November 15, 2018

BioFire Diagnostics, LLC
Kristen Kanack
Senior Vice President, Regulatory & Clinical Affairs
515 Colorow Drive
Salt Lake City, Utah 84108

Re: K181324
Trade/Device Name: FilmArray Pneumonia Panel plus
Regulation Number: 21 CFR 866.4001
Regulation Name: MERS-CoV and common respiratory pathogens multiplex nucleic acid detection system
Regulatory Class: Class II
Product Code: QDS
Dated: May 17, 2018
Received: May 18, 2018

Dear Kristen Kanack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181342

Device Name
FilmArray Pneumonia Panel plus

Indications for Use *(Describe)*
The FilmArray® Pneumonia Panel plus is a multiplexed nucleic acid test intended for use with FilmArray®, FilmArray® 2.0, or FilmArray® Torch systems for the simultaneous detection and identification of nucleic acids from Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria.

Testing with FilmArray Pneumonia Panel plus should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspected MERS-CoV specimens. This includes: clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiological links for which MERS-CoV testing may be indicated.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL
- Acinetobacter calcoaceticus-baumannii complex
- Enterobacter cloacae complex
- Escherichia coli
- Haemophilus influenza
- Klebsiella aerogenes
- Klebsiella oxytoca
- Klebsiella pneumoniae group
- Moraxella catarrhalis
- Proteus spp.
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Streptococcus pneumoniae
- Streptococcus pyogenes

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria
- Chlamydia pneumoniae
- Legionella pneumophila
- Mycoplasma pneumoniae

Viruses
- Adenovirus

• Coronavirus
• Human Metapneumovirus
• Human Rhinovirus/Enterovirus
• Influenza A
• Influenza B
• Parainfluenza Virus
• Respiratory Syncytial Virus

Antimicrobial Resistance Genes
• CTX-M
• IMP
• KPC
• NDM
• OXA-48-like
• VIM
• mecA/C and MREJ

The detection and identification of specific viral and bacterial nucleic acids from MERS-CoV and other respiratory pathogens, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals meeting MERS-CoV clinical and/or epidemiological criteria aids in the differential diagnosis of MERS-CoV infection, if used in conjunction with other clinical and epidemiological information in accordance with the guidelines provided by the appropriate public health authorities.

FilmArray Pneumonia Panel plus MERS-CoV positive results are for the presumptive identification of MERS-CoV. The definitive identification of MERS-CoV requires additional testing and confirmation procedures in consultation with the appropriate public health authorities (e.g., local or state public health departments, etc.) for whom reporting is necessary. The diagnosis of MERS-CoV infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of MERS-CoV.

FilmArray Pneumonia Panel plus MERS-CoV negative results, even in the context of a FilmArray Pneumonia Panel plus positive result for one or more of the common respiratory pathogens, do not preclude MERS-CoV infection and should not be used as the sole basis for patient management decisions. The levels of MERS-CoV that would be present in sputum-like or BAL-like specimens from individuals with early infection and from asymptomatic MERS-CoV carriers are not well understood. A negative FilmArray Pneumonia Panel plus MERS-CoV result in an asymptomatic individual does not rule out the possibility of future illness and does not demonstrate that the individual is not infectious.

Viral culture should not be attempted on specimens with positive FilmArray Pneumonia Panel plus results for MERS-CoV unless a BSL 3 facility is available to receive and culture specimens.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the FilmArray Pneumonia Panel plus may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the FilmArray Pneumonia Panel plus are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease.

Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A "Not Detected" result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A "Detected" result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and FilmArray Pneumonia Panel plus results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Culture is required to identify pathogens not detected by the FilmArray Pneumonia Panel plus, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
BioFire Diagnostics, LLC

FilmArray Pneumonia Panel *plus*

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108

Telephone: 801-736-6354
Facsimile: 801-588-0507

Contact: Kristen J. Kanack, ext. 1330

Date Submitted: May 17, 2018

Device Name and Classification:

Trade Name: FilmArray Pneumonia Panel *plus*

Regulation Number: 21 CFR 866.4001

Classification Name: MERS-CoV and common respiratory pathogens multiplex nucleic acid detection system

Predicate Device:

DEN170017 – FilmArray Respiratory Panel 2 *plus* (RP2*plus)*

Intended Use:

The FilmArray® Pneumonia Panel *plus* is a multiplexed nucleic acid test intended for use with FilmArray®, FilmArray® 2.0, or FilmArray® Torch systems for the simultaneous detection and identification of nucleic acids from Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria.

Testing with FilmArray Pneumonia Panel *plus* should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspected MERS-CoV specimens. This includes: clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV

case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiological links for which MERS-CoV testing may be indicated.

The following bacteria are reported with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL		
Acinetobacter calcoaceticus-baumannii complex	*Klebsiella oxytoca*	*Serratia marcescens*
Enterobacter cloacae complex	*Klebsiella pneumoniae* group	*Staphylococcus aureus*
Escherichia coli	*Moraxella catarrhalis*	*Streptococcus agalactiae*
Haemophilus influenzae	*Proteus* spp.	*Streptococcus pneumoniae*
Klebsiella aerogenes	*Pseudomonas aeruginosa*	*Streptococcus pyogenes*

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria		
Chlamydia pneumoniae	*Legionella pneumophila*	*Mycoplasma pneumoniae*
Viruses		
Middle East Respiratory Syndrome Coronavirus		
Adenovirus	Human Rhinovirus/Enterovirus	Parainfluenza Virus
Coronavirus	Influenza A	Respiratory Syncytial Virus
Human Metapneumovirus	Influenza B	
Antimicrobial Resistance Genes		
CTX-M	NDM	*mecA/C* and MREJ
IMP	OXA-48-like	
KPC	VIM	

The detection and identification of specific viral and bacterial nucleic acids from MERS-CoV and other respiratory pathogens, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals meeting MERS-CoV clinical and/or epidemiological criteria aids in the differential diagnosis of MERS-CoV infection, if used in conjunction with other clinical and epidemiological information in accordance with the guidelines provided by the appropriate public health authorities.

FilmArray Pneumonia Panel *plus* MERS-CoV positive results are for the presumptive identification of MERS-CoV. The definitive identification of MERS-CoV requires additional testing and confirmation procedures in consultation with the appropriate public health authorities (e.g., local or state public health departments, etc.) for whom reporting is necessary. The diagnosis of MERS-CoV infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of MERS-CoV.

FilmArray Pneumonia Panel *plus* MERS-CoV negative results, even in the context of a FilmArray Pneumonia Panel *plus* positive result for one or more of the common respiratory pathogens, do not preclude MERS-CoV infection and should not be used as the sole basis for patient management decisions. The levels of MERS-CoV that would be present in sputum-like or BAL-like specimens from individuals with early infection and from asymptomatic MERS-CoV carriers are not well understood. A negative

FilmArray Pneumonia Panel *plus* MERS-CoV result in an asymptomatic individual does not rule out the possibility of future illness and does not demonstrate that the individual is not infectious.

Viral culture should not be attempted on specimens with positive FilmArray Pneumonia Panel *plus* results for MERS-CoV unless a BSL 3 facility is available to receive and culture specimens.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10^4 copies/mL bin value. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the FilmArray Pneumonia Panel *plus* may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible lower respiratory tract infection.

Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the FilmArray Pneumonia Panel plus are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.

The antimicrobial resistance gene detected may or may not be associated with the agent(s) responsible for disease. Negative results for these antimicrobial resistance gene assays do not indicate susceptibility to corresponding classes of antimicrobials, as multiple mechanisms of antimicrobial resistance exist.

Antimicrobial resistance can occur via multiple mechanisms. A “Not Detected” result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A “Detected” result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and FilmArray Pneumonia Panel *plus* results should be used in conjunction with culture results for determination of bacterial susceptibility or resistance.

Due to the genetic similarity between human rhinovirus and enterovirus, the test cannot reliably differentiate them. A positive Rhinovirus/Enterovirus result should be followed up using an alternate method (*e.g.*, cell culture or sequence analysis) if differentiation is required.

Culture is required to identify pathogens not detected by the FilmArray Pneumonia Panel *plus*, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

Device Description:

The FilmArray Pneumonia Panel *plus* is designed to simultaneously identify Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and 26 other potential pathogens of lower respiratory tract infection (LRTI) and seven associated antimicrobial resistance (AMR) genes from a sputum-like (induced and expectorated sputum as well as endotracheal aspirate, ETA) or bronchoalveolar lavage (BAL)-like (BAL and mini-BAL) specimens obtained from individuals meeting MERS-CoV clinical and/or epidemiological criteria in a time (~1 hour) that allows the test results to be used in determining appropriate patient treatment and management.

The FilmArray Pneumonia Panel *plus* is compatible with BioFire's PCR-based in vitro diagnostic FilmArray, FilmArray 2.0, and FilmArray Torch systems for infectious disease testing. A specific software module (i.e. FilmArray Pneumonia Panel pouch module) is used to perform FilmArray Pneumonia Panel testing on these systems.

MERS-CoV – Qualitative Results	
Middle East Respiratory Syndrome Coronavirus	
Other Common Lower Respiratory Pathogens	
Bacteria –Results with Bin Values	**Antimicrobial Resistance Genes**
Acinetobacter calcoaceticus-baumannii complex	*bla*$_{CTX-M}$ (Extended spectrum beta-lactamase (ESBL))
Enterobacter cloacae complex	*bla*$_{IMP}$ (Carbapenem resistance)
Escherichia coli	*bla*$_{KPC}$ (Carbapenem resistance)
Haemophilus influenzae	*mecA*/*mecC* and MREJ (Methicillin resistance)
Klebsiella aerogenes	*bla*$_{NDM}$ (Carbapenem resistance)
Klebsiella oxytoca	*bla*$_{Oxa48-like}$ (Carbapenem resistance)
Klebsiella pneumoniae group	*bla*$_{VIM}$ (Carbapenem resistance)
Moraxella catarrhalis	**Viruses**
Proteus spp.	Adenovirus
Pseudomonas aeruginosa	Coronavirus
Serratia marcescens	Human Metapneumovirus
Streptococcus agalactiae	Human Rhinovirus/Enterovirus
Streptococcus pneumoniae	Influenza A
Streptococcus pyogenes	Influenza B
Bacteria (Atypical) - Qualitative Results	Parainfluenza Virus
Chlamydia pneumoniae	Respiratory Syncytial Virus
Legionella pneumophila	
Mycoplasma pneumoniae	

A test is initiated by loading Hydration Solution into one port of the FilmArray pouch and a sputum-like or BAL-like sample mixed with the provided Sample Buffer into the other port of the FilmArray Pneumonia Panel *plus* pouch and placing it in a FilmArray instrument. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the FilmArray Software guides the user through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray instruments contain coordinated systems of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically-controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical and chemical lysis followed by purification using standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the FilmArray performs a nested multiplex PCR that is executed in two stages. During the first stage, the FilmArray performs a single, large volume, highly multiplexed reverse transcription PCR (rt-PCR) reaction. The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green® *Plus*, BioFire Diagnostics). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism on the panel.

A new feature of the FilmArray Pneumonia Panel *plus* is the reporting of organism abundance for common bacteria in discrete bins representing 10^4, 10^5, 10^6, and ≥10^7 genomic copies/mL. The panel accomplishes this by comparing the amplification of the bacterial assays with that of a Quantified Standard Material (QSM) present in the pouch.

Substantial Equivalence:

The FilmArray Pneumonia Panel *plus* is substantially equivalent to the FilmArray Respiratory Panel 2 *plus* (RP2*plus*) Application (DEN170017), which was cleared on November 24, 2017 and determined to be a Class II device under the classification product code QDS.

Table 1 compares the FilmArray Pneumonia Panel *plus* to the FilmArray Respiratory Panel 2 *plus* (RP2*plus)* and outlines the similarities and differences between the two systems.

