

SPOTFIRE® RSP Pos & Neg Controls

INTENDED USE:

The SPOTFIRE® RSP Pos & Neg Controls kit is intended for use (as applicable) as an external positive and negative assayed quality control to monitor performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Streptococcus dysgalactiae* (Group C/G Strep), *Streptococcus pyogenes* (Group A Strep), Adenovirus, Coronavirus SARS-CoV-2, Coronavirus (seasonal), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A Subtype H1-2009, Influenza A Subtype H3, Influenza B, Parainfluenza Virus and Respiratory Syncytial Virus using the BIOFIRE® SPOTFIRE Respiratory (R) Panel, BIOFIRE SPOTFIRE Respiratory (R) Panel Mini, BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel and BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini on the BIOFIRE SPOTFIRE System. SPOTFIRE RSP Pos & Neg Controls is designed for and intended to be used solely with the BIOFIRE SPOTFIRE R Panel, BIOFIRE SPOTFIRE R Panel Mini, BIOFIRE SPOTFIRE R/ST Panel, and BIOFIRE SPOTFIRE R/ST Panel Mini assays. The SPOTFIRE RSP Positive Control contains synthetic RNA transcripts in stabilizing solution and the SPOTFIRE RSP Negative Control contains buffers and preservatives. This product is not intended to replace manufacturer internal controls provided with these devices.

Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.

PRODUCT SUMMARY and PRINCIPLE:

The SPOTFIRE RSP Pos & Neg Controls kit is composed of 2 controls, SPOTFIRE RSP Positive Control and SPOTFIRE RSP Negative Control. SPOTFIRE RSP Positive Control contains surrogate control material composed of synthetic RNA corresponding to genome segments of pathogens listed as detected in Tables 1, 2, 3, and 4. SPOTFIRE RSP Negative Control contains no nucleic acid and does not contain any sequence corresponding to genome segments of pathogens listed in Tables 5, 6, 7, and 8.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

INSTRUCTIONS FOR USE:

1. The controls may be shipped on dry ice or cold packs and placed at room temperature (18° – 25°C), or refrigerated (2° – 8°C) upon receipt.
2. Allow the control to come completely to room temperature (18° – 25°C) before use, approximately 30 minutes if frozen due to dry ice shipping.
3. Use the control as provided. Do Not Dilute.
4. Immediately before use, mix the control thoroughly by first flicking the tubes 3 times followed by inverting at least 3 times. Tap the tube 3 times on the bench to remove any control caught in the cap before opening the tube.
5. Refer to the Quality Control Testing section of the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel or SPOTFIRE R/ST Panel Mini Quick Guide to prepare, hydrate and load the SPOTFIRE R Panel Pouch, SPOTFIRE R Panel Mini Pouch, SPOTFIRE R/ST Panel Pouch or SPOTFIRE R/ST Panel Mini Pouch, and to test the QC sample.
Note: It is important to thoroughly mix the QC sample with the Sample Buffer by inverting the Sample Injection Vial 3 times, as described in the Quick Guide.
6. Discard after use according to your local and federal regulations.

For complete SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel, or SPOTFIRE R/ST Panel Mini instructions, refer to the appropriate Quick Guide or Instruction Booklet provided by BioFire Diagnostics, LLC.

COMPOSITION:

The SPOTFIRE RSP Pos & Neg Controls kit is comprised of 12 single use tubes, 6 tubes of SPOTFIRE RSP Positive Control and 6 tubes of SPOTFIRE RSP Negative Control, 300µL each. SPOTFIRE RSP Positive Control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. The synthetic RNA is specifically designed for and intended to be used solely with the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel and BIOFIRE SPOTFIRE R/ST Panel Mini assays on the BIOFIRE SPOTFIRE System. Tables 1, 2, 3 and 4 list the pathogens that are detected in the SPOTFIRE RSP Positive Control when tested with the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel, and BIOFIRE SPOTFIRE R/ST Panel Mini assays, respectively. SPOTFIRE RSP Negative Control contains only buffers and preservatives and no DNA or RNA.

PRECAUTIONS and WARNINGS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* diagnostic use only.
- This product is for use with the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, SPOTFIRE R/ST Panel or SPOTFIRE R/ST Panel Mini assays on the BIOFIRE SPOTFIRE System. It does not contain the entire genome of pathogens listed in Tables 1 - 8.
- Appearance: Positive control is slightly cloudy and Negative control is clear.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- This product cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

SPOTFIRE RSP Pos & Neg Controls can be shipped on dry ice or cold packs, and stored at room temperature (18° – 25°C) or refrigerated (2° – 8°C) upon receipt. The controls are stable through the expiration date printed on the kit label. SPOTFIRE RSP Pos & Neg Controls kit components are for single use. Discard after use according to your local and federal regulations.

