510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K202196

B. Purpose for Submission:

To obtain a substantial equivalence determination for the BioFire RP2.1/RP2.1*plus* Control Panel M441

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

BioFire RP2.1/RP2.1*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, BioFire RP2.1 and RP2.1*plus* assays on the BioFire FilmArray Systems, 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, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*

E. Applicant:

Maine Molecular Quality Controls, Inc. (MMQCI)

F. Proprietary and Established Names:

BioFire RP2.1/RP2.1*plus* Control Panel M441

BioFire RP2.1/RP2.1plus 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):

   BioFire RP2.1/RP2.1*plus* Control Panel M441 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 H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* on the BioFire Respiratory Panel 2.1 (RP2.1), BioFire Respiratory Panel 2.1 *plus* (RP2.1*plus*) and BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) assays performed on BioFire FilmArray systems. BioFire RP2.1/RP2.1plus Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BioFire RP2.1, BioFire RP2.1plus and BioFire RP2.1-EZ 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:

   The BioFire RP2.1/RP2.1*plus* Control Panel was evaluated on the FilmArray 2.0 instrument.

I. Device Description:

BioFire RP2.1/RP2.1*plus* Control Panel M441, P/N M441, is a quality control panel consisting of 2 ready-to-use, liquid controls, BioFire RP2.1/RP2.1*plus* Positive (Positive Control) and BioFire RP2.1/RP2.1*plus* Negative, (Negative Control). The Positive Control contains non-infectious surrogate control material; a solution of synthetic RNA transcripts in

buffer, stabilizers and preservatives. The RNA carries segments of all respiratory pathogens detected by the BioFire Respiratory Panel 2.1 (RP2.1), BioFire Respiratory Panel 2.1*plus* (RP2.1*plus*), and BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) assays (Table 1. below) on the BioFire FilmArray systems, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). BioFire RP2.1/RP2.1*plus* Negative contains buffer and preservatives with no RNA. Each liquid control of BioFire RP2.1/RP2.1*plus*.

Control Panel M441 is processed separately according to BioFire RP2.1, RP2.1*plus*, and RP2.1-EZ 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)).

Table 1: Pathogens Detected by BioFire RP2.1, RP2.1*plus*, and RP2.1-EZ assays.

Respiratory Pathogens	
Adenovirus	Influenza B
Coronavirus 229E	Parainfluenza Virus 1
Coronavirus HKU1	Parainfluenza Virus 2
Coronavirus NL63	Parainfluenza Virus 3
Coronavirus OC43	Parainfluenza Virus 4
Middle East Respiratory Syndrome Coronavirus*	Respiratory Syncytial Virus
Severe Acute Respiratory Syndrome Coronavirus 2	*Bordetella parapertussis (IS001)*
Human Metapneumovirus	*Bordetella pertussis (ptxP)*
Human Rhinovirus/ Enterovirus	*Chlamydia pneumoniae*
Influenza A, subtypes H1, H1-2009, H3	*Mycoplasma pneumoniae*

*Detected by BioFire RP2.1*plus* assay only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FilmArray RP2/RP2*plus* Control Panel, Maine Molecular Quality Controls, Inc.

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

   K173171

3. Comparison with predicate:

Similarities

Similarities		
Item	**Device: BioFire RP2.1/RP2.1*plus* Control (K202196)**	**Prdeciate: FilmArray Pneumonia/Pneumonia*plus* Control (K173171)**
Intended Use	BioFire RP2.1/RP2.1*plus* Control Panel M441 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 H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* on the BioFire Respiratory Panel 2.1 (RP2.1) and BioFire Respiratory Panel 2.1*plus* (RP2.1*plus)* assays performed on the BioFire FilmArray 2.0 and Torch systems. BioFire RP2.1/RP2.1*plus* Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BioFire RP2.1 assay and BioFire RP2.1*plus* assay. This product is not intended to replace manufacturer internal controls provided with the device.	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.
Physical Format	Same	Ready-to-Use Liquid
Directions for Use	Same	Process like patient sample
Assay Steps Monitored	Same	Reverse transcription, amplification, detection, identification