Table 1. Comparison of the FilmArray Pneumonia Panel plus and the FilmArray Respiratory Panel 2 plus

Element	New Device: FilmArray Pneumonia Panel *plus*	Predicate: FilmArray Respiratory Panel 2 *plus* (RP2*plus*) (DEN170017)
Specimen Types	Sputum-like (induced or expectorated sputum, endotracheal aspirates) and BAL-like (BAL or mini-BAL) specimens	NPS in viral transport medium
Organisms Detected	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Element	New Device: FilmArray Pneumonia Panel *plus*	Predicate: FilmArray Respiratory Panel 2 *plus* (RP2*plus*) (DEN170017)
	Bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae* complex, *Escherichia coli* , *Haemophilus influenzae, Klebsiella oxytoca, Klebsiella aerogenes, Klebsiella pneumoniae* group*, Moraxella catarrhalis, Proteus* spp., *Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes* Atypical Bacteria: *Chlamydia pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae* Antimicrobial Resistance Genes: CTX-M, IMP, KPC, *mecA/C* + MREJ, NDM, Oxa48-like, VIM Viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza virus, Respiratory Syncytial virus	Bacteria: *Bordetella parapertussis* (IS*1001*), *Bordetella pertussis* (*ptxP*), *Chlamydia pneumoniae*, *Mycoplasma pneumoniae* Viruses: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, including subtypes H1, H1-2009, and H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus
Analyte	DNA/RNA	Same
Technological Principles	Multiplex nucleic acid	Same
Result types	Detection with bin values (in 1-log rounded copies/mL bins) for Bacteria Qualitative for MERS-CoV, Atypical Bacteria, Antimicrobial Resistance Genes, and Viruses	Qualitative for all analytes
Instrumentation	FilmArray, FilmArray 2.0, or FilmArray Torch	FilmArray 2.0 or FilmArray Torch
Time to result	About 1 hour	~ 45 minutes
Reagent Storage	Room temperature	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Same
User Complexity	Moderate/Low	Same

Summary of Performance Data

Clinical Performance

The clinical performance of the FilmArray Pneumonia Panel *plus* was established during a multi-center study conducted at eight geographically distinct U.S. study sites from October 2016 to July 2017. A total of 904 residual BAL (including mini-BAL) and 925 residual sputum (821 BAL and 83 mini-BAL) and 925 residual sputum (478 sputum and 447 ETA) specimens were acquired for the prospective clinical study. FilmArray Pneumonia Panel *plus* performance in BAL and mini-BAL was similar, as was performance in sputum and ETA; therefore these sample types are not stratified further in performance tables. A total of 58 BAL and 89 sputum specimens were excluded from the final data analysis. The most common reasons for specimen exclusion for both specimen types was reference culture unable to be performed, the specimen was found to not meet the inclusion criteria after the specimen had been enrolled, or the study site was unable to complete the Case Report Form (CRF). The final data set consisted of 846 BAL and 836 sputum specimens. Table 2 and Table 3 provides a summary of demographic information for the specimens included in the prospective study.

Table 2. Overall and Per Site Demographic Analysis for BAL Specimens

BAL										
		Overall	**Site 1[a]**	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**
Sex	Male	480 (57%)	80 (59%)	7 (54%)	138 (55%)	21 (68%)	75 (61%)	82 (52%)	27 (61%)	50 (55%)
	Female	366 (43%)	55 (41%)	6 (46%)	113 (45%)	10 (32%)	48 (39%)	76 (48%)	17 (39%)	41 (45%)
Age	≤ 5 years	23 (3%)	0 (0%)	5 (38%)	0 (0%)	15 (48%)	0 (0%)	3 (2%)	0 (0%)	0 (0%)
	6 - 17 years	27 (3%)	0 (0%)	8 (62%)	0 (0%)	13 (42%)	0 (0%)	4 (3%)	1 (2%)	1 (1%)
	18 - 34 years	70 (8%)	18 (13%)	0 (0%)	17 (7%)	3 (10%)	10 (8%)	10 (6%)	5 (11%)	7 (8%)
	35 - 65 years	470 (56%)	78 (58%)	0 (0%)	152 (61%)	0 (0%)	70 (57%)	88 (56%)	27 (61%)	55 (60%)
	> 65 years	255 (30%)	38 (28%)	0 (0%)	82 (33%)	0 (0%)	43 (35%)	53 (34%)	11 (25%)	28 (31%)
Care Setting	Hospitalized	666 (79%)	116 (86%)	12 (92%)	223 (89%)	9 (29%)	82 (67%)	118 (75%)	25 (57%)	81 (89%)
	Outpatient	159 (19%)	18 (13%)	0 (0%)	28 (11%)	22 (71%)	31 (25%)	39 (25%)	14 (32%)	7 (8%)
	Emergency	21 (2%)	1 (1%)	1 (8%)	0 (0%)	0 (0%)	10 (8%)	1 (1%)	5 (11%)	3 (3%)
Total		**846**	**135**	**13**	**251**	**31**	**123**	**158**	**44**	**91**

[a] Subject age could not be determined for one specimen from Site 1

Table 3. Overall and Per Site Demographic Analysis for Sputum Specimens

Sputum										
		Overall	**Site 1**	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**
Sex	Male	481 (58%)	66 (59%)	54 (54%)	136 (56%)	97 (61%)	14 (82%)	31 (53%)	34 (74%)	49 (47%)
	Female	355 (42%)	45 (41%)	46 (46%)	105 (44%)	61 (39%)	3 (18%)	28 (47%)	12 (26%)	55 (53%)
Age	≤ 5 years	138 (17%)	0 (0%)	49 (49%)	0 (0%)	80 (51%)	0 (0%)	0 (0%)	2 (4%)	7 (7%)
	6 - 17 years	107 (13%)	0 (0%)	35 (35%)	0 (0%)	64 (41%)	0 (0%)	0 (0%)	2 (4%)	6 (6%)
	18 - 34 years	86 (10%)	15 (14%)	16 (16%)	20 (8%)	13 (8%)	1 (6%)	6 (10%)	5 (11%)	10 (10%)
	35 - 65 years	284 (34%)	51 (46%)	0 (0%)	133 (55%)	1 (1%)	6 (35%)	36 (61%)	20 (43%)	37 (36%)
	> 65 years	221 (26%)	45 (41%)	0 (0%)	88 (37%)	0 (0%)	10 (59%)	17 (29%)	17 (37%)	44 (42%)
Care Setti	Hospitalized	682 (82%)	106 (95%)	64 (64%)	219 (91%)	105 (66%)	12 (71%)	52 (88%)	23 (50%)	101 (97%)

Sputum										
		Overall	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8
	Outpatient	73 (9%)	2 (2%)	14 (14%)	18 (7%)	24 (15%)	2 (12%)	5 (8%)	7 (15%)	1 (1%)
	Emergency	81 (10%)	3 (3%)	22 (22%)	4 (2%)	29 (18%)	3 (18%)	2 (3%)	16 (35%)	2 (2%)
Total		**836**	**111**	**100**	**241**	**158**	**17**	**59**	**46**	**104**

All specimens were evaluated with the FilmArray Pneumonia Panel *plus* at clinical study sites. Refrigerated specimen aliquots were sent to a central reference laboratory for quantitative reference culture (qRefCx) and frozen specimen aliquots were also sent to BioFire for evaluation by polymerase chain reaction (PCR)/sequencing-based comparator methods.

The reference methods used in this study were as follows:

Bacterial analytes were compared to qRefCx to evaluate sensitivity and specificity, and the method was considered positive for the presence of the organism of interest if it was recovered in culture and enumerated at a level of 3162 (10^3.5) CFU/mL or greater.

Bacterial analytes were also evaluated by comparison to a single PCR assay for the organism of interest followed by a quantitative molecular assay that included sequencing (qMol) to assess FilmArray bin reporting performance. Atypical bacteria and viruses were compared to two conventional PCR assays followed by bidirectional sequencing. For specimens with an applicable bacteria detected by FilmArray, AMR genes were compared to a single PCR assay (from the specimen) followed by sequencing. A specimen was considered to be positive for an analyte if bi-directional sequencing data meeting pre-defined quality acceptance criteria matched organism-specific sequences deposited in the NCBI GenBank database (www.ncbi.nlm.nih.gov) with acceptable E-values. When two PCR comparator assays were used, any specimen that tested negative by both of the comparator assays was considered Negative.

No reference testing was performed for MERS-CoV as this virus was not circulating in the United States at the time of enrollment; therefore all specimens were assumed to be negative.

Positive Percent Agreement (PPA) or Sensitivity for each analyte was calculated as 100% x (TP / (TP + FN)). True positive (TP) indicates that both the FilmArray Pneumonia Panel *plus* and the comparator method had a positive result for this specific analyte, and false negative (FN) indicates that the FilmArray Pneumonia Panel *plus* result was negative while the comparator result was positive. Negative Percent Agreement (NPA) or Specificity was calculated as 100% x (TN / (TN + FP)). True negative (TN) indicates that both the FilmArray Pneumonia Panel *plus* and the comparator method had negative results, and a false positive (FP) indicates that the FilmArray Pneumonia Panel *plus* result was positive but the comparator result was negative. The exact binomial two-sided 95% confidence interval was calculated. Samples for which false positive and/or false negative results (i.e., discrepant results) were obtained when comparing the FilmArray Pneumonia Panel *plus* results to the comparator method results were further investigated. The discrepancy investigations were primarily performed as follows: for discrepancies between the Pneumonia Panel *plus* and reference culture for bacterial analytes, discrepancies were first examined to see if qRefCx or FilmArray had observed the analyte but reported it as “negative” or “Not Detected” because it was below the detection threshold. If this did not resolve the discrepancy, the results of qMol testing were considered. And if these methods still did not resolve the discrepancy, it was then investigated in the same manner as other analytes that used molecular comparator (i.e. using multiple additional molecular assays followed by sequence analysis). The results of SOC testing were also

considered. The prospective clinical study results are summarized in Table 4 and Table 5 for BAL and sputum specimens, respectively.

Table 4. FilmArray Pneumonia Panel *plus* Clinical Performance Summary for BAL Specimens[a]

BAL							
Analyte	**Reference Method**	**Sensitivity/PPA**			**Specificity/NPA**		
		TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	PCR/Seq	0/0	-	-	846/846	100	99.5-100%
Bacteria							
***Acinetobacter calcoaceticus-baumannii* complex[b]**	qRefCx	0/0	-	-	839/846	99.2	98.3-99.6%
***Enterobacter cloacae* complex[c]**	qRefCx	11/12	91.7	64.6-98.5%	822/834	98.6	97.5-99.2%
***Escherichia coli*[d]**	qRefCx	12/12	100	75.8-100%	826/834	99.0	98.1-99.5%
***Haemophilus influenzae*[e]**	qRefCx	10/10	100	72.2-100%	764/836	91.4	89.3-93.1%
***Klebsiella aerogenes*[f]**	qRefCx	6/7	85.7	48.7-97.4%	832/839	99.2	98.3-99.6%
***Klebsiella oxytoca*[g]**	qRefCx	2/2	100	34.2-100%	835/844	98.9	98.0-99.4%
***Klebsiella pneumoniae* group[h]**	qRefCx	15/15	100	79.6-100%	819/831	98.6	97.5-99.2%
***Moraxella catarrhalis*[i]**	qRefCx	0/0	-	-	817/846	96.6	95.1-97.6%
***Proteus* spp.[j]**	qRefCx	5/5	100	56.6-100%	837/841	99.5	98.8-99.8%
***Pseudomonas aeruginosa*[k]**	qRefCx	36/36	100	90.4-100%	772/810	95.3	93.6-96.6%
***Serratia marcescens*[l]**	qRefCx	6/6	100	61.0-100%	834/840	99.3	98.5-99.7%
***Staphylococcus aureus*[m]**	qRefCx	46/47	97.9	88.9-99.6%	729/799	91.2	89.1-93.0%
***Streptococcus agalactiae*[n]**	qRefCx	1/1	100	-	821/845	97.2	95.8-98.1%
***Streptococcus pneumoniae*[o]**	qRefCx	5/5	100	56.6-100%	817/841	97.1	95.8-98.1%
***Streptococcus pyogenes*[p]**	qRefCx	2/2	100	34.2-100%	838/844	99.3	98.5-99.7%
Atypical Bacteria							
***Chlamydia pneumoniae*[q]**	PCR/Seq	0/0	-	-	844/845	99.9	99.3-100%
Legionella pneumophila	PCR/Seq	2/2	100	34.2-100%	833/833	100	99.5-100%
***Mycoplasma pneumoniae*[r]**	PCR/Seq	3/3	100	43.9-100%	841/842	99.9	99.3-100%
Viruses							
Adenovirus	PCR/Seq	8/8	100	67.6-100%	837/837	100	99.5-100%
Coronavirus[s]	PCR/Seq	18/21	85.7	65.4-95.0%	810/823	98.4	97.3-99.1%
Human Metapneumovirus[t]	PCR/Seq	8/8	100	67.6-100%	836/837	99.9	99.3-100%
Human Rhinovirus/Enterovirus[u]	PCR/Seq	52/54	96.3	87.5-99.0%	771/782	98.6	97.5-99.2%
Influenza A[v]	PCR/Seq	10/10	100	72.2-100%	830/833	99.6	98.9-99.9%
Influenza B[w]	PCR/Seq	5/6	83.3	43.6-97.0%	837/838	99.9	99.3-100%
Parainfluenza Virus[x]	PCR/Seq	16/18	88.9	67.2-96.9%	824/826	99.8	99.1-99.9%
Respiratory Syncytial Virus	PCR/Seq	3/3	100	43.9-100%	841/841	100	99.5-100%

[a] The performance measures of sensitivity and specificity only refer to the bacterial analytes for which the gold-standard of qRefCx was used as the reference method. Performance measures of PPA and NPA refer to all other analytes, for which PCR/sequencing assays were used as comparator methods.

