510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K190222

B. Purpose for Submission:

To obtain a substantial equivalence determination for the FilmArray Pneumonia/Pneumonia*plus* Control, P/N M340

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

FilmArray Pneumonia/Pneumonia*plus* Control is intended for *in vitro* diagnostic use as external assayed quality control materials to monitor the qualitative amplification, detection and identification steps of the laboratory nucleic acid test, FilmArray Pneumonia Panel/Pneumonia *plus* Panel on the FilmArray systems, which detects respiratory pathogens: *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.

E. Applicant:

Maine Molecular Quality Controls, Inc. (MMQCI)

F. Proprietary and Established Names:

FilmArray Pneumonia/Pneumonia*plus* Control, P/N M340

FilmArray Pneumonia/Pneumonia*plus* Control

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3920, Assayed quality control material for clinical microbiology assays

2. Classification:

   Class II (Special Controls)

3. Product code:

   PMN

4. Panel:

   83- Microbiology

H. Indication(s) for use:

1. Indications for use(s):

   FilmArray Pneumonia/Pneumonia*plus* Control is intended for use as an external positive and negative assayed quality control to monitor 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, *mec*A/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* assays performed on FilmArray systems. FilmArray Pneumonia/Pneumonia*plus* Control is composed of synthetic DNA and RNA 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.

2. Special conditions for use statement(s):

   For *in vitro* diagnostic use only

   For prescription use only

3. Special instrument requirements:

   FilmArray Pneumonia/Pneumonia*plus* Control Panel was evaluated on the FilmArray 2.0 instrument.

I. Device Description:

FilmArray Pneumonia/Pneumonia*plus* Control, P/N M340, is a quality control panel consisting of 2 controls, FilmArray Pneumonia/Pneumonia*plus* Positive (Positive Control), P/N M34235, and FilmArray Pneumonia/Pneumonia*plus* Negative, (Negative Control), P/N M34135. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA and RNA in buffers, stabilizers and preservatives. The DNA and RNA in the Positive Control carries nucleic acid corresponding to the genome segments of all the respiratory pathogens and antimicrobial resistance genes detected and identified by the FilmArray Pneumonia Panel and Pneumonia Panel *plus* assays (see Table 1 below) on the FilmArray systems. The Negative Control contains only buffers, stabilizers and preservatives. Each liquid control of FilmArray Pneumonia/Pneumonia*plus* Control is processed separately according to FilmArray Pneumonia Panel or Pneumonia Panel *plus* assays manufacturer's Instructions for Use for patient samples (Sputum) obtained from individuals suspected of lower respiratory tract infection. Each tube of control contains sufficient liquid for a single use.

The FilmArray Pneumonia/Pneumonia*plus* Positive Control is prepared nucleic acid concentrations of 5X-10X LoD for each of the organisms detected by the FilmArray Pneumonia/Pneumonia *plus* assay.

Table 1. Respiratory pathogens and antimicrobial resistance genes detected by FilmArray Pneumonia Panel & Pneumonia Panel *plus* assays.

Bacteria	
Acinetobacter calcoaceticus-baumannii complex	*Pseudomonas aeruginosa*
Enterobacter cloacae complex	*Serratia marcescens*
Escherichia coli	*Staphylococcus aureus*
Haemophilus influenzae	*Streptococcus agalactiae*
Klebsiella aerogenes	*Streptococcus pneumoniae*
Klebsiella oxytoca	*Streptococcus pyogenes*
Klebsiella pneumoniae group	*Chlamydia pneumoniae*
Moraxella catarrhalis	*Legionella pneumophila*
Proteus spp.	*Mycoplasma pneumoniae*
Antimicrobial Resistance Genes	
CTX-M	NDM
IMP	OXA-48 like
KPC	VIM
mecA/C and MREJ	
Viruses	
Adenovirus	Influenza B

Coronavirus	Middle East Respiratory Syndrome Coronavirus*
Human Metapneumovirus	Parainfluenza Virus
Human Rhinovirus/Enterovirus	Respiratory Syncytial Virus
Influenza A	

*Detected by FilmArray Pneumonia Panel *plus* assay only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FilmArray RP EZ Control Panel M265, Maine Molecular Quality Controls, Inc.