Similarities		
Number of Targets	Same	Multiple
Composition	Same	Synthetic RNA & DNA transcripts

Differences		
Item	**Device: BioFire RP2.1/RP2.1*plus* Control (K202196)**	**Prdeciate: FilmArray Pneumonia/Pneumonia*plus* Control (K173171)**
Targets	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, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*	*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

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. External Site Precision:

An external site precision study was performed with the BioFire RP2.1/RP2.1*plus* Control Panel on FilmArray instrument 2.0 and FilmArray Torch systems. Multiple operators participated using three lots each of external control material and three lots of BioFire RP2.1 assays pouch lots were tested across all sites. A total of 52 external controls were tested (27 positive and 25 negative). The results are shown in the Tables 2 below:

Table 2: BioFire RP2.1/RP2.1*plus* Control Panel External Precision Study Summary

Category	#expected results/# tested[1]	% Agreement with Expected Result [1]	Overall Percent Agreement	95% Confidence Interval
BioFire RP2.1/RP2.1*plus* Positive Control	26/27*	100%	100% 26/26	87.1% to 100%%
BioFire RP2.1/RP2.1*plus* Negative Control	25/25	100%	100% 25/25	86.7% to 100%

* 1 Invalid sample was not included in the Percent Correct analysis.

Table 3: External Precision Crossing Point (Cp) Summary

Analyte	Lot #1		Lot #2		Lot #3		All Lot #'s		
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	%CV
Adeno2	18.6	3.1	18.0	0.7	18.1	1.6	18.3	2.1	11.6%
Adeno3	18.4	1.4	17.5	1.7	19.2	1.6	18.4	1.6	8.9%
Adeno6	16.1	1.0	15.4	1.3	16.7	1.1	16.1	1.2	7.5%
Adeno7.1	15.2	0.6	15.2	0.8	15.2	0.6	15.2	0.6	4.3%
Adeno8	13.7	0.4	13.7	0.7	14.1	0.5	13.8	0.5	3.8%
CoV-229E	15.8	0.5	15.9	0.4	15.8	0.5	15.8	0.4	2.7%
CoV-HKU1	17.2	0.4	17.3	0.5	17.3	0.5	17.3	0.5	2.6%
CoV-NL63	16.0	0.5	16.1	0.5	16.1	0.6	16.1	0.5	3.1%
CoV-OC43-2	17.2	0.7	17.3	0.5	17.1	0.8	17.2	0.7	3.8%
MERS1	17.0	0.7	16.9	0.5	16.9	0.5	16.9	0.6	3.3%
MERS2	16.2	0.7	16.2	0.6	16.3	0.7	16.3	0.6	4.0%
SARSCoV2-1	12.4	0.3	12.4	0.4	12.2	0.3	12.4	0.4	2.9%
SARSCoV2-2	15.5	0.4	15.3	0.7	15.3	0.4	15.4	0.5	3.3%
hMPV	14.5	0.7	14.3	0.8	14.3	0.7	14.4	0.7	4.8%
HRV/EV	16.2	0.4	16.3	0.4	16.4	0.6	16.3	0.5	3.0%
FluA-H1-2	18.4	0.5	18.2	0.7	18.3	0.7	18.3	0.6	3.3%
FluA-H1-2009	17.8	0.5	17.8	0.5	17.8	0.5	17.8	0.5	2.7%
FluA-H3	15.3	0.5	15.5	0.4	15.4	0.5	15.4	0.4	2.8%
FluA-pan1	15.3	0.4	15.5	0.5	15.4	0.6	15.4	0.5	3.0%
FluA-pan2	16.1	0.4	16.2	0.5	16.0	0.7	16.1	0.5	3.2%