[b] Evidence of ACB complex was found in all seven FP specimens; one was enumerated below 10^3.5 CFU/mL by qRefCx and six were detected by qMol.

[c] *E. cloacae* complex was observed in the single FN specimen below the 10^4 bin by the FilmArray Pneumonia Panel *plus*. Evidence of *E. cloacae* complex was found in all 12 FP specimens; six were enumerated below 10^3.5 CFU/mL by qRefCx, five were detected by qMol, and one was detected using an additional molecular method.

[d] Evidence of *E. coli* was found in all eight FP specimens; six were enumerated below 10^3.5 CFU/mL by qRefCx and two were detected by qMol.

[e] Evidence of *H. influenzae* was found in all 72 FP specimens; seven were enumerated below 10^3.5 CFU/mL by qRefCx, 56 were detected by qMol, eight were detected using an additional molecular method, and one was identified in SOC culture.

[f] *K. aerogenes* was identified in the single FN specimen in SOC culture. Evidence of *K. aerogenes* was found in all seven FP specimens; four were enumerated below 10^3.5 CFU/mL by qRefCx and three were detected by qMol.

[g] Evidence of *K. oxytoca* was found in all nine FP specimens; three were enumerated below 10^3.5 CFU/mL by qRefCx, five were detected by qMol, and one was detected using an additional molecular method.

[h] Evidence of *K. pneumoniae* group was found in all 12 FP specimens; seven were enumerated below 10^3.5 CFU/mL by qRefCx, four were detected by qMol, and one was detected using an additional molecular method.

[i] Evidence of *M. catarrhalis* was found in all 29 FP specimens; two were enumerated below 10^3.5 CFU/mL by qRefCx, 25 were detected by qMol, and two were detected using an additional molecular method.

[j] Evidence of *Proteus* spp. was found in all four FP specimens; three were enumerated below 10^3.5 CFU/mL by qRefCx and one was detected by qMol.

[k] Evidence of *P. aeruginosa* was found in all 38 FP specimens; 19 were enumerated below 10^3.5 CFU/mL by qRefCx, 16 were detected by qMol, and three were detected using an additional molecular method.

[l] Evidence of *S. marcescens* was found in all six FP specimens; four were enumerated below 10^3.5 CFU/mL by qRefCx and two were detected by qMol.

[m] *S. aureus* was detected in the single FN specimen using an additional molecular method. Evidence of *S. aureus* was found in 69/70 FP specimens; 29 were enumerated below 10^3.5 CFU/mL by qRefCx, 30 were detected by qMol, eight were detected using an additional molecular method, and two were identified in SOC culture.

[n] Evidence of *S. agalactiae* was found in all 24 FP specimens; seven were enumerated below 10^3.5 CFU/mL by qRefCx, 13 were detected by qMol, and four were detected using an additional molecular method.

[o] Evidence of *S. pneumoniae* was found in all 24 FP specimens; five were enumerated below 10^3.5 CFU/mL by qRefCx, 18 were detected by qMol, and one was detected using an additional molecular method.

[p] Evidence of *S. pyogenes* was found in all six FP specimens; two were enumerated below 10^3.5 CFU/mL by qRefCx, three were detected by qMol, and one was detected using an additional molecular method.

[q] The single FP specimen was negative for *C. pneumoniae* when tested with additional molecular methods during discrepancy investigation.

[r] The single FP specimen was negative for *M. pneumoniae* when tested with additional molecular methods during discrepancy investigation.

[s] CoV was detected in 2/3 FN and 8/13 FP specimens using an additional molecular method.

[t] The single FP specimen was negative for hMPV when tested with additional molecular methods during discrepancy investigation.

[u] HRV/EV was detected in both FN specimens using an additional molecular method. HRV/EV was detected in 8/11 FP specimens during discrepancy investigation; seven were detected using an additional molecular method and one was detected upon FilmArray Pneumonia Panel *plus* retest.

[v] FluA was detected in 2/3 FP specimens using an additional molecular method.

[w] FluB was detected in the single FN specimen upon FilmArray Pneumonia Panel *plus* retest. FluB was detected in the single FP specimen using an additional molecular method.

[x] PIV was detected in both FN and both FP specimens using an additional molecular method.

Table 5. FilmArray Pneumonia Panel *plus* Clinical Performance Summary for Sputum Specimens[a]

Sputum							
Analyte	**Reference Method**	**Sensitivity/PPA**			**Specificity/NPA**		
		TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	PCR/Seq	0/0	-	-	836/836	100	99.5-100%
Bacteria							
***Acinetobacter calcoaceticus-baumannii* complex[b]**	qRefCx	10/11	90.9	62.3-98.4%	807/825	97.8	96.6-98.6%
***Enterobacter cloacae* complex[c]**	qRefCx	11/12	91.7	64.6-98.5%	803/824	97.5	96.1-98.3%
***Escherichia coli*[d]**	qRefCx	23/24	95.8	79.8-99.3%	787/812	96.9	95.5-97.9%
***Haemophilus influenzae*[e]**	qRefCx	16/18	88.9	67.2-96.9%	727/818	88.9	86.5-90.9%
***Klebsiella aerogenes*[f]**	qRefCx	3/4	75.0	30.1-95.4%	823/832	98.9	98.0-99.4%
***Klebsiella oxytoca*[g]**	qRefCx	9/9	100	70.1-100%	817/827	98.8	97.8-99.3%
***Klebsiella pneumoniae* group[h]**	qRefCx	21/23	91.3	73.2-97.6%	769/813	94.6	92.8-95.9%
***Moraxella catarrhalis*[i]**	qRefCx	5/5	100	56.6-100%	761/831	91.6	89.5-93.3%
***Proteus* spp.[j]**	qRefCx	15/15	100	79.6-100%	813/821	99.0	98.1-99.5%
***Pseudomonas aeruginosa*[k]**	qRefCx	103/106	97.2	92.0-99.0%	673/730	92.2	90.0-93.9%
***Serratia marcescens*[l]**	qRefCx	26/27	96.3	81.7-99.3%	782/809	96.7	95.2-97.7%
***Staphylococcus aureus*[m]**	qRefCx	111/112	99.1	95.1-99.8%	631/724	87.2	84.5-89.4%
***Streptococcus agalactiae*[n]**	qRefCx	9/9	100	70.1-100%	793/827	95.9	94.3-97.0%
***Streptococcus pneumoniae*[o]**	qRefCx	16/16	100	80.6-100%	785/820	95.7	94.1-96.9%
***Streptococcus pyogenes*[p]**	qRefCx	6/6	100	61.0-100%	825/830	99.4	98.6-99.7%
Atypical Bacteria							
Chlamydia pneumoniae	PCR/Seq	0/0	-	-	835/835	100	99.5-100%
***Legionella pneumophila*[q]**	PCR/Seq	0/1	0	-	826/826	100	99.5-100%
***Mycoplasma pneumoniae*[r]**	PCR/Seq	7/8	87.5	52.9-97.8%	827/827	100	99.5-100%
Viruses							

Sputum							
Analyte	Reference Method	Sensitivity/PPA			Specificity/NPA		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Adenovirus[s]	PCR/Seq	13/17	76.5	52.7-90.4%	815/817	99.8	99.1-99.9%
Coronavirus[t]	PCR/Seq	28/32	87.5	71.9-95.0%	796/802	99.3	98.4-99.7%
Human Metapneumovirus[u]	PCR/Seq	20/21	95.2	77.3-99.2%	812/813	99.9	99.3-100%
Human Rhinovirus/Enterovirus[v]	PCR/Seq	96/96	100	96.2-100%	717/730	98.2	97.0-99.0%
Influenza A[w]	PCR/Seq	13/13	100	77.2-100%	819/822	99.6	98.9-99.9%
Influenza B[x]	PCR/Seq	12/12	100	75.8-100%	821/823	99.8	99.1-99.9%
Parainfluenza Virus[y]	PCR/Seq	28/29	96.6	82.8-99.4%	804/806	99.8	99.1-99.9%
Respiratory Syncytial Virus[z]	PCR/Seq	43/43	100	91.8-100%	787/791	99.5	98.7-99.8%

[a] The performance measures of sensitivity and specificity only refer to the bacterial analytes for which the gold-standard of qRefCx was used as the reference method. Performance measures of PPA and NPA refer to all other analytes, for which PCR/sequencing assays were used as comparator methods.

[b] The isolate recovered from the single FN specimen was misidentified by qRefCx; molecular testing of the isolate identified it as *Pseudomonas fluorescens* during discrepancy investigation. Evidence of ACB complex was found in all 18 FP specimens; 15 were detected by qMol, two were detected using an additional molecular method, and one was identified in SOC culture.

[c] *E. cloacae* complex was detected in the single FN specimen using an additional molecular method. Evidence of *E. cloacae* complex was found in all 21 FP specimens; four were enumerated below 10^3.5 CFU/mL by qRefCx, 16 were detected by qMol, and one was detected using an additional molecular method.

[d] *E. coli* was observed in the single FN specimen below the 10^4 bin by the FilmArray Pneumonia Panel *plus*. Evidence of *E. coli* was found in all 25 FP specimens; six were enumerated below 10^3.5 CFU/mL by qRefCx, 14 were detected by qMol, and five were detected using an additional molecular method.

[e] *H. influenzae* was detected in 1/2 FN specimens by qMol. The isolate recovered from the other FN specimen was misidentified by qRefCx; molecular testing of the isolate identified it as *Haemophilus haemolyticus* during discrepancy investigation. Evidence of *H. influenzae* was found in all 91 FP specimens; four were enumerated below 10^3.5 CFU/mL by qRefCx, 78 were detected by qMol, seven were detected using an additional molecular method, and two were identified in SOC culture.

[f] The isolate recovered from the single FN specimen was misidentified by qRefCx; molecular testing of the isolate identified it as *Hafnia paralvei* during discrepancy investigation. Evidence of *K. aerogenes* was found in all nine FP specimens; three were enumerated below 10^3.5 CFU/mL by qRefCx, five were detected by qMol, and one was detected using an additional molecular method.

[g] Evidence of *K. oxytoca* was found in all 10 FP specimens; three were enumerated below 10^3.5 CFU/mL by qRefCx, five were detected by qMol, and two were detected using an additional molecular method.

[h] *K. pneumoniae* group was detected in 1/2 FN specimens by qMol. The other FN appeared to be a result of a specimen swap at the central reference laboratory. Evidence of *K. pneumoniae* group was found in 43/44 FP specimens; 15 were enumerated below 10^3.5 CFU/mL by qRefCx, 21 were detected by qMol, and seven were detected using an additional molecular method.

[i] Evidence of *M. catarrhalis* was found in all 70 FP specimens; one was enumerated below 10^3.5 CFU/mL by qRefCx, 63 were detected by qMol, five were detected using an additional molecular method, and one was identified in SOC culture.

[j] Evidence of *Proteus* spp. was found in all eight FP specimens; two were enumerated below 10^3.5 CFU/mL by qRefCx, four were detected by qMol, and two were detected using an additional molecular method.

[k] *P. aeruginosa* was observed in 1/3 FN specimens below the 10^4 bin by the FilmArray Pneumonia Panel *plus*. The isolates recovered from the other two FN specimens were misidentified by qRefCx; molecular testing of the isolates identified one as *Pseudomonas denitrificans* and the other as *Pseudomonas fluorescens* during discrepancy investigation. Evidence of *P. aeruginosa* was found in all 57 FP specimens; 21 were enumerated below 10^3.5 CFU/mL by qRefCx, 33 were detected by qMol, two were detected using an additional molecular method, and one was identified in SOC culture.

[l] *S. marcescens* was observed in the single FN specimen below the 10^4 bin by the FilmArray Pneumonia Panel *plus*. Evidence of *S. marcescens* was found in 26/27 FP specimens; seven were enumerated below 10^3.5 CFU/mL by qRefCx, 16 were detected by qMol, and three were detected using an additional molecular method.

[m] *S. aureus* was observed in the single FN specimen below the 10^4 bin by the FilmArray Pneumonia Panel *plus*. Evidence of *S. aureus* was found in all 93 FP specimens; 43 were enumerated below 10^3.5 CFU/mL by qRefCx, 43 were detected by qMol, three were detected using an additional molecular method, and four were identified in SOC culture.