2. Predicate 510(k) number(s):

   K161573

3. Comparison with predicate:

Similarities		
Item	**Device: FilmArray Pneumonia/Pneumonia*plus* Control (K173171)**	**Predicate: FilmArray RP EZ Control Panel M265 (K161573)**
Intended Use	FilmArray Pneumonia/Pneumonia*plus* Control is intended for use as an external positive and negative assayed quality control to monitor 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, *mec*A/C and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory	FilmArray RP EZ Control Panel M265 is intended for use as external positive and negative, surrogate assayed quality control materials 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, Chlamydophila pneumoniae,* and *Mycoplasma pneumonia* on the FilmArray RP EZ assay performed on the FilmArray systems. The control panel also contains a negative control. This product is not intended to replace manufacturer controls provided with the device.

Similarities		
	Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus on the FilmArray Pneumonia Panel or Pneumonia Panel *plus* assays performed on FilmArray systems. FilmArray Pneumonia/Pneumonia*plus* Control is composed of synthetic DNA and RNA 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.	
Physical Format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Assay Steps Monitored	Reverse transcription, amplification, detection, identification	Same
Number of Targets	Multiple	Same

Differences		
Item	**Device: FilmArray Pneumonia/Pneumonia*plus* Control (K173171)**	**Predicate: FilmArray RP EZ Control Panel M265 (K161573)**
Targets	*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, *mec*A/C and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory	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, Chlamydophila pneumoniae*, and *Mycoplasma pneumonia*

Differences		
	Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus	
Composition	Synthetic RNA & DNA transcripts	Synthetic RNA transcripts

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Reproducibility:

A multi-site reproducibility study was performed with the FilmArray Pneumonia/Pneumonia*plus* Control on FilmArray instrument 2.0 and FilmArray Torch systems. Testing consisted of three positive and three negative controls run per day and spanned a period of 10 days. Multiple operators participated in testing at each of the three locations. Three lots each of external control material and three lots of FilmArray Pneumonia/Pneumonia*plus* pouch lots were tested across all sites. A total of 185 external controls were tested (93 positive and 92 negative). The results are shown in the Tables 2 below:

Table 2: FilmArray Pneumonia/Pneumonia*plus* Control Reproducibility Study Summary

Category	SITE						All Sites	All Sites
	Site #1		Site #2		Site #3			
	#expected results/# tested[1]	% Agreement with Expected Result [1]	#expected results/# tested	% Agreement with Expected Result [1]	#expected results/# tested	% Agreement with Expected Result [1]	Overall Percent Agreement	95% Confidence Interval
FilmArray Positive Control	30/30	100%	30/32	93.8%	30/31	96.8%	96.8% 90/93	90.9% to 98.9%
FilmArray Negative Control	30/31	96.8%	30/31	96.8%	30/30	100%	97.8% 90/92	92.4% to 99.4%

[1] Expected result for the FilmArray Pneumonia/Pneumonia*plus* Positive Control is positive. Expected result for the FilmArray Pneumonia/Pneumonia*plus* Negative Control is negative