Analyte	Lot #1		Lot #2		Lot #3		All Lot #'s		
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	%CV
FluB	14.8	0.4	15.2	0.5	15.1	0.4	15.0	0.4	2.9%
PIV1	14.0	0.6	13.8	0.6	13.9	0.8	13.9	0.6	4.4%
PIV2	17.4	0.4	17.5	0.5	17.4	0.5	17.4	0.4	2.5%
PIV3	17.1	0.4	17.3	0.3	17.2	0.5	17.2	0.4	2.2%
PIV4	17.3	0.5	17.5	0.6	17.4	0.5	17.4	0.5	2.8%
RSV	14.8	0.2	15.1	0.4	15.0	0.5	14.9	0.4	2.6%
IS1001	17.7	0.8	17.9	0.7	18.6	1.1	18.0	0.9	5.2%
ptxP	15.4	1.1	15.0	1.1	16.0	1.2	15.5	1.2	7.5%
Cpne	15.2	0.5	15.4	0.5	15.3	0.5	15.3	0.5	3.0%
Mpne	15.5	0.3	15.6	0.4	15.4	0.5	15.5	0.4	2.5%

The results suggest that there are no significant differences between different users and different lots on different days. The external precision study for the BioFire RP2.1/RP2.1*plus* Control Panel are is acceptable.

b. Internal Precision:

An internal precision study for the BioFire RP2.1/RP2.1*plus* Control Panel was conducted over twenty days by testing three BioFire RP2.1/RP2.1*plus* Control Panel lots with three BioFire RP2.1 assay lots performed by three operators using two FilmArray 2.0 instruments. The results are shown in the Table 4 below:

Table 4: BioFire RP2.1/RP2.1plus Control Panel Internal Precision Summary

Category	#expected results/ #tested[1]	Overall Percent Agreement	95% Confidence Interval
BioFire RP2.1/RP2.1*plus* Negative Control	60/60	100%	94% to 100%
BioFire RP2.1/RP2.1*plus* Positive Control	60/60	100%	94% to 100%

Table 5: Precision Internal Crossing Point (Cp) Summary

Analyte	D24APR20A		F28APR20A		C29APR20A		All Lots		
	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	Ave Cp	SD	%CV
Adeno2	17.8	1.5	18.5	1.6	17.9	2.1	18.1	1.8	9.7%
Adeno3	18.1	1.5	18.3	1.5	17.8	1.7	18.1	1.6	8.7%
Adeno6	15.9	1.4	15.9	1.4	15.7	1.4	15.8	1.4	8.7%
Adeno7.1	16.1	1.8	16.1	1.2	15.7	1.3	16.0	1.4	9.0%
Adeno8	14.2	1.3	14.3	1.0	14.0	1.0	14.2	1.1	7.5%