[n] Evidence of *S. agalactiae* was found in all 34 FP specimens; five were enumerated below 10^3.5 CFU/mL by qRefCx, 24 were detected by qMol, and five were detected using an additional molecular method

[o] Evidence of *S. pneumoniae* was found in all 35 FP specimens; one was enumerated below 10^3.5 CFU/mL by qRefCx and 34 were detected by qMol.

[p] Evidence of *S. pyogenes* was found in all five FP specimens; four were detected by qMol and one was detected using an additional molecular method.

[q] *L. pneumophila* was detected in the single FN specimen using an additional molecular method.

[r] The single FN specimen was negative for *M. pneumoniae* when tested with an additional molecular method during discrepancy investigation.

[s] AdV was detected in all four FN and 1/2 FP specimens using an additional molecular method.

[t] CoV was detected in all four FN and 3/6 FP specimens using an additional molecular method.

[u] hMPV was detected in the single FN specimen using an additional molecular method. The single FP specimen was negative for hMPV when tested with an additional molecular method during discrepancy investigation.

[v] HRV/EV was detected in 12/13 FP specimens during discrepancy investigation; 11 were detected using an additional molecular method and one was detected upon FilmArray Pneumonia Panel *plus* retest.

[w] FluA was detected in all three FP specimens using an additional molecular method.

[x] Both FP specimens were negative for FluB when tested with additional molecular methods during discrepancy investigation.

[y] PIV was detected in the single FN and 1/2 FP specimens using an additional molecular method.

[z] RSV was detected in all four FP specimens using an additional molecular method.

A total of 156 BAL specimens and 295 sputum specimens received a FilmArray Pneumonia Panel *plus* Detected result for at least one applicable gram-negative bacterium on the panel and reported results for CTX-M, IMP, KPC, NDM, OXA-48-like, and VIM; a total of 94 BAL specimens and 196 sputum specimens received a FilmArray Pneumonia Panel *plus* Detected result for at least one applicable gram-negative bacterium on the panel and reported results for OXA-48-like; and a total of 116 BAL specimens and 204 sputum specimens received a FilmArray Pneumonia Panel *plus Staphylococcus aureus* Detected result and reported results for *mecA/C* and MREJ. Performance of the Pneumonia Panel *plus* AMR gene assays was calculated by comparing results of qMol direct from these specimens and is shown in Table 6 (five BAL and four sputum specimens were excluded from qMol analysis due to invalid comparator results).

Table 6. FilmArray Pneumonia Panel *plus* Clinical Performance Summary – AMR Genes (comparator method: qMol direct from specimen)[a]

Analyte	BAL						Sputum					
	PPA			NPA			PPA			NPA		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
CTX-M[b]	6/7	85.7	48.7-97.4%	144/144	100	97.4-100%	8/10	80.0	49.0-94.3%	280/281	99.6	98.0-99.9%
IMP	0/0	-	-	151/151	100	97.5-100%	0/0	-	-	291/291	100	98.7-100%
KPC[c]	2/2	100	34.2-100%	148/149	99.3	96.3-99.9%	7/7	100	64.6-100%	284/284	100	98.7-100%
***mecA/C* and MREJ[d]**	40/45	88.9	76.5-95.2%	64/70	91.4	82.5-96.0%	94/98	95.9	90.0-98.4%	91/104	87.5	79.8-92.5%
NDM[e]	0/1	0	-	149/150	99.3	96.3-99.9%	0/0	-	-	291/291	100	98.7-100%
OXA-48-like	0/0	-	-	92/92	100	96.0-100%	0/0	-	-	195/195	100	98.1-100%
VIM[f]	0/0	-	-	151/151	100	97.5-100%	1/1	100	-	289/290	99.7	98.1-99.9%

[a] Performance in this summary table is calculated when *any* applicable organism is detected in the sample.

[b] CTX-M was detected in the single FN BAL and 1/2 FN sputum specimens using an additional molecular method. The single FP sputum specimen was negative for CTX-M when tested during discrepancy investigation. None of the applicable isolates identified by the FilmArray or qRefCx from these specimens had evidence of ESBL activity or CTX-M presence.

[c] KPC was detected in the single FP BAL specimen using an additional molecular method; the isolate recovered from this specimen (*A. baumannii*) exhibited carbapenem resistance but did not carry KPC.

[d] Evidence of *mecA/C* and/or SCC*mec* cassette genetic elements was found in all five FN BAL and all four FN sputum specimens by an additional molecular method; three of these also had a MRSA isolate recovered via qRefCx or SOC culture. Evidence of *mecA/C* and/or SCC*mec* cassette genetic elements was found in 5/6 FP BAL and all 13 FP sputum specimens; nine had a MRSA isolate recovered via qRefCx or SOC culture, and nine additional specimens had evidence of *mecA/C* and/or SCC*mec* cassette genetic elements by an additional molecular method.

[e] NDM was detected in the single FN BAL specimen using an additional molecular method; *P. aeruginosa* was recovered from the specimen and was resistant to carbapenems but carried only KPC. The single FP BAL specimen was negative for NDM when tested with additional molecular methods during discrepancy investigation.

[f] The single FP sputum specimen was negative for VIM when tested with additional molecular methods during discrepancy investigation.

qRefCx isolated one or more applicable gram-negative bacteria from 127 of the 156 BAL specimens and 230 of the 295 sputum specimens that received a FilmArray Pneumonia Panel *plus* Detected result for an applicable gram-negative bacterium for CTX-M, IMP, KPC, NDM, and VIM. For informational purposes, the method used to assess correlation of the CTX-M, IMP, KPC, NDM, and VIM results (Table 7 and Table 8) reported in the specimen by the FilmArray Pneumonia Panel *plus* to identification of the gene in the cultured isolates from that particular specimen was one conventional PCR assay followed by bidirectional sequencing, performed directly on the isolate.

Table 7. CTX-M, IMP, KPC, NDM, and VIM Performance Table (PCR/seq on cultured isolate(s) from BAL specimens)

BAL													
Applicable Bacteria Result (FilmArray)	**N**	**CTX-M**		**IMP**		**KPC**		**NDM**		**VIM**		***Overall*** (any resistance gene)	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall *(any applicable bacteria Detected)*[a]	**127**	**4/4 (100%)**	**121/123 (98.4%)**	**0/0 (-)**	**127/127 (100%)**	**1/1 (100%)**	**124/126 (98.4%)**	**0/0 (-)**	**127/127 (100%)**	**0/0 (-)**	**127/127 (100%)**	**5/5 (100%) [56.6-100%]**	**118/122 (96.7%) [91.9-98.7%]**
Acinetobacter calcoaceticus-baumannii complex	0	-	-	-	-	-	-	-	-	-	-	-	-
Enterobacter cloacae complex	9	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)
Escherichia coli	12	4/4 (100%)	8/8 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	4/4 (100%)	8/8 (100%)
Klebsiella aerogenes	7	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)
Klebsiella oxytoca	2	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)
Klebsiella pneumoniae group	14	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)
Proteus spp.	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Pseudomonas aeruginosa	43	0/0 (-)	42/43 (97.7%)	0/0 (-)	43/43 (100%)	0/0 (-)	43/43 (100%)	0/0 (-)	43/43 (100%)	0/0 (-)	43/43 (100%)	0/0 (-)	42/43 (97.7%)
Serratia marcescens	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Polymicrobial specimens	28	0/0 (-)	27/28[b] (96.4%)	0/0 (-)	28/28 (100%)	1/1[c] (100%)	25/27[d] (92.6%)	0/0 (-)	28/28 (100%)	0/0 (-)	28/28 (100%)	1/1 (100%)	24/27 (88.9%)

[a] An additional nine specimens had no applicable bacteria detected by FilmArray, but had one or more applicable bacteria isolated by qRefCx; no resistance markers were identified in the cultured isolate(s) by PCR/seq from these specimens.

[b] One specimen *E. cloacae* complex and *K. pneumoniae* group detected by FilmArray (*E. cloacae* complex isolated by qRefCx; CTX-M was not identified in this isolate by PCR/seq)

[c] *E. cloacae* complex and *P. aeruginosa* detected by FilmArray and isolated by qRefCx (KPC identified from the *E. cloacae* isolate by PCR/seq)

[d] One specimen *A. calcoaceticus-baumannii* complex and *K. pneumoniae* group detected by FilmArray (*A. calcoaceticus-baumannii* complex isolated by qRefCx; KPC was not identified in this isolate by PCR/seq); one specimen *Proteus* spp. and *P. aeruginosa* detected by FilmArray (*P. aeruginosa* isolated by qRefCx; KPC was not identified in this isolated by PCR/seq)

Table 8. CTX-M, IMP, KPC, NDM, and VIM Performance Table (PCR/seq on cultured isolate(s) from sputum specimens)

Sputum													
Applicable Bacteria Result	**N**	**CTX-M**		**IMP**		**KPC**		**NDM**		**VIM**		***Overall*** **(any resistance gene)**	
		PPA	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**
Overall *(any applicable bacteria Detected)*[a]	**230**	**3/4 (75.0%)**	**221/226 (97.8%)**	**1/1 (100%)**	**229/229 (100%)**	**5/6 (83.3%)**	**223/224 (99.6%)**	**0/0 (-)**	**230/230 (100%)**	**1/1 (100%)**	**229/229 (100%)**	**9/11[b] (81.8%) [52.3-94.9%]**	**214/219 (97.7%) [94.8-99.0%]**
Acinetobacter calcoaceticus-baumannii complex	5[c]	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)
Enterobacter cloacae complex	7[d]	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)
Escherichia coli	10	1/1 (100%)	9/9 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	1/1 (100%)	9/9 (100%)
Klebsiella aerogenes	3	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)

Sputum													
Applicable Bacteria Result	**N**	**CTX-M**		**IMP**		**KPC**		**NDM**		**VIM**		***Overall* (any resistance gene)**	
		PPA	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**
Klebsiella oxytoca	4	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)
Klebsiella pneumoniae group	21	1/1 (100%)	20/20 (100%)	0/0 (-)	21/21 (100%)	1/1 (100%)	20/20 (100%)	0/0 (-)	21/21 (100%)	0/0 (-)	21/21 (100%)	2/2 (100%)	19/19 (100%)
Proteus spp.	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Pseudomonas aeruginosa	68	0/1 (0%)	65/67 (97.0%)	0/0 (-)	68/68 (100%)	0/1 (0%)	67/67 (100%)	0/0 (-)	68/68 (100%)	0/0 (-)	68/68 (100%)	0/2 (0%)	64/66 (97.0%)
Serratia marcescens	14[e]	0/0 (-)	14/14 (100%)	1/1 (100%)	13/13 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	1/1 (100%)	13/13 (100%)
Polymicrobial specimens	92	1/1[f] (100%)	88/91[g] (96.7%)	0/0 (-)	92/92 (100%)	4/4[h] (100%)	87/88[i] (98.9%)	0/0 (-)	92/92 (100%)	1/1[j] (100%)	91/91 (100%)	5/5 (100%)	84/87 (96.6%)

[a] An additional 19 specimens had no applicable bacteria detected by FilmArray, but had one or more applicable bacteria isolated by qRefCx; CTX-M was identified by PCR/seq in one specimen (E. coli isolated by qRefCx), but no other resistance markers were identified in the cultured isolate(s) by PCR/seq from these specimens

[b] One specimen had presence of dual AMR genes (KPC and VIM)

[c] An *A. calcoaceticus-baumannii* isolate was not recovered by qRefCx for one specimen

[d] An *E. cloacae* isolate was not recovered by qRefCx for one specimen

[e] A *S. marcescens* isolate was not recovered by qRefCx for one specimen

[f] *E. coli* and *P. aeruginosa* detected by FilmArray and isolated by qRefCx (CTX-M identified in the *E. coli* isolate by PCR/seq)

[g] One specimen *A. calcoaceticus-baumannii* complex, *K. pneumoniae* group, *Proteus* spp., and *P. aeruginosa* detected by FilmArray (*K. pneumoniae* group and *P. aeruginosa* isolated by qRefCx; CTX-M was not identified in either of these isolates by PCR/seq); one specimen *E. coli*, *K. pneumoniae* group, and *P. aeruginosa* detected by FilmArray (*E. coli* and *P. aeruginosa* isolated by qRefCx; CTX-M was not identified in either of these isolated by PCR/seq); one specimen *Proteus* spp. and *P. aeruginosa* detected by FilmArray (*P. aeruginosa* isolated by qRefCx; CTX-M was not identified in this isolate by PCR/seq)

