



FilmArray® RP Control Panel M210 v1.1

INTENDED USE:

The FilmArray® RP Control Panel M210 v1.1 is intended for *in vitro* use as a quality control to monitor the detection and identification of multiple respiratory viral and bacterial targets in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections when tested by the FilmArray® Respiratory Panel on the FilmArray® instrument.

FilmArray® RP Control Panel M210 v1.1 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray® RP Control Panel M210 v1.1 is synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Best practice is to establish a quality control program for every assay performed by the laboratory.^{1, 2} 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® RP Control Panel M210 v1.1 is comprised of 12 tubes 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 Control Panel M210 v1.1 when tested by the FilmArray® Respiratory Panel on the FilmArray® instrument.

STORAGE and STABILITY:

FilmArray® RP Control Panel M210 v1.1 should be stored frozen (-25°C to -15°C). Unopened FilmArray® RP Control Panel M210 v1.1 material is stable through the expiration date printed on the kit label when continuously stored frozen. FilmArray® RP Control M211 v1.1 and FilmArray® RP Control M212 v1.1 are for single use. Discard after use according to your local and federal regulations.

INSTRUCTIONS FOR USE:

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. Prepare and hydrate a pouch according to FilmArray® Instructions.
4. Immediately before use, mix the control by briefly vortexing the tube for 3 – 5 seconds and then shake the tube down firmly to remove any control caught in the cap.
5. Aspirate the control using the FilmArray® transfer pipette.
6. Analyze the control as you would a patient sample by adding the control to the FilmArray® Sample Buffer.
7. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Do not dilute.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- This product is cloudy in appearance.
- This product does not contain any biological material of human origin.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for FilmArray® RP Control Panel M210 v1.1 in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, reagents and systematic or random errors. The expected results when the controls are analyzed are listed in Table 1.

FilmArray® Result Details Table 1

| Assay | | M211v1.1 Call | M212v1.1 Call |
|----------------------------------|---------------|---------------|---------------|
| Adenovirus | Adeno | Positive | Negative |
| | Adeno2 | Positive | Negative |
| Coronavirus 229E | | Negative | Positive |
| Coronavirus HKU1 | | Negative | Positive |
| Coronavirus NL63 | | Negative | Positive |
| Coronavirus OC43 | | Negative | Positive |
| Human Metapneumovirus | | Positive | Negative |
| Human Rhinovirus/ Enterovirus | Enterovirus 1 | Positive | Negative |
| | Enterovirus 2 | Positive | Negative |
| | HRV1 | Positive | Negative |
| | HRV2 | Positive | Negative |
| | HRV3 | Positive | Negative |
| | HRV4 | Positive | Negative |
| Influenza A H1-2009 | FluA-H1-2009 | Positive | Negative |
| Influenza A H3 | FluA-H1-pan | Positive | Positive |
| | FluA-H3 | Positive | Negative |
| | FluA-pan1 | Negative | Positive |
| | FluA-pan2 | Positive | Negative |
| | Influenza B | Negative | Positive |
| Parainfluenza Virus 1 | | Positive | Negative |
| Parainfluenza Virus 2 | | Negative | Positive |
| Parainfluenza Virus 3 | | Negative | Positive |
| Parainfluenza Virus 4 | | Positive | Negative |
| Respiratory Syncytial Virus | | Negative | Positive |
| <i>Bordetella pertussis</i> | | Negative | Positive |
| <i>Chlamydomphila pneumoniae</i> | | Negative | Positive |
| <i>Mycoplasma pneumoniae</i> | | Negative | Positive |

ORDERING INFORMATION:

FilmArray® RP Control Panel M210 v1.1

Part Number: M210v1.1

Kit Contains: 12 tubes x 300µL
6 each of M211 v1.1 & M212 v1.1

1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000