Analyte	D24APR20A		F28APR20A		C29APR20A		All Lots		
CoV-229E	16.3	0.8	16.8	0.7	16.2	0.7	16.4	0.8	4.7%
CoV-HKU1	17.7	1.2	17.9	0.7	17.6	0.8	17.7	0.9	5.1%
CoV-NL63	17.2	1.2	17.3	0.7	17.1	0.9	17.2	0.9	5.4%
CoV-OC43-2	18.3	1.7	18.4	0.9	18.3	1.3	18.3	1.3	7.2%
MERS1	17.9	1.8	18.0	0.8	17.9	1.4	17.9	1.4	7.6%
MERS2	16.9	1.2	17.2	0.7	16.9	1.1	17.0	1.0	5.9%
SARSCoV2-1	13.2	0.8	13.4	0.5	12.9	0.6	13.2	0.7	5.2%
SARSCoV2-2	16.4	1.3	16.3	0.6	16.0	0.9	16.2	1.0	5.9%
hMPV	15.4	1.7	15.3	1.1	14.9	1.2	15.2	1.4	9.1%
HRV/EV	16.8	1.0	17.2	0.7	16.7	0.8	16.9	0.9	5.1%
FluA-H1-2	19.1	1.4	19.4	1.0	18.9	1.1	19.1	1.2	6.2%
FluA-H1-2009	18.4	1.5	18.5	0.9	18.3	1.1	18.4	1.2	6.4%
FluA-H3	15.9	0.8	16.4	0.5	16.0	0.7	16.1	0.7	4.2%
FluA-pan1	15.7	0.7	16.1	0.5	15.6	0.6	15.8	0.7	4.2%
FluA-pan2	16.8	1.1	17.1	0.9	16.6	0.8	16.8	0.9	5.6%
FluB	15.4	0.7	15.9	0.4	15.5	0.5	15.6	0.6	3.8%
PIV1	15.0	1.6	15.0	1.1	14.8	1.2	14.9	1.3	8.9%
PIV2	18.1	1.3	18.3	0.8	17.9	0.9	18.1	1.0	5.5%
PIV3	17.7	1.2	18.0	0.8	17.6	0.8	17.8	1.0	5.4%
PIV4	17.9	1.2	18.4	0.8	17.9	0.9	18.1	1.0	5.5%
RSV	15.4	0.8	15.8	0.5	15.5	0.5	15.6	0.6	4.1%
IS1001	18.1	1.0	18.6	1.0	18.2	1.1	18.3	1.0	5.7%
ptxP	15.3	1.3	15.7	1.2	15.2	1.3	15.4	1.3	8.2%
Cpne	15.7	0.8	16.2	0.6	15.6	0.6	15.8	0.7	4.5%
Mpne	16.2	1.2	16.4	0.7	16.0	0.8	16.2	0.9	5.8%

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

c. Lot-to-Lot Testing:

Lot-to-lot reproducibility was demonstrated by testing three lots of BioFire RP2.1/RP2.1*plus* Positive using the same pouch lot. Results are shown in the following tables.

Table 6: BioFire RP2.1/RP2.1*plus* Positive Panel Summary of Lot-to-Lot Reproducibility

Control Lot #	Number of Tests	Pouch Lot	Correct Results
D24APR20	5	200409	5/5
F28APR20	5	200409	5/5
C29APR20	5	200409	5/5

Table 7: Lot to Lot Internal Crossing Point (Cp) Summary

Analyte	D24APR20	F28APR20	C29APR20	All lots	All Lots
	Mean Cp	Mean Cp	Mean Cp	Mean Cp	SD
Adeno2	18.9	18.9	19.0	18.9	0.1
Adeno3	19.3	19.8	19.4	19.5	0.3
Adeno6	16.8	17.2	16.7	16.9	0.2
Adeno7.1	16.6	16.9	16.5	16.7	0.2
Adeno8	14.6	14.9	14.6	14.7	0.2
CoV-229E	16.8	16.9	16.8	16.8	0.1
CoV-HKU1	18.1	18.1	18.1	18.1	0.0
CoV-NL63	17.8	17.9	17.7	17.8	0.1
CoV-OC43-2	18.9	19.1	18.7	18.9	0.2
MERS1	18.9	18.8	18.8	18.8	0.1
MERS2	17.6	17.6	17.6	17.6	0.0
SARSCoV2-1	13.7	13.5	13.7	13.7	0.1
SARSCoV2-2	16.8	16.7	16.8	16.8	0.1
hMPV	16.0	15.9	15.9	15.9	0.1
HRV/EV	17.4	17.5	17.4	17.4	0.1
FluA-H1-2	19.7	20.0	19.6	19.7	0.2
FluA-H1-2009	18.9	18.9	18.8	18.8	0.1
FluA-H3	16.4	16.5	16.4	16.4	0.1
FluA-pan1	16.1	16.2	16.1	16.1	0.1
FluA-pan2	17.3	17.4	17.3	17.3	0.1
FluB	15.7	15.9	15.8	15.8	0.1
PIV1	15.7	15.7	15.6	15.6	0.1
PIV2	18.6	18.7	18.5	18.6	0.1
PIV3	18.0	18.2	18.0	18.1	0.1
PIV4	18.4	18.5	18.3	18.4	0.1
RSV	15.8	15.9	15.7	15.8	0.1
IS1001	18.9	19.3	18.9	19.0	0.3
ptxP	16.1	16.5	16.1	16.3	0.2
Cpne	16.1	16.2	16.1	16.2	0.1
Mpne	16.8	16.7	16.6	16.7	0.1