Table 3: Reproducibility External Crossing Point (Cp) Summary

Analyte	Site 1		Site 2		Site 3		*All External Sites*		
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	%CV
Acinetobacter	15.3	0.6	16.0	0.8	16.0	1.0	15.6	0.9	5.6%
Adenovirus 2	11.6	0.9	12.2	0.9	12.3	1.5	11.9	1.2	9.8%
Adenovirus 3	10.7	0.8	11.3	0.8	11.4	1.4	11.0	1.0	9.4%
Adenovirus 7	11.8	0.7	12.1	1.1	11.9	1.0	11.8	1.0	8.1%
C. pneumoniae	12.4	0.6	12.2	0.6	12.6	0.7	12.3	0.6	5.3%
Coronavirus	16.7	1.1	16.6	0.8	17.1	0.9	16.6	0.9	5.6%
CTX-M	12.9	0.9	13.6	0.8	13.7	1.4	13.3	1.1	8.4%
E. coli	12.3	0.6	12.7	0.9	12.8	1.2	12.6	0.9	7.5%
Enterobacter 1	13.4	0.8	14.0	1.0	14.1	1.4	13.7	1.1	8.2%
Enterobacter 2	13.0	0.8	13.6	1.0	13.6	1.2	13.3	1.0	7.8%
H. influenzae	13.8	0.9	14.2	1.3	14.1	1.2	13.9	1.2	8.7%
K. oxytoca	13.0	0.7	13.7	1.0	13.8	1.4	13.4	1.1	8.1%
K. pneumoniae	15.2	0.8	15.8	0.9	15.9	1.3	15.5	1.0	6.7%
M. catarrhalis	13.1	0.7	13.6	1.0	13.5	1.1	13.3	1.0	7.3%
P. aeruginosa	14.8	0.8	15.5	0.9	15.6	1.5	15.1	1.2	7.7%
Proteus	14.2	0.7	14.8	0.9	14.8	0.9	14.4	0.9	6.2%
S. marcescens	15.0	0.6	15.4	0.9	15.4	1.0	15.1	0.9	5.8%
hMPV	16.0	0.8	15.7	0.8	16.3	1.1	15.8	0.9	5.9%
HRV/EV	14.2	0.7	14.0	0.8	14.6	0.9	14.1	0.8	5.7%
IMP	10.7	0.7	11.1	1.0	11.0	1.0	10.8	0.9	8.5%
Flu A	15.4	1.4	15.3	1.3	15.9	1.3	15.4	1.3	8.7%
Flu B	14.2	0.7	14.0	0.7	14.5	0.7	14.1	0.7	5.0%
KPC	16.6	0.8	16.6	0.8	17.3	1.2	16.7	1.0	5.9%

Analyte	Site 1		Site 2		Site 3		*All External Sites*		
	Ave Cp	**SD**	**Ave Cp**	**SD**	**Ave Cp**	**SD**	**Ave Cp**	**SD**	**%CV**
L. pneumophila	13.8	0.8	13.7	0.7	14.4	0.9	13.8	0.8	6.0%
*mec*A/C	14.5	0.9	15.1	1.2	15.0	1.1	14.7	1.1	7.5%
MREJ	14.2	0.8	14.7	1.3	14.5	1.2	14.3	1.1	7.8%
*S. aureus*1	13.5	0.7	14.0	1.0	13.8	1.1	13.6	1.0	7.1%
S. aureus 2	14.3	0.7	14.8	1.0	14.7	1.0	14.5	0.9	6.5%
MERS 1	15.7	1.1	15.6	0.8	16.3	1.1	15.7	1.0	6.7%
MERS 2	14.5	1.3	14.4	1.0	15.0	1.2	14.5	1.2	8.1%
M. pneumoniae	13.6	0.6	13.4	0.6	13.8	0.8	13.5	0.7	4.9%
NDM	12.3	1.0	13.1	1.0	13.3	1.3	12.8	1.1	8.9%
OXAa	13.8	0.7	13.5	0.7	14.1	0.8	13.6	0.7	5.4%
PIV	13.7	0.6	13.5	0.7	14.0	0.6	13.6	0.7	4.9%
S. agalactiae	12.6	0.7	13.1	1.0	13.0	1.0	12.8	0.9	7.3%
S. pneumoniae	12.6	0.7	13.0	0.9	13.0	0.9	12.7	0.9	6.9%
S. pyogenes	13.0	0.6	13.3	0.9	13.3	0.9	13.0	0.9	6.6%
VIM	13.0	0.7	13.6	0.9	13.6	1.2	13.3	1.0	7.3%
RSV	12.0	0.5	11.8	0.6	12.2	0.7	11.9	0.6	5.3%

The results suggest that there are no significant differences between different users and different sites on different days. External reproducibility studies for the FilmArray Pneumonia/Pneumonia*plus* Control are acceptable.

b. Precision:

An internal precision study for the FilmArray Pneumonia/Pneumonia*plus* Control was conducted over sixty days by testing three FilmArray Pneumonia/Pneumonia*plus* Control Panel lots with three FilmArray Pneumonia/Pneumonia*plus* assay lots performed by three operators using two FilmArray 2.0 instruments. All Positive Controls gave correct results except for 3 which gave false negative results. Repeat tests gave correct results on the first retest. All Negative Controls gave correct results. The results are shown in the Table 4 below:

