



FilmArray Pneumonia/Pneumoniaplus Control

INTENDED USE:

FilmArray Pneumonia/Pneumoniaplus Control 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 bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae* complex, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Moraxella catarrhalis*, *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Chlamydia pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*; antimicrobial resistance genes: CTX-M, IMP, KPC, *mecA/C* and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus on the FilmArray Pneumonia Panel or Pneumonia Panel *plus* assay performed on the FilmArray systems. FilmArray Pneumonia/Pneumoniaplus Control is composed of synthetic RNA and DNA specifically designed for and intended to be used solely with the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel *plus* assays. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray Pneumonia/Pneumoniaplus Control is composed of 2 controls, FilmArray Pneumonia/Pneumoniaplus POSITIVE and FilmArray Pneumonia/Pneumoniaplus NEGATIVE. FilmArray Pneumonia/Pneumoniaplus POSITIVE contains surrogate control material composed of synthetic nucleic acid corresponding to genome segments of pathogens listed in Table 1. FilmArray Pneumonia/Pneumoniaplus NEGATIVE contains no RNA or DNA.

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 Pneumonia/Pneumoniaplus Control is comprised of 12 tubes, 6 tubes of positive control and 6 tubes of negative control, 120µL each. FilmArray Pneumonia/Pneumoniaplus POSITIVE contains synthetic RNA and DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. FilmArray Pneumonia/Pneumoniaplus NEGATIVE contains buffers and preservatives. Table 1 lists the pathogens that are monitored by the FilmArray Pneumonia/Pneumoniaplus Control when tested by the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel *plus* assays on the FilmArray systems.

INSTRUCTIONS FOR USE:

- Allow the control to be tested to come completely to room temperature (18° – 25°C).
- Use the control as provided. DO NOT DILUTE.
- Prepare and hydrate a FilmArray Pneumonia Panel pouch or FilmArray Pneumonia Panel *plus* pouch according to the FilmArray Instructions for Use or Quick Guide.
- Prepare the Sample Injection Vial according to the FilmArray Instructions for Use or Quick Guide.
- 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.
 - Open the swab packet and place the flocked tip inside the control tube so that it touches the bottom of the tube.
 - Tilt the tube slightly and gently mix/stir the swab for about 10 seconds, keeping the tip fully immersed in the control liquid to saturate the entire swab. Note: When removing the saturated swab from the tube, be careful not to touch the side of the control tube to ensure that all the liquid remains on the swab.
 - Place the swab end into the Sample Injection Vial, then break off the swab handle. Discard the remaining swab handle and close the Sample Injection Vial lid tightly.
 - The controls are single use only. Discard control tube after use according to your local and federal regulations.
- Continue to process the control according to FilmArray Pneumonia Panel or FilmArray Pneumonia Panel *plus* Instructions for Use or Quick Guide.

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 Pneumonia Panel or FilmArray Pneumonia Panel *plus* on the FilmArray systems. 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 Pneumonia Panel or FilmArray Pneumonia Panel *plus* assays.
- 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 Pneumonia/Pneumoniaplus Control cannot be cloned, sold, or transferred without the explicit written consent of MMQCI

STORAGE and STABILITY:

FilmArray Pneumonia/Pneumoniaplus Control should be stored frozen (-25°C to -15°C). Unopened FilmArray Pneumonia/Pneumoniaplus Control material is stable through the expiration date printed on the kit label when continuously stored frozen. FilmArray Pneumonia/Pneumoniaplus POSITIVE and FilmArray Pneumonia/Pneumoniaplus NEGATIVE are for single use only. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

FilmArray Pneumonia/Pneumoniaplus Control

Part Number: M340
Kit Contains: 12 tubes x 120µL
 6 Positive controls and 6 Negative controls

EXPECTED VALUES:

Table 1 lists the expected results when the controls are analyzed by FilmArray Pneumonia Panel or FilmArray Pneumonia Panel *plus*. Note that the reported Bins (copies/ mL) are approximate and may vary run to run.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for FilmArray Pneumonia/Pneumoniaplus Control in demonstrating adequate system performance.

