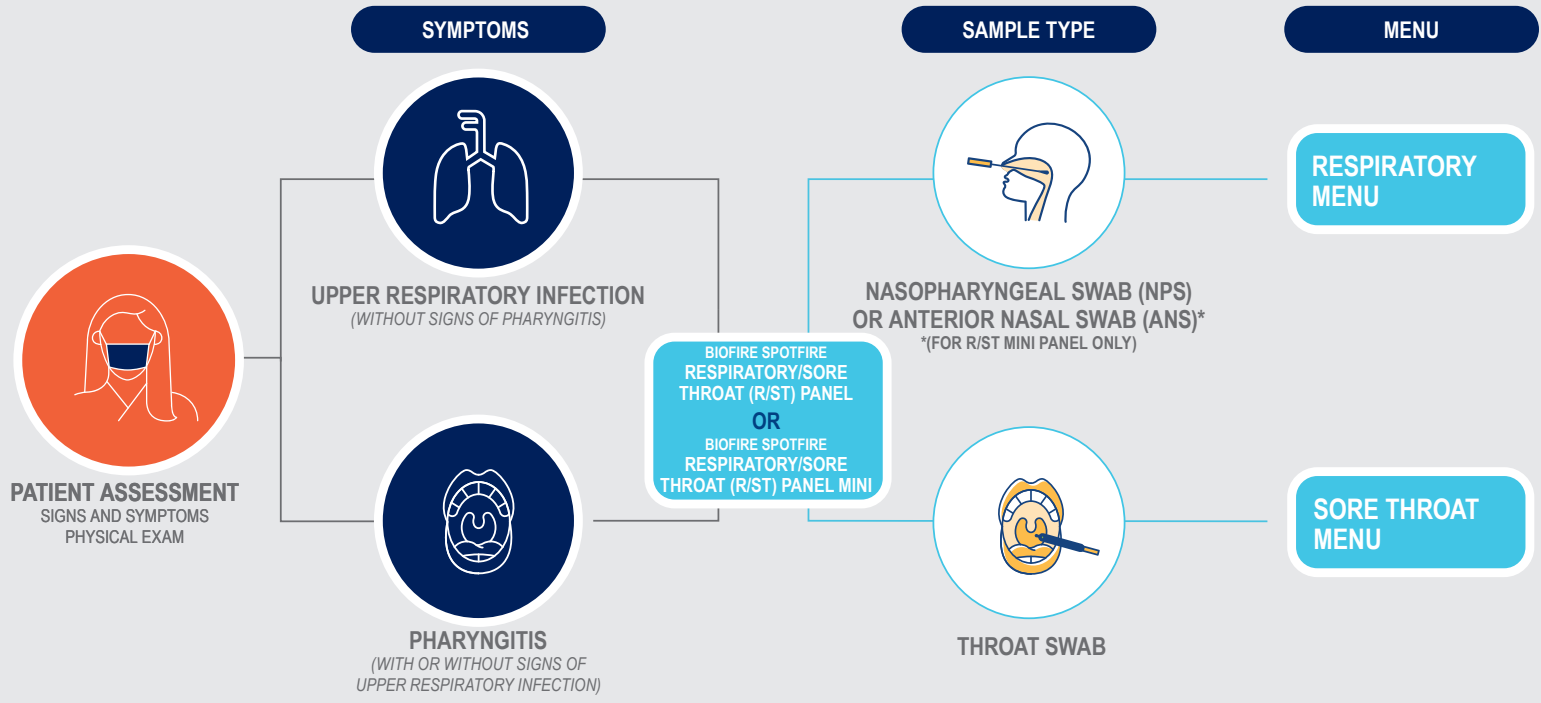
## THE BIOFIRE SPOTFIRE SYSTEM

This user-friendly system empowers the fast, accurate detection needed to make confident decisions, mitigate threats, and protect communities.

- **Technology:** Point-of-care PCR system
- **Capabilities:** Quick detection of infectious diseases
- **Result Time:** 15 minutes (R/ST Panel)
- **Ease of Use:** Compact and user-friendly design
- **Applications:** CLIA-Waived Laboratories



# SPOTFIRE R/ST Panel Workflow



## SPOTFIRE Respiratory/Sore Throat Solution Specifications

|                                     |                                                                                                                                                  |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Hands-on Time:                      | 2 minutes                                                                                                                                        |
| Pouch Storage Conditions:           | All kit components should be stored at room temperature (15° – 25° C)                                                                            |
| Quality Control Storage Conditions: | Positive and negative control materials should be stored at room temperature (18° – 25° C) Maine Molecular Quality Controls, Inc. Products Only. |
| Specimen Transport and Storage:     | Room temperature for up to 4 hours (15° – 25° C), refrigerated for up to 3 days (2° – 8° C) or frozen for up to 30 days (≤ -15° C)               |
| Sample Type:                        | Nasopharyngeal swab (NPS) or throat swab (TS) in 1 to 3 mL of transport media                                                                    |

## Ordering Information

| Product Name                                                              | Quantity                              | Part No.      |
|---------------------------------------------------------------------------|---------------------------------------|---------------|
| BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel Mini Kit                   | 30 pouches                            | 424537        |
| BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel Kit                        | 30 pouches                            | 423485        |
| SPOTFIRE RSP Pos & Neg Controls                                           | 6 positive, 6 negative                | M425          |
| NATtrol™ Respiratory/Sore Throat R/ST Verification Panel Mini             | 1 panel                               | NATRSTM-BIO   |
| NATtrol™ Respiratory/Sore Throat R/ST Verification Panel                  | 1 panel                               | NATRST-BIO    |
| BIOFIRE SPOTFIRE Respiratory/Sore Throat R/ST Panel Mini Verification Kit | 3 x 424537, 5 x M425, 1 x NATRSTM-BIO | 424866        |
| BIOFIRE SPOTFIRE Respiratory/Sore Throat R/ST Panel Verification Kit      | 3 x 423485, 5 x M425, 1 x NATRST-BIO  | 424865        |
| BIOFIRE SPOTFIRE Control Station                                          | 1                                     | FAST-ASY-0001 |
| BIOFIRE SPOTFIRE Module                                                   | 1                                     | FAST-ASY-0002 |

\*Overall performance based on prospective clinical study for the BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel; data on file, bioMérieux.

BioFire Defense is authorized to sell the BIOFIRE® FILMARRAY® and BIOFIRE® SPOTFIRE® Systems and Panels manufactured by its affiliate company bioMérieux to US government agencies.