Table 4: FilmArray Pneumonia/Pneumonia*plus* Control Precision Summary

Category	#expected results/ #tested[1]	Overall Percent Agreement	95% Confidence Interval
FilmArray Pneumonia/Pneumonia*plus* Negative Control	60/60	100%	94% to 100%
FilmArray Pneumonia/Pneumonia*plus* Positive Control	60/63*	95%	86.9% to 98.4%

[1]Expected result for the FilmArray Pneumonia/Pneumonia*plus* Positive Control is positive. Expected result for the FilmArray Pneumonia/Pneumonia*plus* Negative Control is negative.
* Three Positive controls gave initial false negative results, all produced the correct results upon a single retest

Table 5: Precision Internal Crossing Point (Cp) Summary

Analyte	D04MAY18A		A29MAY18A		C12JUN18A		All Lots		
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	%CV
Acinetobacter	16.2	1.1	16.2	1.4	15.7	1.2	16.0	1.2	7.6%
Adenovirus 2	13.3	1.9	13.4	2.4	12.5	1.4	13.1	2.0	15.2%
Adenovirus 3	11.9	2.0	11.8	2.2	10.6	0.9	11.4	1.9	16.4%
Adenovirus 7	12.2	1.3	12.2	1.6	11.7	1.4	12.0	1.5	12.2%
C. pneumoniae	12.7	0.6	12.9	0.7	12.8	0.4	12.8	0.6	4.6%
Coronavirus	17.0	0.7	17.3	0.8	17.2	0.7	17.2	0.7	4.3%
CTX-M	14.6	2.0	14.8	2.4	13.9	1.1	14.4	1.9	13.3%
E. coli	13.2	1.7	13.2	1.9	12.3	0.9	12.9	1.6	12.2%
Enterobacter 1	14.5	1.9	14.6	2.2	13.4	1.2	14.2	1.9	13.2%
Enterobacter 2	13.9	1.7	14.0	2.1	13.2	1.2	13.7	1.7	12.6%
H. influenzae	14.3	1.5	14.2	1.8	13.9	1.4	14.1	1.6	11.3%
K. oxytoca	14.1	2.0	14.2	2.4	12.9	1.1	13.7	2.0	14.6%
K. pneumoniae	16.1	1.6	16.2	1.9	15.0	0.9	15.7	1.6	10.3%
M. catarrhalis	13.6	1.3	13.6	1.5	12.9	1.2	13.4	1.4	10.3%
P. aeruginosa	16.2	2.2	16.2	2.5	15.1	0.9	15.8	2.0	12.7%
Proteus	15.2	1.1	15.2	1.3	14.6	0.8	15.0	1.1	7.3%
S. marcescens	15.6	1.2	15.5	1.5	14.8	1.0	15.3	1.3	8.4%
hMPV	17.2	0.9	17.5	1.1	17.6	2.1	17.4	1.5	8.4%
HRV/EV	14.8	1.3	15.1	1.4	14.6	0.5	14.8	1.2	7.9%
IMP	11.5	1.3	11.4	1.6	11.1	1.5	11.4	1.5	12.8%
Flu A	16.4	1.5	16.7	1.6	16.0	0.8	16.4	1.4	8.3%
Flu B	14.7	0.7	15.0	0.7	14.7	0.4	14.8	0.6	4.2%
KPC	17.5	1.3	17.8	1.5	16.9	0.8	17.4	1.3	7.4%
L. pneumophila	14.4	1.0	14.7	1.0	14.2	0.5	14.4	0.9	6.1%
*mec*A/C	15.2	1.2	15.1	1.5	14.8	1.2	15.0	1.3	8.5%
MREJ	14.8	1.2	14.6	1.5	14.7	1.8	14.7	1.5	10.3%
S. aureus 1	14.0	1.1	14.0	1.4	13.7	1.1	13.9	1.2	8.5%

