



FilmArray RP2/RP2plus Control Panel

INTENDED USE:

FilmArray RP2/RP2plus Control Panel 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, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* on the FilmArray® Respiratory Panel 2 (RP2) and FilmArray® Respiratory Panel 2 plus (RP2plus) assay performed on the FilmArray® 2.0/Torch. FilmArray RP2/RP2plus Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the FilmArray RP2 assay and FilmArray RP2plus assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray RP2/RP2plus Control Panel is composed of 2 controls, FilmArray RP2/RP2plus Positive and FilmArray RP2/RP2plus Negative. FilmArray RP2/RP2plus Positive contains surrogate control material composed of synthetic RNA transcripts corresponding to genome segments of pathogens listed in Table 1. FilmArray RP2/RP2plus Negative contains non-target 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 FilmArray RP2/RP2plus Control Panel is comprised of 12 single use tubes, 300µL each, of synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are monitored by the FilmArray RP2/RP2plus Control Panel when tested by the FilmArray RP2 assay and FilmArray® RP2plus on the FilmArray 2.0/Torch.

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 FilmArray RP2 Pouch or FilmArray RP2plus Pouch, using the control as you would use a patient specimen, according to FilmArray RP2 or FilmArray RP2plus 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 FilmArray RP2 or FilmArray RP2plus on the FilmArray 2.0/Torch. 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 FilmArray RP2 assay or FilmArray RP2plus assay.
- This product is slightly cloudy in appearance.
- 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.
- FilmArray RP2/RP2plus Control Panel cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

FilmArray RP2/RP2plus Control Panel should be stored frozen (-25°C to -15°C). Unopened FilmArray RP2/RP2plus Control Panel material is stable through the expiration date printed on the kit label when consistently stored frozen. FilmArray RP2/RP2plus Positive and FilmArray RP2/RP2plus Negative are for single use. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

Product Name: FilmArray RP2/RP2plus Control Panel
Part Number: M315
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: FilmArray RP2/RP2plus Positive FilmArray Result Summary

Result Summary	
Viruses	
✓ Detected	Adenovirus
✓ Detected	Coronavirus 229E
✓ Detected	Coronavirus HKU1
✓ Detected	Coronavirus NL63
✓ Detected	Coronavirus OC43
✓ Detected	Human Metapneumovirus
✓ Detected	Human Rhinovirus/Enterovirus
✓ Detected	Influenza A H1-2009 ¹
✓ Detected	Influenza A H3
✓ Detected	Influenza B
✓ Detected	Middle East Respiratory Syndrome Coronavirus ²
✓ 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 FilmArray RP2/RP2plus Positive contains both Influenza A H1 and Influenza A H1-2009. Due to 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 RP2plus only.

Table 2: FilmArray RP2/RP2plus Negative FilmArray 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	Human Metapneumovirus
Not Detected	Human Rhinovirus/ Enterovirus
Not Detected	Influenza A
Not Detected	Influenza B
Not Detected	Middle East Respiratory Syndrome Coronavirus ¹
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 RP2plus only

REPRESENTATIVE PERFORMANCE DATA:

Three lots of FilmArray RP2/RP2plus Positive and three lots of FilmArray RP2/RP2plus Negative were tested using the FilmArray RP2plus assay on the FilmArray instrument 2.0 system at 3 external clinical laboratory sites, incorporating 3 unique pouch lots and multiple operators. A total of 180 external controls were tested (90 positive and 90 negative) over 10 days at each site. All controls gave correct results for Total Correct Results of 100%.

Summary of External Results for FilmArray RP2/RP2plus Control Panel								
External 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
1	60	0	30	0	100%	30	0	100%
2	60	0	30	0	100%	30	0	100%
3	60	0	30	0	100%	30	0	100%
All Sites	180	0	90	0	100%	90	0	100%