[h] One specimen *E. coli* and *K. pneumoniae* group detected by FilmArray and isolated by qRefCx (KPC identified in the *K. pneumoniae* isolate by PCR/seq); one specimen *P. aeruginosa* and *S. marcescens* detected by FilmArray and isolated by qRefCx (KPC identified in the *S. marcescens* isolate by PCR/seq); one specimen *A. calcoaceticus-baumannii* complex, *K. aerogenes*, *K. pneumoniae* group, and *P. aeruginosa* detected by FilmArray (*A. calcoaceticus-baumannii*, *K. pneumoniae*, and *P. aeruginosa* isolated by qRefCx; KPC identified in the *K. pneumoniae* isolate by PCR/seq); one specimen *A. calcoaceticus-baumannii* complex, *K. pneumoniae* group, *Proteus* spp., and *P. aeruginosa* detected by FilmArray (*K. pneumoniae* and *P. aeruginosa* isolated by qRefCx; KPC identified in the *K. pneumoniae* isolate by PCR/seq)

[i] One specimen *K. pneumoniae* group and *P. aeruginosa* detected by FilmArray (*P. aeruginosa* isolated by qRefCx; KPC was not identified in this isolate by PCR/seq)

[j] One specimen A. calcoaceticus-baumannii complex, K. aerogenes, K. pneumoniae group, and P. aeruginosa detected by FilmArray (A. calcoaceticus-baumannii, K. pneumoniae, and P. aeruginosa isolated by qRefCx; VIM identified in the P. aeruginosa isolate by PCR/seq)

qRefCx isolated one or more applicable gram-negative bacteria from 79 of the 94 BAL specimens and 131 of the 196 sputum specimens that received a FilmArray Pneumonia Panel *plus* Detected result for an applicable gram-negative bacterium for OXA-48-like. For informational purposes, the method used to assess correlation of the OXA-48-like results (Table 9 and Table 10) reported in the specimen by the FilmArray Pneumonia Panel *plus* to identification of the gene in the cultured isolates from that particular specimen was one conventional PCR assay followed by bidirectional sequencing, performed directly on the isolate.

Table 9. OXA-48-like Performance Table (PCR/seq on cultured isolate(s) from BAL specimens)

BAL						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***0/0***	***-***	***-***	***79/79***	***100***	***95.4-100%***
Enterobacter cloacae complex	0/0	-	-	10/10	100	72.2-100%
Escherichia coli	0/0	-	-	13/13	100	77.2-100%
Klebsiella aerogenes	0/0	-	-	7/7	100	64.6-100%
Klebsiella oxytoca	0/0	-	-	3/3	100	43.9-100%
Klebsiella pneumoniae group	0/0	-	-	15/15	100	79.6-100%
Proteus spp.	0/0	-	-	6/6	100	61.0-100%
Serratia marcescens	0/0	-	-	8/8	100	67.6-100%
Polymicrobial specimens	0/0	-	-	17/17	100	81.6-100%

Table 10. OXA-48-like Performance Table (PCR/seq on cultured isolate(s) from sputum specimens)

Sputum						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***0/0***	***-***	***-***	***131/131***	***100***	***97.2-100%***
Enterobacter cloacae complex	0/0	-	-	9/9	100	70.1-100%
Escherichia coli	0/0	-	-	17/17	100	81.6-100%
Klebsiella aerogenes	0/0	-	-	4/4	100	51.0-100%
Klebsiella oxytoca	0/0	-	-	5/5	100	56.6-100%
Klebsiella pneumoniae group	0/0	-	-	25/25	100	86.7-100%
Proteus spp.	0/0	-	-	9/9	100	70.1-100%
Serratia marcescens	0/0	-	-	25/25	100	86.7-100%
Polymicrobial specimens	0/0	-	-	37/37	100	90.6-100%

qRefCx isolated *S. aureus* from 75 of 116 BAL specimens and 154 of 204 sputum specimens that received a FilmArray Pneumonia Panel *plus* *Staphylococcus aureus* Detected result. The method used to assess correlation of the *mecA/C* and MREJ results (Table 11 and Table 12) reported in the specimen by the FilmArray Pneumonia Panel to identification of the gene in the cultured isolates from that particular specimen was one conventional PCR assay followed by bidirectional sequencing, performed directly on the isolate.

Table 11. mecA/C and MREJ 3x3 Performance Table (qRefCx & PCR/seq on cultured isolate(s) from BAL specimens)

BAL					
S. aureus *mecA/C* and MREJ		**qRefCx: S. aureus PCR/seq: *mecA/C***			
		Org+ / Res+	**Org+ / Res-**	**Org -**	**Total**
FilmArray Result	**Org+ / Res+**	19	2	25	46
	Org+ / Res-	1	24	45	70
	Org -	0	1	729	730
	Total	20	27	799	846
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			19/20	95.0%	76.4-99.1%
Org+ / Res-			24/27	88.9%	71.9-96.1%
Org -			729/799	91.2%	89.1-93.0%
Interpretation			**PPA**	**NPA**	**Prevalence**
MRSA			19/20	799/826	46/846
			(95.0%)	(96.7%)	(5.4%)
MSSA			24/27	773/819	70/846
			(88.9%)	(94.4%)	(8.3%)
S. aureus			46/47	729/799	116/846
			(97.9%)	(91.2%)	(13.7%)

Table 12. mecA/C and MREJ 3x3 Performance Table (qRefCx & PCR/seq on cultured isolate(s) from sputum specimens)

Sputum					
S. aureus *mecA/C* and MREJ		**qRefCx: S. aureus PCR/seq: *mecA/C***			
		Org+ / Res+	**Org+ / Res-**	**Org -**	**Total**
FilmArray Result	**Org+ / Res+**	58	4	45	107
	Org+ / Res-	0	49	48	97
	Org -	0	1	631	632
	Total	58	54	724	836
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			58/58	100%	93.8-100%
Org+ / Res-			49/54	90.7%	80.1-96.0%
Org -			631/724	87.2%	84.5-89.4%
Interpretation			**PPA**	**NPA**	**Prevalence**
MRSA			58/58	729/778	107/836
			(100%)	(93.7%)	(12.8%)
MSSA			49/54	734/782	97/836
			(90.7%)	(93.9%)	(11.6%)
S. aureus			111/112	631/724	204/836
			(99.1%)	(87.2%)	(24.4%)

FilmArray Pneumonia Panel *plus* CTX-M reporting was also compared to the standard phenotypic extended spectrum β-lactamase (ESBL) activity testing methods performed in conjunction with qRefCx. Standard phenotypic ESBL activity was only reported for E. coli and Klebsiella spp. by the central reference laboratory.

Of the 156 BAL specimens that received a FilmArray Pneumonia Panel *plus* Detected result for at least one applicable gram-negative bacterium on the panel, 53 specimens received a Detected result for *E. coli*, *K. oxytoca*, and/or *K. pneumoniae*; qRefCx isolated *E. coli*, *K. oxytoca*, and/or *K. pneumoniae* from 43 of these specimens. Of the 295 sputum specimens that received a FilmArray Pneumonia Panel *plus* Detected result for at least one applicable gram-negative bacterium on the panel, 114 specimens received a Detected result for *E. coli*, *K. oxytoca*, and/or *K. pneumoniae*; qRefCx isolated *E. coli*, *K. oxytoca*, and/or *K. pneumoniae* from 71 of these specimens. The correlation between FilmArray Pneumonia Panel *plus* reporting of CTX-M in a particular specimen as compared to the phenotypic AST results of isolates recovered from the same specimen are stratified by each applicable associated organism in Table 13 and Table 14.

Table 13. CTX-M Performance Table (comparison to phenotypic AST methods for BAL specimens)

BAL						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***4/5***	***80.0***	***37.6-96.4%***	***38/38***	***100***	***90.8-100%***
Escherichia coli	4/4	100	51.0-100%	11/11	100	74.1-100%
Klebsiella oxytoca	0/0	-	-	5/5	100	56.6-100%
Klebsiella pneumoniae group	0/1	0	-	17/17	100	81.6-100%
Polymicrobial specimens	0/0	-	-	5/5	100	56.6-100%

Table 14. CTX-M Performance Table (comparison to phenotypic AST methods for sputum specimens)

Sputum						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***4/7***	***57.1***	***25.1-84.2%***	***63/64***	***98.4***	***91.7-99.7%***
Escherichia coli	2/3	66.7	20.8-93.9%	17/17	100	81.6-100%
Klebsiella oxytoca	0/0	-	-	9/9	100	70.1-100%
Klebsiella pneumoniae group	1/2	50.0	-	26/27	96.3	81.7-99.3%
Polymicrobial specimens	1/2[a]	50.0	-	11/11	100	74.1-100%

[a] One specimen *E. coli* and *K. oxytoca* detected by FilmArray and isolated by qRefCx (ESBL activity identified in the *E. coli* isolate by qRefCx AST); one specimen *E. coli* and *K. pneumoniae* group detected by FilmArray (*E. coli* isolated by qRefCx and ESBL activity identified by qRefCx AST).

The FilmArray Pneumonia Panel *plus* carbapenem resistance gene reporting was also compared to the standard phenotypic carbapenem susceptibility testing methods performed in conjunction with qRefCx. In accordance with current CLSI guidelines, standard phenotypic ertapenem susceptibility is not reported for *A. calcoaceticus-baumannii* complex; therefore carbapenem susceptibility is only based on meropenem susceptibility for this organism. Resistance or intermediate-resistance to either ertapenem or meropenem constituted carbapenem resistance for this analysis. The correlation between FilmArray Pneumonia Panel *plus* reporting of the carbapenem resistance genes in a particular specimen as compared to the phenotypic AST results of isolates recovered from the same specimen are stratified by each applicable associated organism in Table 15 and Table 16.

Table 15. IMP, KPC, NDM, and VIM Performance Table (comparison to phenotypic AST methods for BAL specimens)

BAL											
Applicable Bacteria Result	**N**	**IMP**		**KPC**		**NDM**		**VIM**		***Overall* (any carbapenem resistance gene)**	
		PPA	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**	**PPA**	**NPA**
Overall *(any applicable bacteria Detected)*	**126[a]**	**0/17 (0%)**	**109/109 (100%)**	**3/17 (17.6%)**	**109/109 (100%)**	**0/17 (0%)**	**109/109 (100%)**	**0/17 (0%)**	**109/109 (100%)**	**3/17 (17.6%) [6.2-41.0%]**	**109/109 (100%) [96.6-100%]**
Acinetobacter calcoaceticus-baumannii complex	0	-	-	-	-	-	-	-	-	-	-
Enterobacter cloacae complex	9	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)	0/0 (-)	9/9 (100%)
Escherichia coli	12	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)
Klebsiella aerogenes	7	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)	0/0 (-)	7/7 (100%)
Klebsiella oxytoca	2	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)
Klebsiella pneumoniae group	14	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)
Proteus spp.	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Pseudomonas aeruginosa	42	0/12 (0%)	30/30 (100%)	0/12 (0%)	30/30 (100%)	0/12 (0%)	30/30 (100%)	0/12 (0%)	30/30 (100%)	0/12 (0%)	30/30 (100%)
Serratia marcescens	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Polymicrobial specimens	28	0/5 (0%)	23/23 (100%)	3/5 (60.0%)	23/23 (100%)	0/5 (0%)	23/23 (100%)	0/5 (0%)	23/23 (100%)	3/5[b] (60.0%)	23/23 (100%)

[a] The isolate recovered from one specimen (*P. aeruginosa)* did not yield valid AST results on the VITEK instrument

[b] Of the three specimens that were concordant: one specimen A. calcoaceticus-baumannii complex and K. pneumoniae group detected by FilmArray (A. calcoaceticus-baumannii isolated by qRefCx, carbapenem resistance identified by qRefCx AST, and KPC not identified in the isolate by PCR/seq); one specimen E. cloacae complex and P. aeruginosa detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the E. cloacae isolate by qRefCx AST, and KPC identified in the E. cloacae isolate by PCR/seq); one specimen Proteus spp. and P. aeruginosa detected by FilmArray (P. aeruginosa isolated by qRefCx, carbapenem resistance identified by qRefCx AST, and KPC not identified in the isolate by PCR/seq). Of the two specimens that were not concordant: one specimen A. calcoaceticus-baumannii complex and P. aeruginosa detected by FilmArray (P. aeruginosa isolated by qRefCx, carbapenem resistance identified by qRefCx AST, and KPC not identified in the isolate by PCR/seq); one specimen E. cloacae complex and K. aerogenes detected by FilmArray (E. cloacae isolated by qRefCx, carbapenem resistance identified by qRefCx AST and KPC not identified in the isolate by PCR/seq).