Lot-to-Lot reproducibility studies for the BioFire RP2.1/RP2.1*plus* Positive 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 BioFire RP2.1/RP2.1*plus* Panel 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 BioFire RP2.1/RP2.1*plus* Panel Control. Based on this study, the BioFire RP2.1/RP2.1*plus* Panel 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 BioFire RP2.1/RP2.1*plus* Panel 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 BioFire RP2.1/RP2.1*plus* Panel 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 BioFire RP2.1/RP2.1*plus* Panel 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 BioFire RP2.1/RP2.1*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 BioFire RP2*plus* assay.

The study demonstrated that the BioFire RP2.1/RP2.1*plus* Positive Control is stable for two days on dry ice in MMQCI's standard shipping box. BioFire RP2.1/RP2.1*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:

BioFire RP2.1/RP2.1*plus* Panel Control is a qualitative control and the expected results are listed in the tables below.

Table 10: BioFire RP2.1/RP2.1*plus* Positive & Negative Result Summary

Result Summary

Result Summary		
	Positive	**Negative**
Viruses		
Adenovirus	Detected	Not Detected
Coronavirus 229E	Detected	Not Detected
Coronavirus HKU1	Detected	Not Detected
Coronavirus NL63	Detected	Not Detected
Coronavirus OC43	Detected	Not Detected
Middle East Respiratory Syndrome Coronavirus* (MERS-CoV)[2]	Detected	Not Detected
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Detected	Not Detected
Human Metapneumovirus	Detected	Not Detected
Human Rhinovirus/ Enterovirus	Detected	Not Detected
Influenza A H1-2009[1]	Detected	Not Detected
Influenza A H3	Detected	Not Detected
Influenza B	Detected	Not Detected
Parainfluenza Virus 1	Detected	Not Detected
Parainfluneza Virus 2	Detected	Not Detected
Parainfluenza Virus 3	Detected	Not Detected
Parainfluenza Virus 4	Detected	Not Detected
Respiratory Syncytial Virus	Detected	Not Detected
Bacteria		
Bordetella parapertussis (IS1001)	Detected	Not Detected
Bordetella pertussis (ptxP)	Detected	Not Detected
Chlamydia pneumoniae	Detected	Not Detected
Mycoplasma pneumoniae	Detected	Not Detected

[1] BioFire RP2.1/RP2.1*plus* Positive contains both Influenza A H1 and Influenza A H1-2009. Due to BioFire FilmArray 2.0 Software calling algorithm, only Influenza A H1-2009 will report as Detected, just as if a co-infection of Influenza A H1-2009 and another Influenza A H1 has occurred. To confirm successful detection of Influenza A H1, view the melt curve by following BioFire's Technical Note: Torch Melting Curve Analysis with FilmArray 2.0 Software. For questions related to software, please contact BioFire Technical Support.
[2] Middle East Respiratory Syndrome Coronavirus is reported on RP2.1*plus* assay only.

Matrix Effects:

A study was performed to evaluate the effect of the BioFire RP2.1/RP2.1*plus* Panel Control in the presence of VTM matrix. A VTM sample positive for Influenza A H1N1-2009 was spiked into a negative VTM and into a RP2/RP2*plus* Negative Control matrix and tested in triplicate by the FilmArray Pneumonia/Pneumonia *plus* assay. No inhibition and/or false negative results were observed with either the spiked sample in VTM or the RP2/RP2*plus* Negative Control matrix.

Results demonstrated that samples prepared with VTM matrix showed no inhibition and/or false negative results were observed with either the spiked sample or with the BioFire RP2/RP2*plus* Negative control 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.