

BioFire® RP2.1/RP2.1plus Control Panel M441

INTENDED USE:

The BioFire® RP2.1/RP2.1plus Control Panel M441 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* on the BIOFIRE Respiratory Panel 2.1 (RP2.1) and BIOFIRE Respiratory Panel 2.1plus (RP2.1plus) assays performed on the BIOFIRE FILMARRAY® systems. BioFire RP2.1/RP2.1plus Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BIOFIRE RP2.1 and BIOFIRE RP2.1plus assays. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

The BioFire RP2.1/RP2.1plus Control Panel M441 is composed of 2 controls, BioFire RP2.1/RP2.1plus Positive and BioFire RP2.1/RP2.1plus Negative. BioFire RP2.1/RP2.1plus Positive contains surrogate control material composed of synthetic RNA transcripts corresponding to genome segments of pathogens listed in Table 1. BioFire RP2.1/RP2.1plus Negative contains no RNA.

Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

COMPOSITION:

The BioFire RP2.1/RP2.1plus Control Panel M441 is comprised of 12 single use tubes, 6 tubes of BioFire RP2.1/RP2.1plus Positive and 6 tubes of BioFire RP2.1/RP2.1plus Negative, 300µL each. BioFire RP2.1/RP2.1plus Positive control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. BioFire RP2.1/RP2.1plus Negative control contains buffers and preservatives. Tables 1 and 2 list the pathogens that are monitored by the BioFire RP2.1/RP2.1plus Control Panel M441.

INSTRUCTIONS FOR USE:

1. Allow control to be tested to come completely to room temperature (18°C to 25°C), **approximately 30 minutes**.
2. Use the control as provided. **DO NOT DILUTE**.
3. Immediately before use, **mix the control thoroughly by first inverting several times followed by vortexing the tube for 3-5 seconds**. Tap the tube several times on the bench to remove any control caught in the cap before opening the tube.
4. Prepare Sample Mix, **invert at least 3 times**, load and run a BIOFIRE RP2.1 Pouch or BIOFIRE RP2.1plus Pouch, using the control as you would use a patient specimen, according to BIOFIRE RP2.1 or BIOFIRE RP2.1plus Quick Guide or Instructions for Use.
5. Discard control tube after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* diagnostic use only.
- This product is only for use with BIOFIRE RP2.1 or BIOFIRE RP2.1plus assays on the BIOFIRE FILMARRAY systems. It does not contain the entire genome of the respiratory pathogens listed in Tables 1 and 2.
- This product is not intended for use as a substitute for the internal controls provided in the BIOFIRE RP2.1 or BIOFIRE RP2.1plus assays.
- 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.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- BioFire RP2.1/RP2.1plus Control Panel M441 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

BioFire RP2.1/RP2.1plus Control Panel M441 should be stored frozen (-25°C to -15°C). Unopened BioFire RP2.1/RP2.1plus Control Panel M441 material is stable through the expiration date printed on the kit label when consistently stored frozen. BioFire RP2.1/RP2.1plus Positive and BioFire RP2.1/RP2.1plus Negative are for single use. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

Product Name: BioFire RP2.1/RP2.1plus Control Panel M441
Part Number: M441-CE

CONT Kit Contains: 12 tubes x 300µL
6 Positive (+) controls and 6 Negative (-) controls

EXPECTED VALUES:

The expected results when the controls are analyzed are listed in Tables 1 and 2.

Table 1: BioFire RP2.1/RP2.1plus Positive Result Summary

| Viruses | |
|------------|--|
| ✓ Detected | Adenovirus |
| ✓ Detected | Coronavirus 229E |
| ✓ Detected | Coronavirus HKU1 |
| ✓ Detected | Coronavirus NL63 |
| ✓ Detected | Coronavirus OC43 |
| ✓ Detected | Middle East Respiratory Syndrome Coronavirus (MERS-CoV) ¹ |
| ✓ Detected | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) |
| ✓ Detected | Human Metapneumovirus |
| ✓ Detected | Human Rhinovirus/Enterovirus |
| ✓ Detected | Influenza A H1-2009 ¹ |
| ✓ Detected | Influenza A H3 |
| ✓ Detected | Influenza B |
| ✓ Detected | Parainfluenza Virus 1 |
| ✓ Detected | Parainfluenza Virus 2 |
| ✓ Detected | Parainfluenza Virus 3 |
| ✓ Detected | Parainfluenza Virus 4 |
| ✓ Detected | Respiratory Syncytial Virus |
| Bacteria | |
| ✓ Detected | <i>Bordetella parapertussis</i> (IS1001) |
| ✓ Detected | <i>Bordetella pertussis</i> (ptxP) |
| ✓ Detected | <i>Chlamydia pneumoniae</i> |
| ✓ Detected | <i>Mycoplasma pneumoniae</i> |

¹ BioFire RP2.1/RP2.1plus Positive contains both Influenza A H1 and Influenza A H1-2009. Due to BIOFIRE FILMARRAY 2.0 Software calling algorithm, only Influenza A H1-2009 will report as Detected, just as if a co-infection of Influenza A H1-2009 and another Influenza A H1 has occurred. For questions related to software, please contact BioFire Technical Support.

² Middle East Respiratory Syndrome Coronavirus is reported on BIOFIRE RP2.1plus assay only.

Table 2: BioFire RP2.1/RP2.1plus Negative Result Summary

| Viruses | |
|--------------|--|
| Not Detected | Adenovirus |
| Not Detected | Coronavirus 229E |
| Not Detected | Coronavirus HKU1 |
| Not Detected | Coronavirus NL63 |
| Not Detected | Coronavirus OC43 |
| Not Detected | Middle East Respiratory Syndrome Coronavirus (MERS-CoV) ¹ |
| Not Detected | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) |
| Not Detected | Human Metapneumovirus |
| Not Detected | Human Rhinovirus/Enterovirus |
| Not Detected | Influenza A |
| Not Detected | Influenza B |
| Not Detected | Parainfluenza Virus 1 |
| Not Detected | Parainfluenza Virus 2 |
| Not Detected | Parainfluenza Virus 3 |
| Not Detected | Parainfluenza Virus 4 |
| Not Detected | Respiratory Syncytial Virus |
| Bacteria | |
| Not Detected | <i>Bordetella parapertussis</i> (IS1001) |
| Not Detected | <i>Bordetella pertussis</i> (ptxP) |
| Not Detected | <i>Chlamydia pneumoniae</i> |
| Not Detected | <i>Mycoplasma pneumoniae</i> |

¹ Middle East Respiratory Syndrome Coronavirus is reported on BIOFIRE RP2.1plus assay only

REPRESENTATIVE PERFORMANCE DATA:

Three lots of BioFire RP2.1/RP2.1plus Positive and 3 lots of BioFire RP2.1/RP2.1plus Negative were tested using the BIOFIRE RP2.1plus assay on BIOFIRE FILMARRAY systems at MMQCI and an external site, incorporating 4 unique pouch lots, multiple operators and instruments. A total of 172 controls were tested at the 2 sites. One control gave an Invalid result. All other controls produced correct results for an overall correct result rate of 100%.

| Table 3: Summary of All Test Results: Internal and External Sites | | | | | | | | |
|---|-------------|---------|---------------------------------|-----------------------------------|----------------------------------|---------------------------------|-----------------------------------|----------------------------------|
| Number of Sites | 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 |
| 2 | 172 | 1* | 86 | 0 | 100% | 85 | 0 | 100% |

*The Invalid result was not included in percent correct.

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