REPRESENTATIVE PERFORMANCE DATA:

Three lots of SPOTFIRE RSP Positive Control and 4 lots of SPOTFIRE RSP Negative Control were tested over 9 months using the SPOTFIRE R and R/ST Panel assays on SPOTFIRE Systems at 5 near-patient clinical laboratory sites, facilities holding a CLIA Certificate of Waiver (U.S.), or similar Near Patient Testing (NPT) settings (Outside U.S.). Testing incorporated 25 pouch lots, multiple operators and instruments. Of the 232 samples tested, there were 7 Invalid results. Out of 225 tests with valid results, correct results were obtained in 224 tests for an overall success rate of 99.6%.

| Summary of Performance Data | | | | | | | | |
|-----------------------------|-------------|---------|---------------------------------|-----------------------------------|----------------------------------|---------------------------------|-----------------------------------|----------------------------------|
| Site | Total Tests | Invalid | Correct Positive Control Result | Incorrect Positive Control Result | Percent Correct Positive Control | Correct Negative Control Result | Incorrect Negative Control Result | Percent Correct Negative Control |
| 1 | 26 | 0 | 13 | 0 | 100% | 13 | 0 | 100% |
| 2 | 33 | 1 | 13 | 0 | 100% | 19 | 0 | 100% |
| 3 | 120 | 4 | 53 | 1 | 98.1% | 62 | 0 | 100% |
| 4 | 44 | 1 | 21 | 0 | 100% | 22 | 0 | 100% |
| 5 | 9 | 1 | 8 | 0 | 100% | NA | NA | N/A |
| All Sites | 232 | 7* | 108 | 1 | 99.1% | 116 | 0 | 100% |

*Invalid results were not included in percent correct.

ORDERING INFORMATION:

Product Name: SPOTFIRE RSP Pos & Neg Controls

Part Number: M425

Kit Contains: 12 tubes x 300µL

6 tubes each of Positive control and Negative control

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Rx Only

SPOTFIRE® RSP Pos & Neg Controls

SPOTFIRE RSP Positive Control EXPECTED VALUES:

The expected results when the SPOTFIRE RSP Positive Control is tested as a Quality Control (QC icon) with SPOTFIRE R Panel (Table 1), SPOTFIRE R Panel Mini (Table 2), SPOTFIRE R/ST Panel (Table 3), and SPOTFIRE R/ST Panel Mini (Table 4).

Table 1. SPOTFIRE R Panel Results: **R** Positive QC Test

| PASS | |
|---|--|
| Bacteria | Viruses |
| Positive ✓ <i>Bordetella parapertussis</i> | Positive ✓ Adenovirus |
| Positive ✓ <i>Bordetella pertussis</i> | Positive ✓ Coronavirus SARS-CoV-2 |
| Positive ✓ <i>Chlamydia pneumoniae</i> | Positive ✓ Coronavirus (seasonal) |
| Positive ✓ <i>Mycoplasma pneumoniae</i> | Positive ✓ Human Metapneumovirus |
| | Positive ✓ Human Rhinovirus/Enterovirus |
| | Positive ✓ Influenza A Virus |
| | Positive ✓ Influenza A virus A/H1-2009 |
| | Positive ✓ Influenza A virus A/H3 |
| | Positive ✓ Influenza B Virus |
| | Positive ✓ Parainfluenza Virus |
| | Positive ✓ Respiratory Syncytial Virus |

Table 2. SPOTFIRE R Panel Mini Results: **R** Positive QC Test

| PASS |
|---|
| Viruses |
| Positive ✓ Coronavirus SARS-CoV-2 |
| Positive ✓ Human Rhinovirus |
| Positive ✓ Influenza A Virus |
| Positive ✓ Influenza B Virus |
| Positive ✓ Respiratory Syncytial Virus |

