



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

INTENDED USE:

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), BioFire® Respiratory Panel 2.1plus (RP2.1plus) and BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) assay 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, BioFire RP2.1plus and BioFire RP2.1-EZ assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

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°–25°C).
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 and run a BioFire RP2.1 Pouch or BioFire RP2.1plus Pouch or BioFire RP2.1-EZ Pouch, using the control as you would use a patient specimen, according to BioFire RP2.1 or BioFire RP2.1plus 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* analytical testing.
- This product is only for use with BioFire RP2.1 or BioFire RP2.1plus or BioFire RP2.1-EZ 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 or BioFire RP2.1plus or BioFire RP2.1-EZ assay.
- 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/RP2.1plus 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.

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

| 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 | <i>Bordetella parapertussis</i> (IS1001) |
| ✓ Detected | <i>Bordetella pertussis</i> (ptxP) |
| ✓ Detected | <i>Chlamydia pneumoniae</i> |
| ✓ Detected | <i>Mycoplasma pneumoniae</i> |

¹BioFire 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. 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.

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

³BioFire 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/RP2.1plus 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 | <i>Bordetella parapertussis</i> (IS1001) |
| Not Detected | <i>Bordetella pertussis</i> (ptxP) |
| Not Detected | <i>Chlamydia pneumoniae</i> |
| Not Detected | <i>Mycoplasma pneumoniae</i> |

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

²BioFire 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.

ORDERING INFORMATION:

Product Name: BioFire RP2.1/RP2.1plus Control Panel M441
Part Number: M441
Kit Contains: 12 tubes x 300µL
 6 Positive controls and 6 Negative control

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

USAGE:

BioFire RP2.1/RP2.1plus 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 2.1plus (RP2.1plus) et BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) réalisés avec les systèmes BioFire FilmArray®. Le contrôle Positif de BioFire RP2.1/RP2.1plus est composé de transcrits d'ARN synthétiques spécifiquement développés pour les tests BioFire RP2.1, BioFire RP2.1plus 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/RP2.1plus Control Panel M441 est composé de 2 contrôles, BioFire RP2.1/RP2.1plus Positif and BioFire RP2.1/RP2.1plus Négatif. BioFire RP2.1/RP2.1plus Positif 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/RP2.1plus Négatif 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/RP2.1plus Control Panel M441 est composé de 12 tubes à usage unique, 6 tubes de BioFire RP2.1/RP2.1plus Positif et 6 tubes de BioFire RP2.1/RP2.1plus Négatif, de 300µL chacun. BioFire RP2.1/RP2.1plus Positif contient de l'ARN synthétique suspendu dans une solution non-infectieuse de tampons, conservateurs et stabilisants. BioFire RP2.1/RP2.1plus Négatif 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:

- Placer le flacon à tester à température ambiante jusqu'à ce qu'il atteigne une température de 18°C à 25°C.
- Utiliser le contrôle tel quel. **NE PAS LE DILUER.**
- 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.
- Préparer la cassette BioFire RP2.1 ou BioFire RP2.1plus ou BioFire RP2.1-EZ pour l'analyse. Utiliser le contrôle de façon identique à un échantillon de patient, selon les instructions du fabricant (voir BioFire RP2.1 ou BioFire RP2.1plus ou BioFire RP2.1-EZ Quick Guide ou Instructions for Use).
- 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 aux analyses *in vitro*.
- Ce produit doit être uniquement utilisé avec BioFire RP2.1 ou BioFire RP2.1plus 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 le test BioFire RP2.1 ou BioFire RP2.1plus 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/RP2.1plus Control Panel M441 ne peut pas être cloné, vendu ou transféré sans le consentement écrit explicite de MMQCI.

CONSERVATION ET STABILITÉ:

BioFire RP2.1/RP2.1plus Control Panel M441 doit être stocké congelé (-25°C au -15°C). Les flacons non-ouverts de BioFire RP2.1/RP2.1plus Control Panel M441 sont stables jusqu'à leur date de péremption indiquée sur l'étiquette, sous réserve d'avoir été constamment maintenus à -20°C lors du stockage. Les flacons BioFire RP2.1/RP2.1plus Positif et BioFire RP2.1/RP2.1plus Négatif 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/RP2.1plus 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 | <i>Bordetella parapertussis (IS1001)</i> |
| ✓ Detected | <i>Bordetella pertussis (ptxP)</i> |
| ✓ Detected | <i>Chlamydia pneumoniae</i> |
| ✓ Detected | <i>Mycoplasma pneumoniae</i> |

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. 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 RP2.1plus 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/RP2.1plus 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 | <i>Bordetella parapertussis (IS1001)</i> |
| Not Detected | <i>Bordetella pertussis (ptxP)</i> |
| Not Detected | <i>Chlamydia pneumoniae</i> |
| Not Detected | <i>Mycoplasma pneumoniae</i> |

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

MODALITES DE COMMANDE:

Nom du produit: BioFire RP2.1/RP2.1plus Control Panel M441

Reference du produit M441

Contenu du kit : 12 tubes x 300µL

6 contrôles Positifs et 6 contrôles Négatifs