Analyte	D04MAY18A		A29MAY18A		C12JUN18A		All Lots		
S. aureus 2	15.0	1.1	14.9	1.3	14.5	1.0	14.8	1.2	7.8%
MERS1	16.6	1.2	16.9	0.9	16.5	0.5	16.7	0.9	5.6%
MERS2	15.3	1.3	15.6	1.2	15.2	0.8	15.4	1.1	7.1%
M. pneumoniae	14.0	0.6	14.2	0.7	14.2	0.6	14.1	0.6	4.4%
NDM	13.2	1.8	13.2	2.2	12.0	1.0	12.8	1.8	14.1%
OXAa	14.2	0.9	14.5	0.9	14.0	0.6	14.3	0.8	5.8%
PIV	13.9	0.6	14.2	0.7	14.0	0.8	14.0	0.7	4.9%
S. agalactiae	13.1	1.2	13.1	1.3	12.9	1.1	13.0	1.2	9.0%
S. pneumoniae	13.2	1.3	13.2	1.5	12.5	1.0	13.0	1.3	9.8%
S. pyogenes	13.6	1.0	13.6	1.3	13.3	0.9	13.5	1.1	7.9%
VIM	13.9	1.4	13.8	1.7	13.0	0.9	13.5	1.4	10.2%
RSV	12.0	0.6	12.3	0.6	12.1	0.7	12.1	0.6	5.2%

There appears to be no significant differences in mean Cp value when testing different control lots on different days. Precision studies are acceptable.

c. Within-run Testing:

Within-run precision was demonstrated in a separate study conducted by one operator testing one lot of FilmArray Pneumonia/Pneumonia*plus* Control with one lot of FilmArray Pneumonia/Pneumonia *plus* pouches on the FilmArray 2.0, each within one day. The results are shown in the tables below:

Table 6: FilmArray Pneumonia/Pneumonia*plus* Control Panel Summary of Within-run Precision

Control	#expected results/ #tested[1]	Overall Percent Agreement	95% Confidence Interval
FilmArray Pneumonia / Pneumonia*plus* Positive Control	6/6	100%	61%-100%
FilmArray Pneumonia / Pneumonia*plus* Negative Control	6/6	100%	61%-100%

[1]Expected result for the FilmArray Pneumonia/Pneumonia*plus* Positive Control is positive. Expected result for the FilmArray Pneumonia/Pneumonia*plus* Negative Control is negative.

Table 7: Within-run Precision Internal Crossing Point (Cp) Summary

Analyte	Mean Cp	Standard Deviation
Acinetobacter	15.7	0.8
Adenovirus 2	12.8	1.9
Adenovirus 3	11.5	1.5
Adenovirus 7	11.4	0.5
C. pneumoniae	12.9	0.2
Coronavirus	17.8	0.5
CTX-M	14.1	1.6
E. coli	12.5	1.1
Enterobacter 1	13.7	1.2
Enterobacter 2	13.1	1.0
H. influenzae	13.0	0.3
K. oxytoca	13.2	1.2
K. pneumoniae	15.9	1.0
M. catarrhalis	13.1	0.5
P. aeruginosa	15.6	1.7
Proteus	14.5	0.6
S. marcescens	15.1	0.6
hMPV	17.0	0.7
HRV/EV	14.6	0.8
IMP	10.7	0.7
Flu A	16.9	0.8
Flu B	15.1	0.3
KPC	17.8	0.6
L. pneumophila	14.7	0.7
*mec*A/C	14.2	0.4
MREJ	13.7	0.3
S. aureus 1	13.4	0.4
S. aureus 2	14.2	0.4
MERS1	17.1	0.8
MERS2	16.1	0.7
M. pneumoniae	14.1	0.3
NDM	12.9	1.5
OXAa	14.7	0.5
PIV	14.1	0.3
S. agalactiae	12.3	0.3
S. pneumoniae	12.3	0.6
S. pyogenes	12.9	0.4
VIM	13.3	0.6
RSV	12.0	0.1

Within-run reproducibility studies for the FilmArray Pneumonia/Pneumonia*plus* Control are acceptable.

d. Lot-to-Lot Testing:

Lot-to-lot reproducibility was demonstrated by testing three lots of FilmArray Pneumonia/Pneumonia*plus* Positive Control using the same pouch lot. Results are shown in the following tables.