Table 3. SPOTFIRE R/ST Panel Results: **R ST** Positive QC Test

| PASS | |
|---|--|
| Bacteria | Viruses |
| Positive ✓ <i>Bordetella parapertussis</i> | Positive ✓ Adenovirus |
| Positive ✓ <i>Bordetella pertussis</i> | Positive ✓ Coronavirus SARS-CoV-2 |
| Positive ✓ <i>Chlamydia pneumoniae</i> | Positive ✓ Coronavirus (seasonal) |
| Positive ✓ <i>Mycoplasma pneumoniae</i> | Positive ✓ Human Metapneumovirus |
| Positive ✓ <i>Streptococcus dysgalactiae</i> (group C/G Strep) | Positive ✓ Human Rhinovirus/Enterovirus |
| Positive ✓ <i>Streptococcus pyogenes</i> (group A Strep) | Positive ✓ Influenza A Virus |
| | Positive ✓ Influenza A virus A/H1-2009 |
| | Positive ✓ Influenza A virus A/H3 |
| | Positive ✓ Influenza B Virus |
| | Positive ✓ Parainfluenza Virus |
| | Positive ✓ Respiratory Syncytial Virus |

Table 4. SPOTFIRE R/ST Panel Mini Results: **R ST** Positive QC Test

| PASS | |
|---|---|
| Bacteria | Viruses |
| Positive ✓ <i>Streptococcus pyogenes</i> (group A Strep) | Positive ✓ Coronavirus SARS-CoV-2 |
| | Positive ✓ Human Rhinovirus |
| | Positive ✓ Influenza A Virus |
| | Positive ✓ Influenza B Virus |
| | Positive ✓ Respiratory Syncytial Virus |

SPOTFIRE RSP Negative Control EXPECTED VALUES:

The expected results when the SPOTFIRE RSP Negative Control is tested as a Quality Control (QC icon) with SPOTFIRE R Panel (Table 5), SPOTFIRE R Panel Mini (Table 6), SPOTFIRE R/ST Panel (Table 7) and SPOTFIRE R/ST Panel Mini (Table 8).

Table 5. SPOTFIRE R Panel Results: **R** Negative QC Test

| PASS | |
|---|--|
| Bacteria | Viruses |
| Negative <i>Bordetella parapertussis</i> | Negative Adenovirus |
| Negative <i>Bordetella pertussis</i> | Negative Coronavirus SARS-CoV-2 |
| Negative <i>Chlamydia pneumoniae</i> | Negative Coronavirus (seasonal) |
| Negative <i>Mycoplasma pneumoniae</i> | Negative Human Metapneumovirus |
| | Negative Human Rhinovirus/Enterovirus |
| | Negative Influenza A Virus |
| | Negative Influenza A virus A/H1-2009 |
| | Negative Influenza A virus A/H3 |
| | Negative Influenza B Virus |
| | Negative Parainfluenza Virus |
| | Negative Respiratory Syncytial Virus |

Table 6. SPOTFIRE R Panel Mini Results: **R** Negative QC Test

| PASS |
|---|
| Viruses |
| Negative Coronavirus SARS-CoV-2 |
| Negative Human Rhinovirus |
| Negative Influenza A Virus |
| Negative Influenza B Virus |
| Negative Respiratory Syncytial Virus |

Table 7. SPOTFIRE R/ST Panel Results: **R ST** Negative QC Test

| PASS | |
|---|--|
| Bacteria | Viruses |
| Negative <i>Bordetella parapertussis</i> | Negative Adenovirus |
| Negative <i>Bordetella pertussis</i> | Negative Coronavirus SARS-CoV-2 |
| Negative <i>Chlamydia pneumoniae</i> | Negative Coronavirus (seasonal) |
| Negative <i>Mycoplasma pneumoniae</i> | Negative Human Metapneumovirus |
| Negative <i>Streptococcus dysgalactiae</i> (group C/G Strep) | Negative Human Rhinovirus/Enterovirus |
| Negative <i>Streptococcus pyogenes</i> (group A Strep) | Negative Influenza A Virus |
| | Negative Influenza A virus A/H1-2009 |
| | Negative Influenza A virus A/H3 |
| | Negative Influenza B Virus |
| | Negative Parainfluenza Virus |
| | Negative Respiratory Syncytial Virus |

Table 8. SPOTFIRE R/ST Panel Mini Results: **R ST** Negative QC Test

| PASS | |
|---|---|
| Bacteria | Viruses |
| Negative <i>Streptococcus pyogenes</i> (group A Strep) | Negative Coronavirus SARS-CoV-2 |
| | Negative Human Rhinovirus |
| | Negative Influenza A Virus |
| | Negative Influenza B Virus |
| | Negative Respiratory Syncytial Virus |