For *in vitro* diagnostic use
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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/RP2.1plus 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.
- 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**
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	Parainfluenza 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. To confirm successful detection of Influenza A H1, view the melt curve by following BioFire's Technical Note: Torch Melting Curve Analysis with FilmArray 2.0 Software. 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	Parainfluenza 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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BioFire® RP2.1/RP2.1*plus* Control Panel M441

USAGE :

BioFire® RP2.1/RP2.1*plus* Control Panel M441 est conçu en tant que test de Contrôle Qualité externe, positif et négatif, pour le suivi des performances des analyses *in vitro* d'acide nucléique en laboratoire pour la détection qualitative de 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*, et *Mycoplasma pneumoniae* avec les tests BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Respiratory Panel 2.1*plus* (RP2.1*plus)* et BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) réalisés avec les sytèmes BioFire® FilmArray®. Le contrôle Positif de BioFire RP2.1/RP2.1*plus* est composé de transcrits d'ARN synthétiques spécifiquement développés pour les tests BioFire RP2.1, BioFire RP2.1*plus* et BioFire RP2.1-EZ et conçu pour être utilisé uniquement avec ces tests. Ce contrôle n'est pas conçu pour remplacer les contrôles du fabricant fournis avec l'instrument.

PRÉSENTATION ET PRINCIPE DU PRODUIT :

BioFire RP2.1/RP2.1*plus* Control Panel M441 est composé de 2 contrôles, BioFire RP2.1/RP2.1*plus* Positive and BioFire RP2.1/RP2.1*plus* Negative. BioFire RP2.1/RP2.1*plus* Positive contient du matériel de contrôle de substitution composé de transcrits d'ARN synthétiques correspondant à des segments de génome des agents pathogènes listés dans la Table 1. BioFire RP2.1/RP2.1*plus* Negative ne contient pas d'ARN.
Une utilisation routinière des matériels de référence, cohérente de lot à lot, permet aux laboratoires d'identifier les changements, les tendances et l'augmentation des erreurs aléatoires causées par les variations du système d'analyse comme des réactifs défectueux. Une investigation précoce peut prévenir l'échec des analyses réalisées.

COMPOSITION :

BioFire RP2.1/RP2.1*plus* Control Panel M441 est composé de 12 tubes à usage unique, 6 tubes de BioFire RP2.1/RP2.1*plus* Positive et 6 tubes de BioFire RP2.1/RP2.1*plus* Negative, de 300µL chacun. BioFire RP2.1/RP2.1*plus* Positive contient de l'ARN synthétique suspendu dans une solution non-infectieuse de tampons, conservateurs et stabilisants. BioFire RP2.1/RP2.1*plus* Negative contient des tampons et conservateurs. Les Tables 1 et 2 listent les agents pathogènes détectés par le BioFire RP2.1/RP2.1plus Control Panel M441.

UTILISATION :

1. Placer le flacon à tester à température ambiante jusqu'à ce qu'il atteigne une température de 18ºC à 25ºC, **environ 30 minutes**.
2. Utiliser le contrôle tel quel. ***NE PAS LE DILUER.***
3. Juste avant l'analyse, **bien mélanger le contrôle en inversant le tube plusieurs fois puis en le passant au vortex 3 à 5 secondes.** Tapoter le tube à plusieurs reprises sur la paillasse afin d'éliminer tout excès de liquide présent dans le bouchon avant de l'ouvrir.
4. Utiliser le contrôle de façon identique à un échantillon de patient, selon les instructions du fabricant (voir BioFire RP2.1, BioFire RP2.1*plus* ou BioFire RP2.1-EZ Quick Guide ou Instructions for Use).
   Préparer le Sample Injection Vial (Flacon de l'échantillon), **retourner délicatement le flacon au moins trois fois pour mélanger**, charger l'échantillon préparé et lancer l'analyse avec la cassette BioFire RP2.1, BioFire RP2.1*plus* ou BioFire RP2.1-EZ.
5. Jeter chaque bouteille après usage conformément aux réglementations locales et fédérales.

PRÉCAUTIONS, MISES EN GARDE ET RESTRICTIONS :

- Ne pas diluer. Utilisez le produit de contrôle tel quel.
- Ce produit est destiné uniquement à un usage diagnostique *in vitro*.
- Ce produit doit être uniquement utilisé avec BioFire RP2.1, BioFire RP2.1*plus* ou BioFire RP2.1-EZ sur les systèmes BioFire FilmArray. Il ne contient pas le génome complet des agents pathogènes respiratoires listés dans les Tables 1 et 2. Ce produit n'est pas compatible avec le test FilmArray Respiratory Panel (RP).
- Ce produit n'est pas conçu pour être utilisé en substitution des contrôles internes fournis avec les tests BioFire RP2.1, BioFire RP2.1*plus* ou BioFire RP2.1-EZ.
- Aspect : Le contrôle Positif est légèrement trouble, le contrôle Négatif est transparent.
- Ce produit ne contient aucune matière biologique d'origine humaine ou animale. Le respect des précautions universelles n'est PAS nécessaire lors de la manipulation de ce produit.
- Les matériels de contrôle Qualité doivent être employés en accord avec les lois locales, d'Etat et fédérales ainsi que les exigences d'accréditation.
- BioFire RP2.1/RP2.1*plus* Control Panel M441 ne peut pas être cloné, vendu ou transféré sans le consentement écrit explicite de MMQCI.

CONSERVATION ET STABILITÉ :

BioFire RP2.1/RP2.1*plus* Control Panel M441 doit être stocké congelé (-25°C à -15°C). Les flacons non-ouverts de BioFire RP2.1/RP2.1*plus* Control Panel M441 sont stables jusqu'à leur date de péremption indiquée sur l'étiquette, sous réserve d'avoir été constamment maintenus congelés lors du stockage. Les flacons BioFire RP2.1/RP2.1*plus* Positive et BioFire RP2.1/RP2.1*plus* Negative sont à usage unique. Jeter chaque bouteille après usage conformément aux réglementations locales et fédérales.

VALEURS ATTENDUES :

Les résultats attendus lors de l'analyse des contrôles sont listés dans les Tables 1 et 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. To confirm successful detection of Influenza A H1, view the melt curve by following BioFire's Technical Note: Torch Melting Curve Analysis with FilmArray 2.0 Software. 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.

DONNÉES DE PERFORMANCE REPRÉSENTATIVES :

Trois lots de BioFire RP2.1/RP2.1*plus* Positive et 3 lots de BioFire RP2.1/RP2.1*plus* Negative ont été testés utilisant le test BioFire RP2.1*plus* sur les systèmes BioFire FilmArray par MMQCI et un site externe, incorporant 4 lots distincts de cassettes, de multiple opérateurs et instruments. Un total de 172 Contrôles ont été testés par les 2 sites. Un contrôle a reçu un résultat Invalide. L'ensemble des autres contrôles a reçu les resultats attendus, donnant un taux global de concordance avec le résultat attendu de 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.

BioFire et FilmArray sont des marques déposées de BioFire Diagnostics, LLC

MODALITES DE COMMANDE :

Nom du produit : BioFire RP2.1/RP2.1*plus* Control Panel M441
Référence du produit M441
Contenu du kit : 12 tubes x 300µL
6 contrôles Positifs et 6 contrôles Négatifs