Table 16. IMP, KPC, NDM, and VIM Performance Table (comparison to phenotypic AST methods for sputum specimens)

Sputum											
Applicable Bacteria Result	**N**	**IMP**		**KPC**		**NDM**		**VIM**		***Overall*** (any carbapenem resistance gene)	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall *(any applicable bacteria Detected)*	**229**[a]	**0/35 (0%)**	**194/194 (100%)**	**6/35 (17.1%)**	**193/194 (99.5%)**	**0/35 (0%)**	**194/194 (100%)**	**1/35 (2.9%)**	**194/194 (100%)**	**6/35**[b] **(17.1%) [8.1-32.7%]**	**193/194 (99.5%) [97.1-99.9%]**
Acinetobacter calcoaceticus-baumannii complex	5[c]	0/2 (0%)	3/3 (100%)	0/2 (0%)	3/3 (100%)	0/2 (0%)	3/3 (100%)	0/2 (0%)	3/3 (100%)	0/2 (0%)	3/3 (100%)
Enterobacter cloacae complex	7[d]	0/1 (0%)	6/6 (100%)	0/1 (0%)	6/6 (100%)	0/1 (0%)	6/6 (100%)	0/1 (0%)	6/6 (100%)	0/1 (0%)	6/6 (100%)
Escherichia coli	10	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)	0/0 (-)	10/10 (100%)
Klebsiella aerogenes	3	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)	0/0 (-)	3/3 (100%)
Klebsiella oxytoca	4	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)
Klebsiella pneumoniae group	21	0/2 (0%)	19/19 (100%)	1/2 (50.0%)	19/19 (100%)	0/2 (0%)	19/19 (100%)	0/2 (0%)	19/19 (100%)	1/2 (50.0%)	19/19 (100%)
Proteus spp.	6	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)	0/0 (-)	6/6 (100%)
Pseudomonas aeruginosa	67	0/16 (0%)	51/51 (100%)	0/16 (0%)	51/51 (100%)	0/16 (0%)	51/51 (100%)	0/16 (0%)	51/51 (100%)	0/16 (0%)	51/51 (100%)
Serratia marcescens	14[e]	0/1 (0%)	13/13 (100%)	1/1 (100%)	13/13 (100%)	0/1 (0%)	13/13 (100%)	0/1 (0%)	13/13 (100%)	1/1 (100%)	13/13 (100%)
Polymicrobial specimens	92	0/13 (0%)	79/79 (100%)	4/13 (30.8%)	78/79 (98.7%)	0/13 (0%)	79/79 (100%)	1/13 (7.7%)	79/79 (100%)	4/13[f] (30.8%)	78/79 (98.7%)

[a] The isolate recovered from one specimen (*P. aeruginosa)* did not yield valid AST results on the VITEK instrument

[b] One specimen had presence of dual AMR genes (KPC and VIM)

[c] An *A. calcoaceticus-baumannii* isolate was not recovered by qRefCx for one specimen

[d] An *E. cloacae* isolate was not recovered by qRefCx for one specimen

[e] A *S. marcescens* isolate was not recovered by qRefCx for one specimen

[f] Of the four specimens that were concordant: one specimen A. calcoaceticus-baumannii complex, K. aerogenes, K. pneumoniae group, and P. aeruginosa detected by FilmArray (A. calcoaceticus-baumannii, K. pneumoniae, and P. aeruginosa isolated by qRefCx, carbapenem resistance identified in all three isolates by qRefCx AST, KPC identified in the K. pneumoniae isolate by PCR/seq, and VIM identified in the P. aeruginosa isolate by PCR/seq); one specimen A. calcoaceticus-baumannii complex, K. pneumoniae group, Proteus spp., and P. aeruginosa detected by FilmArray (K. pneumoniae and P. aeruginosa isolated by qRefCx, carbapenem resistance identified in the K. pneumoniae isolate by qRefCx AST, and KPC identified in the K. pneumoniae isolate by PCR/seq); one specimen E. coli and K. pneumoniae group detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the K. pneumoniae isolate by qRefCx AST and KPC identified in the isolate by PCR/seq); one specimen P. aeruginosa and S. marcescens detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the S. marcescens isolate by qRefCx AST and KPC identified in the isolate by PCR/seq). Of the nine specimens that were not concordant: one specimen A. calcoaceticus-baumannii complex and Proteus spp. detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the A. calcoaceticus-baumannii isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq); one specimen E. cloacae complex and P. aeruginosa detected by FilmArray (P. aeruginosa isolated by qRefCx, carbapenem resistance identified by qRefCx AST, and KPC not identified in the isolate by PCR/seq); one specimen E. coli and P. aeruginosa detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the P. aeruginosa isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq); one specimen K. pneumoniae group and P. aeruginosa detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the K. pneumoniae isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq); one specimen Proteus spp. and P. aeruginosa detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the P. aeruginosa isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq); one specimen P. aeruginosa and S. marcescens detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the S. marcescens isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq); one specimen P. aeruginosa and S. marcescens detected by FilmArray (P. aeruginosa isolated by qRefCx, carbapenem resistance identified by qRefCx AST, and KPC not identified in the isolate by PCR/seq); one specimen A. calcoaceticus-baumannii complex, E. coli, K. pneumoniae group, and P. aeruginosa detected by FilmArray (E. coli and P. aeruginosa isolated by qRefCx, carbapenem resistance identified in the P. aeruginosa isolate by qRefCx AST, and KPC not identified in either isolate by PCR/seq); one specimen A. calcoaceticus-baumannii complex, Proteus spp., P. aeruginosa, and S. marcescens detected by FilmArray (Proteus spp. and P. aeruginosa isolated by qRefCx; carbapenem resistance identified in the P. aeruginosa isolate by qRefCx AST and KPC not identified in either isolate by PCR/seq).

Table 17. OXA-48-like Performance Table (comparison to phenotypic AST methods for BAL specimens)

BAL						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***0/2***	***0***	***-***	***77/77***	***100***	***95.2-100%***
Enterobacter cloacae complex	0/1	0	-	9/9	100	70.1-100%
Escherichia coli	0/0	-	-	13/13	100	77.2-100%
Klebsiella aerogenes	0/0	-	-	7/7	100	64.6-100%
Klebsiella oxytoca	0/0	-	-	3/3	100	43.9-100%
Klebsiella pneumoniae group	0/0	-	-	15/15	100	79.6-100%
Proteus spp.	0/0	-	-	6/6	100	61.0-100%
Serratia marcescens	0/0	-	-	8/8	100	67.6-100%
Polymicrobial specimens	0/1[a]	0	-	16/16	100	80.6-100%

[a] *E. cloacae* complex and *K. aerogenes* detected by FilmArray (*E. cloacae* complex isolated by qRefCx and carbapenem resistance identified by qRefCx AST)

Table 18. OXA-48-like Performance Table (comparison to phenotypic AST methods for sputum specimens)

Sputum						
Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***0/10***	***0***	***-***	***121/121***	***100***	***96.9-100%***
Enterobacter cloacae complex	0/1	0	-	8/8	100	67.6-100%
Escherichia coli	0/0	-	-	17/17	100	81.6-100%
Klebsiella aerogenes	0/0	-	-	4/4	100	51.0-100%
Klebsiella oxytoca	0/0	-	-	5/5	100	56.6-100%
Klebsiella pneumoniae group	0/3	0	-	22/22	100	85.1-100%
Proteus spp.	0/0	-	-	9/9	100	70.1-100%
Serratia marcescens	0/3	0	-	22/22	100	85.1-100%
Polymicrobial specimens	0/3[a]	0	-	34/34	100	89.8-100%

[a] One specimen *E. coli* and *K. pneumoniae* group detected by FilmArray and isolated by qRefCx (carbapenem resistance identified in the *K. pneumoniae* group isolate by qRefCx AST); one specimen *K. aerogenes* and *K. pneumoniae* group detected by FilmArray (*K. pneumoniae* group isolated by qRefCx and carbapenem resistance identified by qRefCx AST); one specimen *K. pneumoniae* group and *Proteus* spp. detected by FilmArray (*K. pneumoniae* group isolated by qRefCx and carbapenem resistance identified by qRefCx AST)

FilmArray Pneumonia Panel *plus mecA/C* and MREJ reporting was also compared to the standard phenotypic cefoxitin susceptibility testing methods performed in conjunction with qRefCx. The correlation between FilmArray Pneumonia Panel *plus* reporting of mecA/C and MREJ in a particular specimen as compared to the phenotypic AST results of isolates recovered from the same specimen is shown in Table 19 and Table 20.

Table 19. mecA/C and MREJ 3x3 Performance Table (qRefCx & phenotypic AST on cultured isolate(s) from BAL specimens)

BAL					
S. aureus mecA/C and MREJ		**qRefCx:** S. aureus **qRefCx Phenotypic AST:** cefoxitin susceptibility			
		Org+ / Res+	Org+ / Res-	Org -	Total
FilmArray Result	Org+ / Res+	18	3	25	46
	Org+ / Res-	1	24	45	70
	Org -	0	1	729	730
	Total	19	28	799	846
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			18/19	94.7%	75.4-99.1%
Org+ / Res-			24/28	85.7%	68.5-94.3%
Org -			729/799	91.2%	89.1-93.0%
Interpretation			**PPA**	**NPA**	**Prevalence**
MRSA			18/19	799/827	46/846
			(94.7%)	(96.6%)	(5.4%)
MSSA			24/28	772/818	70/846
			(85.7%)	(94.4%)	(8.3%)
S. aureus			46/47	729/799	116/846
			(97.9%)	(91.2%)	(13.7%)

Table 20. mecA/C and MREJ 3x3 Performance Table (qRefCx & phenotypic AST on cultured isolate(s) from sputum specimens)

Sputum					
S. aureus mecA/C and MREJ		**qRefCx:** S. aureus **qRefCx Phenotypic AST:** cefoxitin susceptibility			
		Org+ / Res+	Org+ / Res-	Org -	Total
FilmArray Result	Org+ / Res+	59	3	45	107
	Org+ / Res-	1	48	48	97
	Org -	0	1	631	632
	Total	60	52	724	836
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			59/60	98.3%	91.1-99.7%
Org+ / Res-			48/52	92.3%	81.8-97.0%
Org -			631/724	87.2%	84.5-89.4%
Interpretation			**PPA**	**NPA**	**Prevalence**
MRSA			59/60	728/776	107/836
			(98.3%)	(93.8%)	(12.8%)
MSSA			48/52	735/784	97/836
			(92.3%)	(93.8%)	(11.6%)
S. aureus			111/112	631/724	204/836
			(99.1%)	(87.2%)	(24.4%)

The FilmArray Pneumonia Panel *plus* bin performance compared to the quantitative molecular assay (qMol) comparator is shown for BAL (Table 21) and sputum (Table 22). The qMol values are broken into one-log ranges correlating to the reported semi-quantitative FilmArray Pneumonia Panel *plus* bins. The relationship between qMol quantitative bins in copies/mL and traditional culture quantification in CFU/mL is unknown.

Table 21. FilmArray Pneumonia Panel *plus* Overall Bin Performance Summary for BAL Specimens (qMol)

BAL							
qMol Binned Values[a] (copies/mL)		**ND to <10^3.5**	**10^4.0**	**10^5.0**	**10^6.0**	**≥10^7.0**	**Total**
FilmArray Bin (copies/mL)	ND	12025	35	5	0	2	12067
	10^4	47	48	21	0	1	117
	10^5	5	23	57	22	2	109
	10^6	3	3	29	40	13	88
	≥10^7	2	0	4	41	112	159
% concordant		**12025/12082 (99.5%)**	**48/109 (44.0%)**	**57/116 (49.1%)**	**40/103 (38.8%)**	**112/130 (86.2%)**	**12540**

[a] Shaded cells indicate results considered concordant between the FilmArray Pneumonia Panel *plus* and qMol.

Table 22. FilmArray Pneumonia Panel *plus* Overall bin performance for Sputum Specimens (qMol)

Sputum							
qMol Range of Values [a] (copies/mL)		**ND to <10^3.5**	**<10^4.0**	**<10^5.0**	**<10^6.0**	**≥10^7.0**	**Total**
FilmArray Bin (copies/mL)	ND	11392	85	17	2	2	11498
	10^4	79	87	41	7	0	214
	10^5	12	33	104	43	5	197
	10^6	2	4	39	88	41	174
	≥10^7	4	0	1	44	288	337
% concordant		**11392/11489 (99.2%)**	**87/209 (41.6%)**	**104/202 (51.5%)**	**88/184 (47.8%)**	**288/336 (67.9%)**	**12420**
			567/931 (60.9%)				

[a] Shaded cells indicate results considered concordant between the FilmArray Pneumonia Panel and qMol.

