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SPOTFIRE® RSP Negative Control

INTENDED USE:

SPOTFIRE® RSP Negative Control is intended for use as an external 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*, Adenovirus, seasonal Coronavirus, Coronavirus SARS-CoV-2, 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 performed on the BIOFIRE® SPOTFIRE® System. SPOTFIRE RSP Negative Control is comprised of a solution that does not contain target analytes and is designed for and intended to be used solely with the BIOFIRE SPOTFIRE R Panel. This product is not intended to replace manufacturer internal controls provided with the device.

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

PRODUCT SUMMARY and PRINCIPLE:

SPOTFIRE RSP Negative Control contains no nucleic acid and does not contain any sequence corresponding to genome segments of pathogens listed as detected in Table 1.

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 Negative Control kit is comprised of 6 single use tubes, 300µL each, containing a non-infectious solution of buffers and preservatives. There is no DNA or RNA in the SPOTFIRE RSP Negative Control.

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 Quick Guide to prepare, hydrate and load the SPOTFIRE R 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 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 Negative Control is for use with the SPOTFIRE R Panel on the BIOFIRE SPOTFIRE System.
- Appearance: 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.
- SPOTFIRE RSP Negative Control cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

SPOTFIRE RSP Negative 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 Negative 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 Negative Control is tested as a Quality Control (QC icon) are listed in Table 1.

Table 1. Expected results for SPOTFIRE RSP Negative Control tested as QC.

| R Negative QC Test | |
|--|---------------------------------------|
| PASS | |
| Organisms Tested: | |
| 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 |

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 Panel assay 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 External Results for 3 Control Lots of SPOTFIRE RSP Control Panel M425 | | | | | | | | | |
|---|-------------|---------|---------------------------------|-----------------------------------|----------------------------------|---------------------------------|-----------------------------------|----------------------------------|-----------------------|
| 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 | 100% |
| 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 Negative Control
 Part Number: M42738
 Kit Contains: 6 tubes x 300µL

Rx Only

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