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

INTENDED USE:

BioFire® RP2.1/RP2.1*plus* 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), BioFire® Respiratory Panel 2.1*plus* (RP2.1*plus)* and BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) assays performed on the BioFire® FilmArray® systems. BioFire RP2.1/RP2.1*plus* Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BioFire RP2.1, BioFire RP2.1*plus* and BioFire RP2.1-EZ assays. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

BioFire RP2.1/RP2.1*plus* Control Panel M441 is composed of 2 controls, BioFire® RP2.1/RP2.1*plus* Positive and BioFire® RP2.1/RP2.1*plus* Negative. BioFire RP2.1/RP2.1*plus* Positive contains surrogate control material composed of synthetic RNA transcripts corresponding to genome segments of pathogens listed in Table 1. BioFire RP2.1/RP2.1*plus* 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/RP2.1*plus* Control Panel M441 is comprised of 12 single use tubes, 6 tubes of BioFire RP2.1/RP2.1*plus* Positive and 6 tubes of BioFire RP2.1/RP2.1*plus* Negative, 300µL each. BioFire RP2.1/RP2.1*plus* Positive control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. BioFire RP2.1/RP2.1*plus* Negative control contains buffers and preservatives. Tables 1 and 2 list the pathogens that are monitored by the BioFire RP2.1/RP2.1*plus* Control Panel M441.

INSTRUCTIONS FOR USE:

1. Allow control to be tested to come completely to room temperature (18°–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, BioFire RP2.1*plus* Pouch or BioFire RP2.1-EZ Pouch, using the control as you would use a patient specimen, according to BioFire RP2.1, BioFire RP2.1*plus* or BioFire RP2.1-EZ 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, BioFire RP2.1*plus* or BioFire RP2.1-EZ 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 compatible with the FilmArray Respiratory Panel (RP) assay.
- This product is not intended for use as a substitute for the internal controls provided in the BioFire RP2.1, BioFire RP2.1*plus* or BioFire RP2.1-EZ assays.
- Not all BioFire assays listed for use with the BioFire RP2.1/RP2.1*plus* Control Panel M441 are authorized in every regulatory region.
- 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, federal regulations and accreditation requirements.
- BioFire RP2.1/RP2.1*plus* Control Panel M441 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

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

ORDERING INFORMATION:

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

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/RP2.1*plus* Positive Result Summary

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)[2]
✓ 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[3]
✓ Detected	Parainfluneza Virus 2[3]
✓ Detected	Parainfluenza Virus 3[3]
✓ Detected	Parainfluenza Virus 4[3]
✓ Detected	Respiratory Syncytial Virus
Bacteria	
✓ Detected	*Bordetella parapertussis (IS1001)*
✓ Detected	*Bordetella pertussis (ptxP)*
✓ Detected	*Chlamydia pneumoniae*
✓ Detected	*Mycoplasma pneumoniae*

[1] BioFire RP2.1/RP2.1*plus* 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 RP2.1*plus* assay only.
[3] BioFire RP2.1-EZ software interprets each of the four assays for Parainfluenza viruses (PIV1, PIV2, PIV3 and PIV4) independently, however, the results are reported as a single test result for the virus.

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

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[2]
Not Detected	Parainfluneza Virus 2[2]
Not Detected	Parainfluenza Virus 3[2]
Not Detected	Parainfluenza Virus 4[2]
Not Detected	Respiratory Syncytial Virus
Bacteria	
Not Detected	*Bordetella parapertussis (IS1001)*
Not Detected	*Bordetella pertussis (ptxP)*
Not Detected	*Chlamydia pneumoniae*
Not Detected	*Mycoplasma pneumoniae*

[1] Middle East Respiratory Syndrome Coronavirus is reported on RP2.1*plus* only
[2] BioFire RP2.1-EZ software interprets each of the four assays for Parainfluenza viruses (PIV1, PIV2, PIV3 and PIV4) independently, however, the results are reported as a single test result for the virus.

REPRESENTATIVE PERFORMANCE DATA:

Three lots of BioFire RP2.1/RP2.1*plus* Positive and 3 lots of BioFire RP2.1/RP2.1*plus* Negative were tested using the BioFire RP2.1*plus* 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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