The FilmArray Pneumonia Panel bin performance compared to qRefCx quantification and semi-quantification values provided by the source lab is shown for BAL and sputum in Table 23 - Table 34. Data is shown for overall performance, as well as for some individual organisms. In these tables, the values reported by culture are broken into ranges. A FilmArray Pneumonia Panel bin *plus* result is considered concordant if the culture value is within 0.5 log of the bin boundary. For example, the 10^5 FilmArray Pneumonia Panel *plus* bin (10^4.5-10^5.5) is concordant with the culture range of 10^4-10^6 CFU/mL.

Table 23. FilmArray Pneumonia Panel *plus* Overall bin performance for BAL Specimens (qRefCx)

BAL							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin	ND	12202	1	2	0	0	0
	10^4	116	1	3	0	0	0

	10^5	90	10	11	0	1	0
	10^6	61	10	17	2	1	0
	≥10^7	61	10	36	32	11	12
% concordant		**12202/12530 (97.4%)**	**1/32 (3.1%)**	**14/69 (20.3%)**	**2/34 (5.9%)**	**12/13 (92.3%)**	**12/12 (100%)**
			41/160 (25.6%)				

Table 24. FilmArray Pneumonia Panel *plus* Overall bin performance for Sputum Specimens (qRefCx)

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	11596	4	6	2	0	1
	10^4	193	14	9	0	0	0
	10^5	139	19	28	14	1	0
	10^6	94	19	36	21	4	1
	≥10^7	121	8	88	53	49	20
% concordant		**11596/12143 (95.5%)**	**14/64 (21.9%)**	**37/167 (22.2%)**	**35/90 (38.9%)**	**53/54 (98.1%)**	**20/22 (90.9%)**
			159/397 (40.1%)				

Table 25. FilmArray Pneumonia Panel *plus H. influenzae* bin performance for BAL Specimens (qRefCx)

BAL							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	764	0	0	0	0	0
	10^4	17	0	0	0	0	0
	10^5	12	0	0	0	0	0
	10^6	13	2	0	0	0	0
	≥10^7	30	0	2	5	0	1
% concordant		**764/836 (91.4%)**	**0/2 (0%)**	**0/2 (0%)**	**0/5 (0%)**	**0/0 (-)**	**1/1 (100%)**
			1/10 (10.0%)				

Table 26. FilmArray Pneumonia Panel *plus H. influenzae* bin performance for Sputum Specimens (qRefCx)

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	727	0	1	1	0	0
	10^4	21	0	0	0	0	0
	10^5	19	0	0	1	0	0
	10^6	13	0	1	0	0	0
	≥10^7	38	0	10	2	2	0
% concordant		**727/818 (88.9%)**	**0/0 (-)**	**0/12 (0%)**	**1/4 (25.0%)**	**2/2 (100%)**	**0/0 (-)**
			3/18 (16.7%)				

Table 27. FilmArray Pneumonia Panel *plus P. aeruginosa* bin performance for BAL Specimens (qRefCx)

BAL							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	772	0	0	0	0	0
	10^4	12	0	1	0	0	0
	10^5	14	2	1	0	0	0
	10^6	5	1	2	1	1	0
	≥10^7	7	1	11	12	1	2
% concordant		**772/810 (95.3%)**	**0/4 (0.0%)**	**2/15 (13.3%)**	**1/13 (7.7%)**	**2/2 (100%)**	**2/2 (100%)**
			7/36 (19.4%)				

Table 28. FilmArray Pneumonia Panel *plus P. aeruginosa* bin performance for Sputum Specimens (qRefCx)

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	673	2	1	0	0	0
	10^4	16	3	1	0	0	0
	10^5	17	3	6	2	0	0
	10^6	12	4	8	3	1	0
	≥10^7	12	3	26	19	18	6
% concordant		**673/730 (92.2%)**	**3/15 (20.0%)**	**7/42 (16.7%)**	**5/24 (20.8%)**	**19/19 (100%)**	**6/6 (100%)**
			40/106 (37.7%)				

Table 29.FilmArray Pneumonia Panel *plus S. aureus* bin performance for BAL Specimens (qRefCx)

BAL							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	729	1	0	0	0	0
	10^4	33	0	0	0	0	0
	10^5	23	3	0	0	0	0
	10^6	13	2	7	1	0	0
	≥10^7	1	5	12	8	5	3
% concordant		**729/799 (91.2%)**	**0/11 (0.0%)**	**0/19 (0.0%)**	**1/9 (11.1%)**	**5/5 (100%)**	**3/3 (100%)**
			9/47 (19.1%)				

Table 30. FilmArray Pneumonia Panel *plus S. aureus* bin performance for Sputum Specimens (qRefCx)

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	631	1	0	0	0	0
	10^4	39	1	3	0	0	0
	10^5	33	7	8	4	1	0
	10^6	12	7	13	9	1	1

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
	≥10^7	9	2	21	15	11	7
% concordant		**631/724 (87.2%)**	**1/18 (5.6%)**	**11/45 (24.4%)**	**13/28 (46.4%)**	**12/13 (92.3%)**	**7/8 (87.5%)**
			44/112 (39.3%)				

Table 31. FilmArray Pneumonia Panel *plus S. pneumoniae* bin performance for BAL Specimens (qRefCx)

BAL							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	817	0	0	0	0	0
	10^4	8	1	0	0	0	0
	10^5	7	0	1	0	0	0
	10^6	5	0	1	0	0	0
	≥10^7	4	1	0	1	0	0
% concordant		**817/841 (97.1%)**	**1/2 (50.0%)**	**1/2 (50.0%)**	**0/1 (0.0%)**	**0/0 (-%)**	**0/0 (-%)**
			2/5 (40%)				

Table 32. FilmArray Pneumonia Panel *plus S. pneumoniae* bin performance for Sputum Specimens (qRefCx)

Sputum							
qRefCx Range of Values [CFU/mL] (Predicted FilmArray Bin)		**ND to <10^3.5** (ND)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)
FilmArray Bin (copies/mL)	ND	785	0	0	0	0	0
	10^4	10	2	0	0	0	0
	10^5	8	0	2	0	0	0
	10^6	9	1	0	0	0	0
	≥10^7	8	0	4	2	4	1
% concordant		**785/820 (95.7%)**	**2/3 (66.7%)**	**2/6 (33.3%)**	**0/2 (0.0%)**	**4/4 (100%)**	**1/1 (100%)**
			9/16 (56.3%)				

Table 33. FilmArray Pneumonia Panel *plus* Bin Performance Summary for BAL Specimens comparted to qRefCx

BAL						
qRefCx Range of Values (Concordant FilmArray Bin)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)	**Overall**
***Acinetobacter calcoaceticus-baumannii* complex**	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
***Enterobacter cloacae* complex**	0/1 (0%)	1/7 (14.3%)	0/3 (0%)	0/0 (-)	1/1 (100%)	2/12 (16.7%)
Escherichia coli	0/4 (0%)	1/7 (14.3%)	0/0 (-)	0/0 (-)	1/1 (100%)	2/12 (16.7%)
Haemophilus influenzae	0/2 (0%)	0/2 (0%)	0/5 (0%)	0/0 (-)	1/1 (100%)	1/10 (10.0%)
Klebsiella aerogenes	0/1 (0%)	1/2 (50.0%)	0/1 (0%)	2/3 (66.7%)	0/0 (-)	3/7 (42.9%)
Klebsiella oxytoca	0/0 (-)	1/2 (50.0%)	0/0 (-)	0/0 (-)	0/0 (-)	1/2 (50.0%)

BAL						
qRefCx Range of Values (Concordant FilmArray Bin)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)	**Overall**
***Klebsiella pneumoniae* group**	0/5 (0%)	3/5 (60.0%)	0/0 (-)	2/2 (100%)	3/3 (100%)	8/15 (53.3%)
Moraxella catarrhalis	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
***Proteus* spp.**	0/1 (0%)	1/1 (100%)	0/1 (0%)	1/1 (100%)	1/1 (100%)	3/5 (60.0%)
Pseudomonas aeruginosa	0/4 (0%)	2/15 (13.3%)	1/13 (7.7%)	2/2 (100%)	2/2 (100%)	7/36 (19.4%)
Serratia marcescens	0/1 (0%)	1/4 (25.0%)	0/1 (0%)	0/0 (-)	0/0 (-)	1/6 (16.7%)
Staphylococcus aureus	0/11 (0.0%)	0/19 (0%)	1/9 (11.1%)	5/5 (100%)	3/3 (100%)	9/47 (19.1%)
Streptococcus agalactiae	0/0 (-)	0/1 (0%)	0/0 (-)	0/0 (-)	0/0 (-)	0/1 (0%)
Streptococcus pneumoniae	1/2 (50.0%)	1/2 (50.0%)	0/1 (0%)	0/0 (-)	0/0 (-)	2/5 (40.0%)
Streptococcus pyogenes	0/0 (-)	2/2 (100%)	0/0 (-)	0/0 (-)	0/0 (-)	2/2 (100%)

Table 34. FilmArray Pneumonia Panel *plus* Bin Performance Summary for Sputum Specimens comparted to qRefCx

Sputum						
qRefCx Range of Values (Concordant FilmArray Bin)	**10^3.5 to <10^4.0** (10^4)	**10^4.0 to <10^5.0** (10^4 or 10^5)	**10^5.0 to <10^6.0** (10^5 or 10^6)	**10^6.0 to <10^7.0** (10^6 or 10^7)	**≥10^7.0** (≥10^7)	**Overall**
***Acinetobacter calcoaceticus-baumannii* complex**	1/5 (20.0%)	1/1 (100%)	0/2 (0%)	3/3 (100%)	0/0 (-)	5/11 (45.5%)
***Enterobacter cloacae* complex**	0/1 (0%)	3/6 (50.0%)	1/3 (33.3%)	1/1 (100%)	1/1 (100%)	6/12 (50.0%)
Escherichia coli	2/3 (66.7%)	1/13 (7.7%)	2/5 (40.0%)	1/1 (100%)	2/2 (100%)	8/24 (33.3%)
Haemophilus influenzae	0/0 (-)	0/12 (0%)	1/4 (25.0%)	2/2 (100%)	0/0 (-)	3/18 (16.7%)
Klebsiella aerogenes	1/1 (100%)	0/1 (0%)	0/1 (0%)	1/1 (100%)	0/0 (-)	2/4 (50.0%)
Klebsiella oxytoca	1/3 (33.3%)	0/3 (0%)	2/2 (100%)	1/1 (100%)	0/0 (-)	4/9 (44.4%)
***Klebsiella pneumoniae* group**	3/6 (50.0%)	2/7 (28.6%)	5/7 (71.4%)	2/2 (100%)	0/1 (0%)	12/23 (52.2%)
Moraxella catarrhalis	0/1 (0%)	0/1 (0%)	0/1 (0%)	1/1 (100%)	1/1 (100%)	2/5 (40.0%)
***Proteus* spp.**	0/1 (0%)	5/10 (50.0%)	2/3 (66.7%)	1/1 (100%)	0/0 (-)	8/15 (53.3%)
Pseudomonas aeruginosa	3/15 (20.0%)	7/42 (16.7%)	5/24 (20.8%)	19/19 (100%)	6/6 (100%)	40/106 (37.7%)
Serratia marcescens	0/4 (0%)	4/12 (33.3%)	3/6 (50.0%)	4/4 (100%)	1/1 (100%)	12/27 (44.4%)
Staphylococcus aureus	1/18 (5.6%)	11/45 (24.4%)	13/28 (46.4%)	12/13 (92.3%)	7/8 (87.5%)	44/112 (39.3%)
Streptococcus agalactiae	0/3 (0%)	1/5 (20.0%)	0/1 (0%)	0/0 (-)	0/0 (-)	1/9 (11.1%)
Streptococcus pneumoniae	2/3 (66.7%)	2/6 (33.3%)	0/2 (0%)	4/4 (100%)	1/1 (100%)	9/16 (56.3%)
Streptococcus pyogenes	0/0 (-)	0/3 (0%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	3/6 (50.0%)

A 'rank order' analysis was performed on polymicrobial specimens to compare the relative abundance of each analyte within a specimen as reported by qRefCx to the order reported by the FilmArray Pneumonia Panel *plus*. In this analysis, there were 20 specimens with two or more organisms reported by qRefCx for BAL and 84 for sputum. In these specimens, the FilmArray Pneumonia Panel *plus* was in agreement with SOC for the most abundant organism 78.8% of the time (41/52) for BAL and 85.9% of the time (85/99) for sputum. For the second most abundant organism, the FilmArray Pneumonia Panel *plus* was in agreement qRefCx for the most abundant organism 45.0% of the time (9/20) for BAL and 41.7% of the time (35/84) for sputum. For the second most abundant organism, the FilmArray Pneumonia Panel was in agreement with qRefCx 30.0% of the time (6/20) for BAL and 26.2% of the time (22/84) for sputum, and was in agreement for the third most abundant organism 7.7% of the time (1/13) for BAL and 3.8% of the time (2/52) for sputum.