Table 8: FilmArray Pneumonia/Pneumonia*plus* Control Panel Summary of Lot-to-Lot Reproducibility

Control Lot #	Number of Tests	Pouch Lot	Correct Results
D04MAY18A	7	697017	7/7
A29MAY18A	8	697017	7/8*
C12JUN18A	7	697017	7/7

*1 false negative result for hMPV

Table 9: Lot to Lot Internal Crossing Point (Cp) Summary

Analyte	D04MAY18A	A29MAY18A	C12JUN18A	All lots	All Lots
	Mean Cp	Mean Cp	Mean Cp	Mean Cp	SD
Acinetobacter	15.5	15.1	15.0	15.2	0.5
Adenovirus 2	12.3	11.8	11.9	12.0	0.9
Adenovirus 3	10.7	10.4	10.2	10.5	0.7
Adenovirus 7	11.2	10.7	10.9	10.9	0.4
C. pneumoniae	12.4	12.6	12.6	12.5	0.4
Coronavirus	17.4	17.7	17.5	17.5	0.4
CTX-M	13.4	13.1	13.4	13.3	0.7
E. coli	11.9	11.7	11.6	11.7	0.5
Enterobacter 1	13.1	12.8	12.9	12.9	0.5
Enterobacter 2	12.5	12.3	12.3	12.4	0.5
H. influenzae	12.8	12.4	12.7	12.7	0.3
K. oxytoca	12.6	12.3	12.2	12.4	0.6
K. pneumoniae	15.4	15.2	14.8	15.1	0.5
M. catarrhalis	12.7	12.4	12.4	12.5	0.4
P. aeruginosa	15.0	14.5	14.7	14.7	0.7
Proteus	14.3	14.0	14.0	14.1	0.4
S. marcescens	15.0	14.3	14.8	14.7	0.4
hMPV	17.0	16.9	17.2	17.1	0.7
HRV/EV	14.0	14.3	14.3	14.2	0.5
IMP	*10.5*	*10.0*	*10.2*	*10.2*	*0.5*
Flu A	16.6	16.9	16.1	16.6	0.7
Flu B	14.5	14.8	14.7	14.7	0.4
KPC	17.2	17.3	17.0	17.2	0.5
L. pneumophila	14.2	14.5	14.2	14.3	0.6
*mec*A/C	14.0	13.7	13.9	13.8	0.3

Analyte	D04MAY18A	A29MAY18A	C12JUN18A	All lots	All Lots
	Mean Cp	Mean Cp	Mean Cp	Mean Cp	SD
MREJ	13.6	13.2	13.7	13.5	0.4
S. aureus 1	13.2	12.8	13.2	13.1	0.4
S. aureus 2	14.2	13.7	14.1	14.0	0.4
MERS1	16.7	16.8	16.5	16.7	0.7
MERS2	15.6	15.9	15.4	15.6	0.7
M. pneumoniae	13.7	13.9	14.1	13.9	0.5
NDM	12.0	11.9	11.4	11.8	0.6
OXAa	14.2	14.3	14.3	14.3	0.5
PIV	13.6	13.9	13.9	13.8	0.4
S. agalactiae	12.2	11.9	12.1	12.1	0.3
S. pneumoniae	12.0	11.8	11.8	11.9	0.4
S. pyogenes	12.7	12.4	12.7	12.6	0.4
VIM	12.8	12.5	12.5	12.6	0.3
RSV	11.6	12.0	11.8	11.8	0.4

Lot-to-Lot reproducibility studies for the FilmArray Pneumonia/Pneumonia*plus* Control Panel are acceptable.

e. Linearity/assay reportable range:

Not applicable

f. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

Not applicable

Stability:

Open Vial Stability: Not applicable because FilmArray Pneumonia/Pneumonia*plus* Control is packaged for single use.

Closed Vial Real-time Stability: An accelerated stability study was performed to establish the shelf life stability claims for FilmArray Pneumonia/Pneumonia*plus* Control. Based on this study, the FilmArray Pneumonia/Pneumonia*plus* Control is expected to be stable until the expiration date (24 months) when stored frozen (–20°C or colder) and unopened. This product is for single use.

Real-Time Stability Program: Real-time stability studies are ongoing to support product claims and to monitor potential assay modifications for which the FilmArray

Pneumonia/Pneumonia*plus* Control is indicated for use. Real-time stability study protocols and acceptance criteria were reviewed and found to be acceptable.

