

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K173171

B. Purpose for Submission:

To obtain a substantial equivalence determination for the FilmArray RP2/RP2*plus* Control Panel, P/N M315

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

FilmArray RP2/RP2*plus* Control Panel 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 RP2/RP2*plus* assay on the FilmArray 2.0 instrument or FilmArray Torch system, which detects respiratory pathogens: 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*.

E. Applicant:

Maine Molecular Quality Controls, Inc. (MMQCI)

F. Proprietary and Established Names:

FilmArray RP2/RP2*plus* Control Panel, P/N M315

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 RP2/RP2*plus* Control Panel 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 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* by BioFire's FilmArray RP2 and RP2*plus* assays on the FilmArray 2.0 or the FilmArray Torch Systems. FilmArray RP2/RP2*plus* Control Panel is composed of synthetic RNA designed for and intended to be used solely with the FilmArray RP2 and RP2*plus* assays. This product is not intended to replace manufacturer internal controls provided with the test system.

2. Special conditions for use statement(s):

For *in vitro* diagnostic use only

For prescription use only

3. Special instrument requirements:

FilmArray RP2/RP2*plus* Control Panel was evaluated on FilmArray 2.0 instrument.

I. Device Description:

FilmArray RP2/RP2*plus* Control Panel is a quality control panel consisting of two controls: FilmArray RP2/RP2*plus* Positive Control and FilmArray RP2/RP2*plus* Negative Control. The Positive Control contains non-infectious surrogate control material; a solution of synthetic RNA transcripts in buffers, stabilizers and preservatives. The RNA carries segments of all respiratory pathogens detected by the FilmArray RP2 and RP2*plus* assays (see Table below) on the FilmArray 2.0 or FilmArray Torch systems. The RNA in the Negative Control is non-specific RNA in buffers, stabilizers and preservatives. Each liquid control of FilmArray RP2/RP2*plus* Control Panel M265 is processed separately according to FilmArray RP2 and RP2*plus* assays manufacturer's Instructions for Use for patient samples

(nasopharyngeal swabs) obtained from individuals suspected of respiratory tract infection and placed in Viral Transport Media (VTM)).

The FilmArray RP2/RP2plus Positive Control is prepared nucleic acid concentrations of 5X-10X LoD for each of the organisms detected by the FilmArray RP2/RP2plus assay.

Respiratory pathogens detected by FilmArray RP2 and RP2plus assay	
Adenovirus	Parainfluenza Virus 1
Coronavirus 229E	Parainfluenza Virus 2
Coronavirus HKU1	Parainfluenza Virus 3
Coronavirus NL63	Parainfluenza Virus 4
Coronavirus OC43	Respiratory Syncytial Virus
Human Metapneumovirus	<i>Bordetella parapertussis (IS001)</i>
Human Rhinovirus/ Enterovirus	<i>Bordetella pertussis (ptxP)</i>
Influenza A, subtypes H1, H1-2009, H3	<i>Chlamydia pneumoniae</i>
Influenza B	<i>Mycoplasma pneumoniae</i>
Middle East Respiratory Syndrome Coronavirus*	

*Detected by FilmArray RP2plus 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:

There are no differences between the intended uses of the predicate (K161573) and the new device which raise new questions of safety and effectiveness.

Similarities		
Item	FilmArray RP2/RP2plus Control Panel M315	FilmArray RP EZ Control Panel M265 (K161573)
Intended Use	<p>FilmArray RP2/RP2<i>plus</i> Control Panel is intended for use as an external positive and negative assayed quality control to monitor performance of <i>in vitro</i> 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, <i>Chlamydia pneumoniae</i>, and <i>Mycoplasma pneumoniae</i> by BioFire's FilmArray RP2 and RP2<i>plus</i> assays on the FilmArray 2.0 or the FilmArray Torch Systems. FilmArray RP2/RP2<i>plus</i> Control Panel is composed of synthetic RNA designed for and intended to be used solely with the FilmArray RP2 and RP2<i>plus</i> assays. This product is not intended to replace manufacturer internal controls provided with the test system.</p>	<p>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 <i>in vitro</i> 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, <i>Bordetella pertussis</i>, <i>Chlamydia pneumoniae</i>, and <i>Mycoplasma pneumoniae</i> 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.</p>
Format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample Same	Same
Composition	Synthetic RNA transcripts	Same
Assay Steps Monitored	Reverse transcription, amplification, detection, identification	Same
Number of Targets	Multiple	Same

