



FilmArray RP EZ Control Panel M265

INTENDED USE:

FilmArray RP EZ Control Panel M265 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 H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydomphila pneumoniae*, and *Mycoplasma pneumoniae* on the FilmArray® RP EZ assay performed on the FilmArray® systems. FilmArray RP EZ Positive Control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the FilmArray® RP EZ assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray RP EZ Control Panel M265 is composed of 2 controls, FilmArray RP EZ Positive Control and FilmArray RP EZ Negative Control. FilmArray RP EZ Positive Control contains surrogate control material composed of synthetic RNA transcripts corresponding to genome segments of pathogens listed in Table 1. FilmArray RP EZ Negative Control 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. At a minimum, controls should be run at the frequency recommended by the FilmArray® RP EZ manufacturer's recommendations for external quality control testing.

STORAGE and STABILITY:

FilmArray RP EZ Control Panel M265 should be stored frozen (-25°C to -15°C). Unopened FilmArray RP EZ Control Panel M265 material is stable through the expiration date printed on the kit label when continuously stored frozen. FilmArray RP EZ Positive Control and FilmArray RP EZ Negative Control are for single use. Discard after use according to your local and federal regulations.

COMPOSITION:

The FilmArray RP EZ Control Panel M265 is comprised of 12 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 RP EZ Control Panel M265 when tested by the FilmArray® RP EZ on the FilmArray instrument.

INSTRUCTIONS FOR USE:

Note: Use one FilmArray® RP EZ Pouch to perform the negative control test, and another FilmArray® RP EZ Pouch to perform the positive control test.

1. Allow the control to be tested to come 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 at least 3 times. Tap the tube 3 times on the bench to remove any control caught in the cap before opening the tube.
4. Prepare and run a FilmArray® RP Pouch, using the control as you would use a patient specimen, according to FilmArray® RP EZ Quick Guide or Instruction Booklet.
5. Discard control tube after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute.
- For *In Vitro* Diagnostic Use.
- This product is only for use with FilmArray® Respiratory Panel (RP EZ) on the FilmArray® 2.0 EZ configuration system. It does not contain the entire genome of the respiratory pathogens listed in Table 1.
- This product is not intended for use as a substitute for the internal controls provided in the FilmArray Respiratory Panel (RP EZ).
- This product is 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 RP EZ Control Panel M265 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

ORDERING INFORMATION:

FilmArray RP EZ Control Panel M265

Part Number: M265

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 RP EZ Positive Control FilmArray Result Summary

** *FilmArray RP EZ Positive Control Sample does NOT need to be retested. Multiple Influenza A subtypes are intentionally included in the control.*

| Multiple Organisms Detected. Influenza A – Multiple Subtypes Detected Retest the Sample ONCE** | |
|--|--------------|
| Results Summary | |
| Detected | Not Detected |
| Adenovirus Coronavirus Human Metapneumovirus Human Rhinovirus/ Enterovirus Influenza A H1-2009 Influenza A H3 Influenza B Parainfluenza Virus Respiratory Syncytial Virus <i>Bordetella pertussis</i> <i>Chlamydomphila pneumoniae</i> <i>Mycoplasma pneumoniae</i> | |

Table 2: FilmArray RP EZ Negative Control FilmArray Result Summary

| Negative Report the Results | |
|---------------------------------------|---|
| Results Summary | |
| Detected | Not Detected |
| | Adenovirus Coronavirus Human Metapneumovirus Human Rhinovirus/ Enterovirus Influenza A Influenza B Parainfluenza Virus Respiratory Syncytial Virus <i>Bordetella pertussis</i> <i>Chlamydomphila pneumoniae</i> <i>Mycoplasma pneumoniae</i> |

REPRESENTATIVE PERFORMANCE DATA:

Three lots of FilmArray RP EZ Control Panel M265 were tested by the FilmArray® RP EZ assay on the FilmArray® instrument 2.0 EZ Configuration system at 3 external sites over multiple days by multiple operators, incorporating 3 lots of RP EZ pouches across all sites. A total of 182 external controls were tested (91 positive and 91 negative). Two tests were excluded from final data analysis due to invalid results caused by internal pouch control failures. Data for the remaining 180 control tests are shown below in Table 3.

| External Site | Total Tests | Invalid | Correct Positive Control Result | Incorrect Positive Control Result | % Correct* Positive Control | Correct Negative Control Result | Incorrect Negative control Result | % Correct* Negative Control |
|---------------|-------------|---------|---------------------------------|-----------------------------------|-----------------------------|---------------------------------|-----------------------------------|-----------------------------|
| 1 | 61 | 1 | 30 | 0 | 100% | 30 | 0 | 100% |
| 2 | 61 | 1 | 30 | 0 | 100% | 30 | 0 | 100% |
| 3 | 60 | 0 | 30 | 0 | 100% | 28 | 2 | 93.3% |
| All | 182 | 2 | 90 | 0 | 100% | 88 | 2 | 97.8% |

*The 2 Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis.