

FDA **CLEARED** CLIA **WAIVED**

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BIOFIRE® SPOTFIRE® Respiratory/Sore Throat Solution



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

1 PCR test. 5 targets. ~15 minutes. Based on the sample type collected, users can select either the Respiratory or Sore Throat menu.

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%

Sample type: Nasopharyngeal swab in 3 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.

RESPIRATORY | 15 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 | 14 TARGETS

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

SORE THROAT 5 TARGETS

VIRUSES

VIRUSES

Human rhinovirus

Influenza A virus

Influenza B virus

Respiratory syncytial virus

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

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

BACTERIA

BACTERIA

Performance[†]

(TS specimens):

Streptococcus pyogenes

PPA: 96.2% | NPA: 97.9%

(group A Strep)

Overall Sore Throat

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%

The BIOFIRE® SPOTFIRE® System

Requires Minimal benchtop space

With a footprint slightly larger than a sheet of paper, the SPOTFIRE System can easily integrate into any clinic space.

Scalable throughput

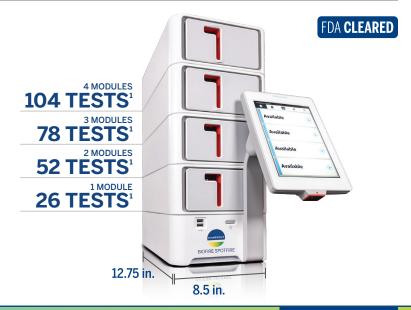
The system can be vertically scaled up to 4 modules, enabling clinics to meet their unique testing needs.

Easy to use

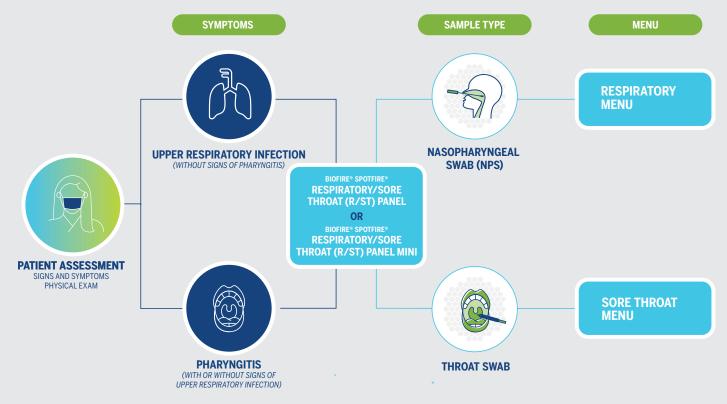
The streamlined workflow and intuitive system interface have been designed to be used by any healthcare professional, in any setting.

Seamless connectivity

The system interfaces with LIS, point-of-care (POC) middleware, and POC data management systems, automating data transfer to ensure data quality and enable workflow flexibility.



SPOTFIRE R/ST Panels: 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)	

Ordering Information

PRODUCT NAME	QUANTITY	PART NUMBERS
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 [™] R/ST Respiratory/Sore Throat 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

¹Overall performance based on prospective clinical study for the BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel; data on file, bioMérieux. 1. Calculation based on running the BIOFIRE[®] SPOTFIRE[®] Respiratory Panels (~15 minutes) in an 8-hour shift Product availability varies by country. Consult your bioMérieux representative.

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