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 RP2/RP2*plus* Control Panel on FilmArray instrument 2.0. Testing consisted of three positive and three negative controls run per day, and spanned a period of 10 days (total of 60 control runs per site). Multiple operators participated in testing at each of the three locations. Three lots each of external control material and three lots of FilmArray RP2 pouches were tested across all sites. A total of 180 external controls were tested (90 positive and 90 negative). The results are shown in the tables below:

FilmArray RP2/RP2<i>plus</i> Control Panel Summary of External Reproducibility Test Results								
Category	SITE						All Sites	All Sites
	Site #1		Site #2		Site #3		Overall Percent Agreement	95% Confidence Interval
	#expected results/# tested¹	% Agreement with Expected Result ¹	#expected results/# tested	% Agreement with Expected Result ¹	#expected results/# tested	% Agreement with Expected Result ¹		
FilmArray RP2/RP2 <i>plus</i> Positive Control	30/30	100%	30/30	100%	30/30	100%	100% 90/90	95.9% to 100%
FilmArray RP2/RP2 <i>plus</i> Negative Control	30/30	100%	30/30	100%	30/30	100%	100% 90/90	95.9% to 100%

¹ Expected result for the FilmArray RP2/RP2*plus* Positive Control is positive. Expected result for the FilmArray RP2/RP2*plus* Negative Control is negative

Crossing Point (Cp) Data for FilmArray RP2/RP2plus Panel External Reproducibility Study

Respiratory Pathogen Analyte	Site 1		Site 2		Site 3		All External Sites	
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD
Adeno2	19.9	2.0	18.8	2.0	19.5	1.6	19.4	1.9
Adeno3	17.5	1.5	17.5	1.9	18.4	1.3	17.8	1.6
Adeno6	15.4	1.7	15.2	1.6	16.0	1.4	15.6	1.6
Adeno7.1	16.1	1.9	15.9	1.4	16.0	1.9	16.0	1.7
Adeno8	13.8	1.4	13.9	1.2	14.0	1.2	13.9	1.3
IS1001	18.1	1.2	18.2	1.4	18.6	0.9	18.3	1.2
ptxP	14.6	1.4	14.6	1.4	15.2	1.2	14.8	1.4
Cpne	15.6	0.9	15.7	1.1	15.5	0.7	15.6	0.9
CoV-229E	16.1	1.2	16.2	1.1	16.1	0.9	16.1	1.0
CoV-HKU1	17.6	1.3	17.6	1.2	17.8	1.0	17.6	1.2
CoV-NL63	17.3	2.2	17.2	1.3	17.1	1.4	17.2	1.7
CoV-OC43-2	19.6	2.6	19.1	1.5	19.1	1.9	19.2	2.0
CoV-OC43	16.3	0.9	16.5	1.0	16.5	0.9	16.4	1.0
hMPV	17.7	2.5	16.7	1.6	16.8	2.1	17.1	2.1
HRV/EV	16.4	0.8	16.4	1.1	16.6	0.8	16.5	0.9
FluA-H1-2	19.3	1.8	19.1	1.1	19.2	1.7	19.2	1.5
FluA-H1-2009	19.0	1.2	18.8	1.3	19.2	1.5	19.0	1.4
FluA-H3	16.0	0.7	16.0	1.4	16.1	0.6	16.0	1.0
FluA-pan1	15.3	0.8	15.5	1.1	15.4	0.6	15.4	0.9
FluA-pan2	16.8	1.9	16.5	1.2	16.3	1.4	16.5	1.5
FluB	15.8	1.1	15.9	1.1	15.7	0.7	15.8	1.0
MERS1	19.2	2.2	18.9	1.4	19.3	1.8	19.1	1.8
MERS2	17.2	1.4	17.3	1.4	17.6	1.0	17.4	1.3
Mpne	16.5	1.6	16.5	1.2	16.5	1.3	16.5	1.4
PIV1	16.4	2.6	15.7	1.6	15.8	1.6	16.0	2.0
PIV2	19.2	1.8	19.0	1.3	19.1	1.7	19.1	1.6
PIV3	17.6	1.3	17.5	1.1	17.4	1.1	17.5	1.2
PIV4	19.1	1.6	18.7	1.3	18.8	1.3	18.9	1.4
RSV	15.4	1.2	15.4	1.0	15.3	0.8	15.4	1.0

The results suggest that there are no significant differences between different users and different sites on different days. External reproducibility studies for the FilmArray RP2/RP2plus Panel are acceptable.

b. Precision:

An internal precision study for the FilmArray RP2/RP2*plus* was conducted over twenty days by testing three FilmArray RP2/RP2*plus* Control Panel lots with four FilmArray RP2/RP2*plus* assay lots performed by four operators using two FilmArray 2.0 instruments. The results are shown in the table below:

FilmArray RP2/RP2<i>plus</i> Control Panel Summary of Internal Precision Test Results			
Category	#expected results/ #tested¹	Overall Percent Agreement	95% Confidence Interval
FilmArray RP2/RP2 <i>plus</i> Positive Control	60/60	100%	94% to 100%
FilmArray RP2/RP2 <i>plus</i> Negative Control	60/61	98.4%	91.3% to 99.7%

¹Expected result for the FilmArray RP2/RP2*plus* Positive Control is positive. Expected result for the FilmArray RP2/RP2*plus* Negative Control is negative.

Crossing Point (Cp) data for FilmArray RP2/RP2plus Control Panel Internal Precision Study									
Respiratory Pathogen Analyte	C11MAY17		G12JUN17		B21JUN17		All Lots	All Lots	All Lots
	Mean Cp	SD	Mean Cp	SD	Mean Cp	SD	<i>Mean Cp</i>	<i>SD</i>	<i>%CV</i>
Adeno2	19.0	1.4	19.2	1.2	18.9	1.4	18.9	1.3	7.0%
Adeno3	17.1	1.5	17.6	1.5	17.6	1.3	17.5	1.5	8.4%
Adeno6	15.1	1.3	15.4	1.4	15.5	1.2	15.4	1.4	8.8%
Adeno7.1	15.5	1.3	15.5	1.3	16.0	1.1	15.7	1.3	8.3%
Adeno8	13.5	0.8	13.7	1.1	14.1	0.8	13.8	0.9	6.7%
IS1001	18.1	1.0	18.3	1.0	18.2	1.0	18.2	1.0	5.5%
ptxP	14.5	1.1	15.0	1.1	15.0	1.0	14.9	1.1	7.5%
Cpne	15.3	0.5	15.4	0.6	15.2	0.5	15.3	0.5	3.4%
CoV-229E	16.3	0.8	16.7	1.0	16.5	0.7	16.6	0.8	5.1%
CoV-HKU1	17.5	0.6	17.5	0.8	17.7	0.6	17.6	0.7	3.9%
CoV-NL63	17.0	0.9	17.1	1.0	17.2	0.8	17.1	0.9	5.1%
CoV-OC43-2	20.3	1.5	20.5	1.4	20.9	1.2	20.8	1.2	6.0%
CoV-OC43	16.1	1.0	16.4	1.3	16.4	1.0	16.3	1.1	6.9%
hMPV	17.4	1.3	17.5	1.4	17.9	1.0	17.7	1.3	7.2%
HRV/EV	16.5	0.7	16.7	1.1	16.7	0.8	16.7	0.9	5.3%
FluA-H1-2	19.3	1.1	19.5	1.2	19.9	0.8	19.7	1.1	5.5%
FluA-H1-2009	18.8	0.8	18.7	1.3	18.8	0.8	18.8	1.0	5.3%
FluA-H3	15.7	0.4	15.5	0.7	15.5	0.6	15.5	0.6	3.8%
FluA-pan1	15.2	0.5	15.5	0.7	15.3	0.6	15.4	0.6	3.8%
FluA-pan2	16.5	1.1	16.7	1.0	17.0	0.8	16.8	1.0	5.9%
FluB	15.6	0.5	15.4	0.6	15.6	0.5	15.5	0.5	3.3%
MERS1	19.5	1.1	19.8	1.3	19.8	0.9	19.9	1.1	5.3%
MERS2	17.5	0.9	17.9	1.1	17.6	0.9	17.8	1.0	5.4%
Mpne	16.1	0.9	16.0	1.0	16.0	0.9	16.0	0.9	5.7%
PIV1	15.8	1.4	15.7	1.4	16.0	1.5	15.8	1.4	9.1%
PIV2	18.4	1.2	18.0	1.2	18.3	1.1	18.2	1.2	6.5%
PIV3	17.3	0.7	17.2	0.8	17.3	0.6	17.3	0.7	4.2%
PIV4	18.1	0.7	17.9	0.8	17.9	0.6	17.9	0.7	3.9%
RSV	15.4	0.6	15.3	0.7	15.5	0.5	15.5	0.6	3.9%
Bper	18.8	0.6	19.2	0.3	19.2	0.3	19.2	0.4	7.0%
Cpne	16.0	1.8	15.6	1.9	15.9	1.9	15.7	1.9	8.4%
Mpne	19.0	1.4	19.2	1.2	18.9	1.4	18.9	1.3	8.8%

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 reproducibility was demonstrated in a separate study conducted by one operator testing one lots of FilmArray RP2/RP2plus with one lot of FilmArray RP2 pouches on the FilmArray 2.0, each within one day. The results are shown in the tables below:

FilmArray RP2/RP2plus Control Panel Summary of Within-run Reproducibility Results				
Control	Control Lot#	No. of Tests	Pouch Lot	Correct Results
FilmArray RP2/RP2plus Positive Control	G12JUN17A	6	606817	6/6 (100%)
FilmArray RP2/RP2plus Negative Control	F12JUN17A	6	606817	6/6 (100%)

Crossing Point (Cp) data for FilmArray RP2/RP2plus Control Panel Within-run Reproducibility		
Respiratory Pathogen Analyte	FilmArray RP2/RP2plus Positive (Lot G12JUN17A)	
	Mean Cp	SD
Adeno2	19.4	1.5
Adeno3	16.5	1.2
Adeno6	14.1	1.1
Adeno7.1	14.4	1.2
Adeno8	13.1	0.9
IS1001	17.7	0.9
ptxP	14.2	0.8
Cpne	15.3	0.5
CoV-229E	16.7	0.7
CoV-HKU1	17.3	0.8
CoV-NL63	16.4	0.9
CoV-OC43-2	20.0	1.8
CoV-OC43	16.1	0.5
hMPV	16.6	1.3
HRV/EV	16.4	0.7
FluA-H1-2	18.7	1.1
FluA-H1-2009	18.4	1.2
FluA-H3	15.4	0.6
FluA-pan1	15.5	0.5
FluA-pan2	15.8	0.8
FluB	15.1	0.4
MERS1	19.4	1.4
MERS2	17.8	1.1
Mpne	15.2	0.8
PIV1	14.5	1.2
PIV2	16.9	0.9
PIV3	16.9	0.7
PIV4	17.6	0.9

Within-run reproducibility studies for the FilmArray RP2/RP2*plus* Control Panel are acceptable.

d. Lot-to-Lot Testing:

Lot-to-lot reproducibility was demonstrated by testing three lots of FilmArray RP2/RP2*plus* Positive Control using the same pouch lot. Results are shown in the following tables.

FilmArray RP2/RP2<i>plus</i> Control Panel Summary of Lot-to-Lot Reproducibility Results			
Control Lot #	Number of Tests	Pouch Lot	Correct Results
C11MAY17A	5	455917	5/5 (100%)
G12JUN17A	5	455917	5/5 (100%)
B21JUN17A	5	455917	5/5 (100%)

Crossing Point (Cp) data for FilmArray RP2/RP2<i>plus</i> Control Panel Lot-to-Lot Reproducibility					
Respiratory Pathogen Analyte	C11MAY17A	G12JUN17A	B21JUN17A	All lots	All Lots
	Mean Cp	Mean Cp	Mean Cp	Mean Cp	SD
Adeno2	18.3	18.7	18.7	18.6	0.2
Adeno3	18.0	17.8	18.0	17.9	0.1
Adeno6	16.0	15.7	16.1	16.0	0.2
Adeno7.1	16.4	16.2	17.0	16.5	0.4
Adeno8	13.7	13.7	14.2	13.8	0.3
IS1001	18.4	18.2	18.2	18.3	0.1
ptxP	14.9	14.9	15.0	14.9	0.1
Cpne	15.3	15.2	15.2	15.2	0.0
CoV-229E	16.0	16.2	16.1	16.1	0.1
CoV-HKU1	17.4	17.2	17.5	17.4	0.2
CoV-NL63	17.6	17.4	17.7	17.5	0.1
CoV-OC43-2	21.0	20.7	21.4	21.0	0.3
CoV-OC43	15.5	15.5	15.8	15.6	0.2
hMPV	18.1	17.8	18.6	18.1	0.4
HRV/EV	16.2	16.1	16.2	16.2	0.1
FluA-H1-2	19.8	19.7	20.2	19.9	0.3
FluA-H1-2009	18.3	18.1	18.4	18.3	0.2
FluA-H3	15.4	15.2	15.3	15.3	0.1
FluA-pan1	15.1	15.1	15.1	15.1	0.0
FluA-pan2	17.3	17.1	17.6	17.3	0.2

FluB	15.7	15.5	15.7	15.6	0.1
MERS1	19.8	19.7	20.0	19.8	0.2
MERS2	17.5	17.4	17.5	17.5	0.1
Mpne	16.8	16.7	16.9	16.8	0.1
PIV1	17.1	16.9	17.8	17.3	0.4
PIV2	19.4	19.0	19.5	19.3	0.3
PIV3	17.2	17.0	17.3	17.2	0.2
PIV4	17.9	17.9	18.0	17.9	0.1
RSV	15.5	15.2	15.6	15.4	0.2

Lot-to-Lot reproducibility studies for the FilmArray RP2/RP2plus 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 RP2/RP2plus Control Panel 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 RP2/RP2plus Control Panel. Based on this study, the FilmArray RP2/RP2plus Control Panel is expected to be stable until the expiration date (12 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 RP2/RP2plus Control Panel 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 RP2/RP2plus Control Panel 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 -20°C, as indicated in the FilmArray RP2/RP2plus Control Panel 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 (2) lots of the FilmArray RP2/RP2*plus* Positive Control placed in dry ice and was stored for two (2) days at ambient temperature then tested using the FilmArray RP2*plus* Assay. To simulate a shipping delay, two (2) lots of the FilmArray RP2/RP2*plus* Positive Control were stored for up to 5 days at ambient temperature and tested using the FilmArray RP2*plus* Assay.

The study demonstrated that the FilmArray RP2/RP2*plus* Positive Control is stable for two (2) days on dry ice in MMQCI's standard shipping box. FilmArray RP2/RP2*plus* Positive Control is stable after five (5) days at ambient temperatures of approximately 19-21°C. The FilmArray RP2/RP2*plus* Positive Control should be stored frozen (-20°C or colder) as indicated in the package insert.

Expected Values:

FilmArray RP2/RP2*plus* Control Panel is a qualitative control and the expected results are listed in the tables below.

FilmArray RP2/RP2<i>plus</i> Positive Control FilmArray 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
Detected	Influenza A H3
Detected	Influenza B
Detected	Middle East Respiratory Syndrome*
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 (IS1001)</i>
Detected	<i>Bordetella pertussis (ptxP)</i>
Detected	<i>Chlamydia pneumoniae</i>
Detected	<i>Mycoplasma pneumoniae</i>

* Middle East Respiratory Syndrome Coronavirus is reported on RP2*plus* only

FilmArray RP2/RP2plus Negative Control FilmArray 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 H1-2009
Not Detected	Influenza A H3
Not Detected	Influenza B
Not Detected	Middle East Respiratory Syndrome*
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 (IS1001)</i>
Not Detected	<i>Bordetella pertussis (ptxP)</i>
Not Detected	<i>Chlamydia pneumoniae</i>
Not Detected	<i>Mycoplasma pneumoniae</i>

* Middle East Respiratory Syndrome Coronavirus is reported on RP2plus only

Matrix Effects:

A study was performed to evaluate the effect of the FilmArray RP2/RP2plus Control Panel in the presence of viral transport media (VTM). Equal volumes of the same concentration of inactivated Influenza A H1N1-2009 were spiked into 370µL of VTM as well as 370µL of FilmArray RP2/RP2plus Negative Control, which contains the identical matrix found in the FilmArray RP2/RP2plus Positive Control. Both sample types of the H1N1-2009 were tested in triplicate by the FilmArray RP2plus assay.

Results demonstrated that samples prepared with FilmArray RP2/RP2plus Control Panel matrix generate equivalent results to samples prepared with VTM. Study results are shown in the table below:

Respiratory Pathogen Analyte	Spiked BEI H1N1-2009 Crossing Point (Cp)							
	VTM			Mean Cp	MMQCI Matrix			Mean Cp
FluA-H1-2009	17.7	19.1	18.3	18.4	16.9	18.7	17.9	17.8
FluA-pan1	12.8	13.5	12.9	13.1	12.0	12.2	12.3	12.2
FluA-pan2	19.1	19.9	19.8	19.6	19.0	19.3	19.7	19.3

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 is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809 and the special controls for this device type.

O. Conclusion:

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