Shipping Stability: MMQCI ships the FilmArray Pneumonia/Pneumonia*plus* Control on dry ice with overnight delivery, ensuring that the control material remains frozen upon receipt. The frozen control material is then to be stored at -20ºC, as indicated in the FilmArray Pneumonia/Pneumonia*plus* Control package insert. A shipping study was performed to confirm the shipping process and to investigate the outcome of a possible shipping delay and subsequent arrival with no dry ice. The study evaluated two lots of the FilmArray Pneumonia/Pneumonia*plus* Positive control that was placed in dry ice that was stored for two days at ambient temperature of approximately 19-21°C and then tested using the FilmArray Pneumonia/Pneumonia *plus* assay. To simulate a shipping delay, additional samples of the two lots of the Positive Control that had been stored in dry ice, were removed from the dry ice and placed at ambient temperature for six days. The 'delayed' samples were tested at two and six days of ambient temperature with the FilmArray Pneumonia/Pneumonia *plus* assay.

The study demonstrated that the FilmArray Pneumonia/Pneumonia*plus* Positive Control is stable for two days on dry ice in MMQCI's standard shipping box. FilmArray Pneumonia/Pneumonia*plus* Positive Control is stable after six days at ambient temperatures of approximately 19-21°C. The FilmArray Pneumonia/Pneumonia*plus* Positive Control should be stored frozen (–20°C or colder) as indicated in the package insert.

Expected Values:

FilmArray Pneumonia/Pneumonia*plus* Control is a qualitative control and the expected results are listed in the tables below.

Table 10: FilmArray Pneumonia/Pneumonia*plus* Positive & Negative Result Summary

Result Summary			
	Positive M34235		**Negative M34135**
Bacteria		**Bin † (copies/mL)**	
Acinetobacter calcoaceticus-baumannii complex	Detected	10^5	Not Detected
Enterobacter cloacae complex	Detected	10^6	Not Detected
Escherichia coli	Detected	10^5	Not Detected
Haemophilus influenzae	Detected	10^5	Not Detected
Klebsiella aerogenes	Detected	10^5	Not Detected
Klebsiella oxytoca	Detected	10^5	Not Detected
Klebsiella pneumoniae group	Detected	10^5	Not Detected
Moraxella catarrhalis	Detected	10^5	Not Detected
Proteus spp.	Detected	10^5	Not Detected
Pseudomonas aeruginosa	Detected	10^5	Not Detected

Result Summary			
Serratia marcescens	Detected	10^6	Not Detected
Staphylococcus aureus	Detected	10^6	Not Detected
Streptococcus agalactiae	Detected	10^6	Not Detected
Streptococcus pneumoniae	Detected	10^5	Not Detected
Streptococcus pyogenes	Detected	10^6	Not Detected
Antimicrobial Resistance Genes			
CTX-M	Detected		N/A
IMP	Detected		N/A
KPC	Detected		N/A
mecA/C and MREJ	Detected		N/A
NDM	Detected		N/A
OXA-48-like	Detected		N/A
VIM	Detected		N/A
Atypical Bacteria			
Chlamydia pneumoniae	Detected		Not Detected
Legionella pneumophila	Detected		Not Detected
Mycoplasma pneumoniae	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.

Matrix Effects:

A study was performed to evaluate the effect of the FilmArray Pneumonia/Pneumonia*plus* Control Panel in the presence of sputum matrix. A sputum sample positive for *M. catarrhalis* was spiked into a negative (by culture) sputum patient sample and into a negative MMQCI matrix sample and tested in triplicate by the FilmArray Pneumonia/Pneumonia *plus* assay. No inhibition and/or false negative results were observed with either the spiked clinical patient sample or MMQCI's negative matrix.

Results demonstrated that samples prepared with FilmArray Pneumonia/Pneumonia*plus* Control sputum matrix showed no inhibition and/or false negative results were observed with either the spiked clinical patient sample or MMQCI's negative matrix.

g. Detection limit:

Not applicable

h. Analytical Reactivity (Inclusivity):

Not applicable

i. Cross Reactivity:

Not applicable

j. Interference:

Not applicable

k. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

3. Clinical Studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not Applicable.

N. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.