

## Health Program & Insurance Guide for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

bioMérieux developed the following Health Program & Insurance Guide for healthcare providers who administer the FDA-cleared and CLIA-waived BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini ([https://www.accessdata.fda.gov/cdrh\\_docs/pdf24/K241194.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241194.pdf)). Described below is our current understanding of the coverage, coding, and payment for administering the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini as of: July 30, 2024.

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

The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19; (Respiratory menu) or in throat swab (TS) specimens from individuals with signs and symptoms of pharyngitis (Sore Throat menu). The BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini is authorized for use under a CLIA Certificate of Waiver.

The user can choose to perform the Respiratory menu or Sore Throat menu. The following targets are performed based on the menu selection.

Respiratory Targets	Sore Throat Targets
<ul style="list-style-type: none"> <li>Coronavirus SARS-CoV-2           <ul style="list-style-type: none"> <li>Human rhinovirus</li> <li>Influenza A virus</li> <li>Influenza B virus</li> </ul> </li> <li>Respiratory syncytial virus</li> </ul>	<ul style="list-style-type: none"> <li><i>Streptococcus pyogenes</i> (Group A Strep)</li> <li>Human rhinovirus</li> <li>Influenza A virus</li> <li>Influenza B virus</li> <li>Respiratory syncytial virus</li> </ul>

Based on currently available information, the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini may be described by the following CPT code(s) based on the specific panel selected for testing:

#### Respiratory Targets Applicable Code

**CPT code 87631 – Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets**

#### Sore Throat Targets Applicable Codes

**CPT code 87631 – Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets**

AND

**CPT code 87651 - Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique**

**If the practice/lab running the test has a CLIA Certificate of Waiver, a QW modifier is required.**

#### Coverage

Coverage is a payor's determination that items and services are medically necessary for a patient and may be included under the patient's health insurance benefits. Coverage varies by payor.

#### Coding

Coding enables healthcare providers to communicate to payors the items and services furnished to a patient to obtain payment for those items and services. It is the sole responsibility of the healthcare provider to determine the most appropriate codes to report on a claim, upon consultation of specific payor policies.

#### Payment

Payment is the amount that a payor renders to a healthcare provider for furnishing items and services to a patient. Patients may also have cost-sharing obligations, including deductibles, coinsurance, or copayments, depending on their health insurance benefits. Payment amounts vary by payor and by geographic location and are frequently updated.

For more information on Medicare and select state Medicaid programs' allowable rates for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini, please consult CodeMap at: <http://www.codemap.com/biofire>.

This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Note that payors that follow NCCI guidance may recommend the use of alternate code(s). It is always the provider's responsibility to determine and submit appropriate codes for services that are rendered, consistent with applicable payor guidance. bioMérieux recommends that you consult with your payer, reimbursement specialist and/or legal counsel regarding coding, coverage, and reimbursement matters. Payor coding, coverage, and reimbursement policies may vary and should be verified prior to claim submission. *This information is gathered from third-party sources and is subject to change without notice, including as a result of changes in laws, regulations, rules, and policies. BFR0002-8506-01*