Table 1: FilmArray Pneumonia/Pneumoniaplus POSITIVE M342 & NEGATIVE M341 Result Summary

Result Summary			
	M34235		M34135
Bacteria		Bin † (copies/mL)	
<i>Acinetobacter calcoaceticus-baumannii</i> complex	✓ Detected	10 ⁵	Not Detected
<i>Enterobacter cloacae</i> complex	✓ Detected	10 ⁶	Not Detected
<i>Escherichia coli</i>	✓ Detected	10 ⁵	Not Detected
<i>Haemophilus influenzae</i>	✓ Detected	10 ⁵	Not Detected
<i>Klebsiella aerogenes</i>	✓ Detected	10 ⁵	Not Detected
<i>Klebsiella oxytoca</i>	✓ Detected	10 ⁵	Not Detected
<i>Klebsiella pneumoniae</i> group	✓ Detected	10 ⁵	Not Detected
<i>Moraxella catarrhalis</i>	✓ Detected	10 ⁵	Not Detected
<i>Proteus</i> spp.	✓ Detected	10 ⁵	Not Detected
<i>Pseudomonas aeruginosa</i>	✓ Detected	10 ⁵	Not Detected
<i>Serratia marcescens</i>	✓ Detected	10 ⁶	Not Detected
<i>Staphylococcus aureus</i>	✓ Detected	10 ⁶	Not Detected
<i>Streptococcus agalactiae</i>	✓ Detected	10 ⁶	Not Detected
<i>Streptococcus pneumoniae</i>	✓ Detected	10 ⁵	Not Detected
<i>Streptococcus pyogenes</i>	✓ Detected	10 ⁶	Not Detected
Antimicrobial Resistance Genes			
CTX-M	✓ Detected		⊖ N/A
IMP	✓ Detected		⊖ N/A
KPC	✓ Detected		⊖ N/A
<i>mecA/C</i> and MREJ	✓ Detected		⊖ N/A
NDM	✓ Detected		⊖ N/A
OXA-48-like	✓ Detected		⊖ N/A
VIM	✓ Detected		⊖ N/A
Atypical Bacteria			
<i>Chlamydia pneumoniae</i>	✓ Detected		Not Detected
<i>Legionella pneumophila</i>	✓ Detected		Not Detected
<i>Mycoplasma pneumoniae</i>	✓ Detected		Not Detected
Viruses			
Adenovirus	✓ Detected		Not Detected
Coronavirus	✓ Detected		Not Detected
Human Metapneumovirus	✓ Detected		Not Detected
Human Rhinovirus/Enterovirus	✓ Detected		Not Detected
Influenza A	✓ Detected		Not Detected
Influenza B	✓ Detected		Not Detected
Middle East Respiratory Syndrome Coronavirus (MERS-CoV) ‡	✓ Detected		Not Detected
Parainfluenza Virus	✓ Detected		Not Detected
Respiratory Syncytial Virus	✓ Detected		Not Detected

† Bins (copies/ mL) are approximate and may vary run to run.

‡ Middle East Respiratory Syndrome Coronavirus is reported on FilmArray Pneumonia Panel *plus* assay only.

REPRESENTATIVE PERFORMANCE DATA:

Three lots of FilmArray Pneumonia/Pneumoniaplus POSITIVE and three lots of FilmArray Pneumonia/Pneumoniaplus NEGATIVE were tested using the FilmArray Pneumonia/Pneumoniaplus Panel assay on FilmArray® systems at 3 external clinical laboratory sites, incorporating 3 unique pouch lots and multiple operators. A total of 185 external controls were tested over 10 days at each site. Two Negative Controls gave initial false positive results and three Positive controls gave initial false negative results. All produced the correct results upon a single retest for an overall correct result rate of 97.3%.

Summary of External Results for 3 Control Lots of FilmArray Pneumonia/Pneumoniaplus Control								
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	61	0	30	0	100%	30	1	96.8%
2	63	0	30	2	93.8%	30	1	96.8%
3	61	0	30	1	96.8%	30	0	100%
All Sites	185	0	90	3	96.8%	90	2	97.8%