

SPOTFIRE® RSP Positive Control

INTENDED USE:

SPOTFIRE® RSP Positive Control is intended for use (as applicable) as an external positive 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, and BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel on the BIOFIRE SPOTFIRE System. SPOTFIRE RSP Positive Control is comprised of *in vitro* RNA transcripts and stabilizing solution and is designed for and intended to be used solely with the BIOFIRE SPOTFIRE R Panel, BIOFIRE SPOTFIRE R Panel Mini, and BIOFIRE SPOTFIRE R/ST Panel assays. 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:

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, and 3.

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.

COMPOSITION:

SPOTFIRE RSP Positive Control kit is comprised of 6 single use tubes, 300µL each, containing 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, and SPOTFIRE R/ST Panel assays on the BIOFIRE SPOTFIRE System. Tables 1, 2, and 3 list the pathogens that are detected in the SPOTFIRE RSP Positive Control when tested with the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, and SPOTFIRE R/ST Panel assays, respectively.

INSTRUCTIONS FOR USE:

- 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.
- Allow the control to come completely to room temperature (18° – 25°C) before use, **approximately 30 minutes** if frozen due to dry ice shipping.
- Use the control as provided. Do Not Dilute.
- 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.
- Refer to the Quality Control Testing section of the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, or SPOTFIRE R/ST Panel Quick Guide to prepare, hydrate and load the SPOTFIRE R Panel Pouch, SPOTFIRE R Panel Mini Pouch, or SPOTFIRE R/ST Panel 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.*
- Discard after use according to your local and federal regulations.

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

PRECAUTIONS and WARNINGS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* diagnostic use only.
- SPOTFIRE RSP Positive Control is for use with the SPOTFIRE R Panel, SPOTFIRE R Panel Mini, or SPOTFIRE R/ST Panel assays on the BIOFIRE SPOTFIRE System. It does not contain the entire genome of pathogens listed in Tables 1, 2, and 3.
- Appearance: Positive control is slightly cloudy.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- SPOTFIRE RSP Positive Control cannot be cloned, sold, or transferred without the explicit written consent of MMQCCI.

STORAGE and STABILITY:

SPOTFIRE RSP Positive Control 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 Positive Control kit components are for single use. Discard after use according to your local and federal regulations.

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), and SPOTFIRE R/ST Panel (Table 3).

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

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	Total Percent Correct
1	26	0	13	0	100%	13	0	100%	100%
2	33	1	13	0	100%	19	0	100%	100%
3	120	4	53	1	98.1%	62	0	100%	99.1%
4	44	1	21	0	100%	22	0	100%	100%
5	9	1	8	0	100%	NA	NA	NA	N/A
All Sites	232	7*	108	1	99.1%	116	0	100%	99.6%

*Invalid results were not included in percent correct.

ORDERING INFORMATION:

SPOTFIRE RSP Positive Control
Part Number: M42638, 6 tubes x 300µL
SPOTFIRE RSP Pos & Neg Controls
Part Number: M425, 2 boxes: 1 box each of M42638 & M42738

Rx Only
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