Table 35. Concordance of Abundance in Polymicrobial Specimens (as compared to qRefCx)

Ranking Performance	BAL			Sputum		
	Correct	Total	%	Correct	Total	%
Most Abundant	9	20	45.0%	35	84	41.7%
Second Most Abundant	6	20	30.0%	22	84	26.2%
Third Most Abundant	1	13	7.7%	2	52	3.8%

'Rank concordance' analysis was performed on polymicrobial specimens to determine the ability of the FilmArray Pneumonia Panel to measure relative abundance of the nucleic acid for an organism with respect to other organisms in the specimen, as compared to qRefCx. In this analysis, the detected organisms from individual polymicrobial specimens (110 BAL and 246 sputum) were ranked in descending order based on their quantification values from qRefCx. The rank determined by the FilmArray Pneumonia Panel bin result was compared to the qRefCx ranking. False positives results were always considered discordant (i.e. only exact rank matches are considered concordant).

Table 36. Concordance of Organism Ranking in Polymicrobials Specimens (as compared to qRefCx); false positive results considered discordant

Ranking Performance	BAL			Sputum		
	Concordant	Total	%	Concordant	Total	%
***Acinetobacter calcoaceticus-baumannii* complex**	1	6	16.7%	7	25	28.0%
***Enterobacter cloacae* complex**	9	14	64.3%	9	25	36.0%
Escherichia coli	6	13	46.2%	14	39	35.9%
Haemophilus influenzae	9	47	19.1%	10	62	16.1%
Klebsiella aerogenes	4	9	44.4%	4	9	44.4%
Klebsiella oxytoca	3	10	30.0%	5	17	29.4%
***Klebsiella pneumoniae* group**	8	16	50.0%	15	43	34.9%
Moraxella catarrhalis	0	15	0.0%	3	59	5.1%
***Proteus* spp.**	2	6	33.3%	5	20	25.0%
Pseudomonas aeruginosa	17	25	68.0%	59	107	55.1%
Serratia marcescens	5	10	50.0%	17	43	39.5%
Staphylococcus aureus	30	55	54.5%	59	141	41.8%
Streptococcus agalactiae	6	19	31.6%	10	35	28.6%
Streptococcus pneumoniae	4	23	17.4%	7	37	18.9%
Streptococcus pyogenes	1	5	20.0%	2	5	40.0%

The overall success rate for initial specimen tests in the prospective study was 98.1% (1764/1798); 34 tests were unsuccessful (two due to an incomplete test and 32 due to control failures). Two tests (2/1798; 0.1%) did not complete on the initial run, resulting in an instrument success rate of 99.9% (1796/1798) for initial specimen tests. Both specimens were able to be retested and valid results were produced after a single retest.

Thirty-two (32) tests (32/1764; 1.8%) did not produce valid pouch controls, resulting in a pouch control success rate of 98.2% (1764/1796) for completed runs in the initial specimen tests. Twenty-eight (28) of the 32 invalid specimens were able to be retested; 25 produced valid control results after a single retest, while the remaining three did not produce valid control results after retesting and were not able to be retested further due to insufficient specimen volume; four were not able to be retested at all due to insufficient specimen volume. Three additional studies were also conducted to demonstrate all aspects of clinical performance (see Testing of Preselected Archived Specimens – MERS-CoV, Testing of Preselected Archived Specimens – Common Lower Respiratory Specimens, and Testing of Contrived Specimens below).

Testing of Preselected Archived Specimens – MERS-CoV

Some of the analytes on the FilmArray Pneumonia Panel *plus*, including MERS-CoV, were of low prevalence and were not encountered in large enough numbers during the prospective study to adequately demonstrate system performance. To supplement the results of the prospective clinical study, an evaluation of preselected archived retrospective specimens was performed. Due to the BSL3 requirements for handling specimens that are positive for MERS-CoV, testing of archived specimens containing this analyte was performed as a separate study. A summary of testing of for the rest of the archived specimens can be found in the Testing of Preselected Archived Specimens – Common Lower Respiratory Specimens section below.

In this study, eight bronchoalveolar lavage (BAL) and ten sputum specimens that tested positive for MERS-CoV during a 2015 outbreak in South Korea were evaluated using the FilmArray Pneumonia Panel *plus*. Testing was performed in the BSL3 laboratory at Seoul National University Hospital (Seoul, South Korea). At the completion of testing, one BAL specimen was excluded due to a MERS-CoV Equivocal result that could not be retested due to insufficient volume.

The FilmArray Pneumonia Panel plus demonstrated 100% positive percent agreement (PPA) with previous laboratory results for MERS-CoV for both BAL and sputum. NPA was not evaluated in this study. The performance for MERS-CoV is shown in Table 37.

Table 37. FilmArray Pneumonia Panel *plus* MERS-CoV Archived Specimen Performance Data Summary

Analyte	PPA		
	TP/(TP + FN)	%	95% CI
BAL			
MERS-CoV	7/7	100	64.6-100
Sputum			
MERS-CoV	10/10	100	72.3-100

Testing of Preselected Archived Specimens – Common Lower Respiratory Specimens

Some of the analytes on the FilmArray Pneumonia Panel *plus* were of low prevalence and were not encountered in large enough numbers during the prospective study to adequately demonstrate system performance. To supplement the results of the prospective clinical study, an evaluation of preselected archived retrospective specimens was performed at BioFire.

A total of 171 frozen archived specimens were received for testing from external laboratories. Eighteen (18) specimens were negatives (13 BAL and 5 sputum) and 153 specimens (139 BAL and 14 sputum) contained at least one analyte of interest. Twenty-two (22) specimens contained two or more analytes of interest. The set included specimens known to be positive for: *Acinetobacter calcoaceticus-baumannii* complex, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Proteus* spp., *Serratia marcescens*, *Streptococcus pyogenes*, *Chlamydia pneumoniae*, *Legionella pneumophila*, adenovirus, human metapneumovirus, influenza A, influenza B, parainfluenza virus (PIV), respiratory syncytial virus, various gram-negative bacteria with extended-spectrum β-lactamase (ESBL) phenotype, and various gram-negative bacteria with a carbapenem resistant phenotype.

Prior to testing with the FilmArray Pneumonia Panel *plus*, the composition/integrity of the specimens was first confirmed with confirmatory molecular methods. At the completion of testing, four specimens were excluded due to invalid confirmation tests; these specimens had insufficient volume for retesting. Results from the remaining 18 negative and 149 positive specimens (containing 173 analytes) are presented here.

The reported analyte (as determined by the source laboratory) was confirmed for 117 analytes (107 in BAL and 10 in sputum) of the expected positive results (117/173; 67.6 %). More than three quarters of the unconfirmed analytes were specimens previously identified as positive for gram-negative bacteria exhibiting phenotypic ESBL or carbapenamase activity (44/57; 77.2%). This is expected since this phenotypic activity can be conferred by alternative mechanisms beyond the antibiotic resistance genes found on the FilmArray Pneumonia Panel *plus*. Specimens with unconfirmed (or unexpected) analytes were excluded from performance calculations for that particular analyte and FilmArray test results are reported separately.

The FilmArray Pneumonia Panel *plus* demonstrated positive percent agreement (PPA) of 100% with previous laboratory results for 11 of 14 analytes tested in BAL specimens (Table 38) and all of the analytes tested in sputum specimens (Table 39). The exceptions were *Klebsiella aerogenes*, *Proteus* spp. and RSV with a PPA of 50.0%, 80.0%, and 93.8% respectively, due to one false negative (FN) for each analyte. While PPA for most analytes was 100%, an insufficient number of specimens were tested for all but influenza A, parainfluenza virus, and respiratory syncytial virus in BAL. Contrived specimen testing was used to demonstrate performance for these analytes in an additional contrived study (see Testing of Contrived Specimens). Negative percent agreement (NPA) was 100% for all analytes except parainfluenza virus in BAL and influenza A in sputum; however, NPA was more thoroughly evaluated in the prospective clinical study.

Table 38. FilmArray Pneumonia Panel *plus* Archived BAL Specimen Performance Data Summary

Analyte	PPA			NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Quantitative Bacteria						
Acinetobacter calcoaceticus-baumannii complex	4/4	100	51.0-100%	53/53	100	93.2-100%
Klebsiella aerogenes	1/2	50.0	-	53/53	100	93.2-100%
Proteus spp.	4/5	80.0	37.6-96.4%	48/48	100	92.6-100%

Analyte	PPA			NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Serratia marcescens	10/10	100	72.2-100%	46/46	100	92.3-100%
Streptococcus pyogenes	1/1	100	-	57/57	100	93.7-100%
Antimicrobial Resistance Genes						
CTX-M	7/7	100	64.6-100%	29/29	100	88.3-100%
Atypical Bacteria						
Chlamydia pneumoniae	1/1	100	-	90/90	100	95.9-100%
Legionella pneumophila	1/1	100	-	57/57	100	93.7-100%
Viruses						
Adenovirus	8/8	100	67.6-100%	81/81	100	95.5-100%
Human metapneumovirus	11/11	100	74.1-100%	77/77	100	95.2-100%
Influenza A	21/21	100	84.5-100%	69/69	100	94.7-100%
Influenza B	3/3	100	43.9-100%	86/86	100	95.7-100%
Parainfluenza virus	17/17	100	81.6-100%	68/69	99.0	92.2-99.7%
Respiratory syncytial virus	15/16	93.8	71.7-98.9%	74/74	100	95.1-100%

Table 39. FilmArray Pneumonia Panel *plus* Archived Sputum Specimen Performance Data Summary

Analyte	PPA			NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Quantitative Bacteria						
Streptococcus pyogenes	7/7	100	64.6-100%	8/8	100	67.6-100%
Antimicrobial Resistance Genes						
CTX-M	1/1	100	-	12/12	100	75.8-100%
Viruses						
Influenza A	2/2	100	34.2-100%	0/1	0	-

Testing of Contrived Specimens

A prospective clinical evaluation of the FilmArray Pneumonia Panel *plus* was performed during the 2016-2017 respiratory infection season at several geographically diverse clinical laboratories. Over 1600 specimens were analyzed from subjects whose specimens were submitted for microbial evaluation of lower respiratory tract pathogens. In the prospective study, some analytes were of insufficient prevalence to adequately demonstrate system performance and additional archived, preselected positive specimens containing rare analytes were also tested. Several analytes were so rare that both prospective and archived testing efforts were insufficient to demonstrate system performance. In this study, contrived clinical specimens were created to evaluate the sensitivity and specificity of the FilmArray Pneumonia Panel *plus* assays for these rare analytes (Table 40).

Table 40. Contrived Clinical Specimen Analytes

Analyte	Matrix	
	BAL	Sputum
Middle East Respiratory Syndrome Coronavirus	X	X
Bacteria		
Acinetobacter calcoaceticus-baumannii complex	X	
Klebsiella aerogenes	X	X

Klebsiella oxytoca	X	
Proteus spp.	X	
Serratia marcescens	X	
Streptococcus pyogenes	X	X
Atypical Bacteria		
Chlamydia pneumoniae	X	X
Legionella pneumophila	X	X
Mycoplasma pneumoniae	X	X
Viruses		
Adenovirus	X	X
Human metapneumovirus	X	X
Influenza A	X	X
Influenza B	X	X
Antibiotic Resistance Markers		
CTX-M	X	X
IMP	X	X
KPC	X	X
NDM	X	X
OXA-48 like	X	X
VIM	X	X

Contrived specimens (N=1225) were spiked using residual clinical samples that were pre-screened with the FilmArray Pneumonia Panel *plus* and found to be negative for the analytes of interest. Specimens were spiked with a variety of different isolates/strains for each organism at concentrations spanning observed ranges in clinical specimens. Different isolates of organisms were used from those used in analytical testing when possible. Samples positive for one analyte served as negatives for other analytes.

For the majority of analytes reported qualitatively, at least 25 of the contrived positive specimens had analyte concentrations at 2 × the limit of detection (LoD), while the remaining specimens were tested at additional concentrations that spanned clinically observed ranges. The "clinically observed range" was based on data from previous FilmArray Pneumonia Panel *plus* positive test results (e.g. observations from the prospective or archived studies). If a clinically observed range could not be determined for a particular analyte, specimens were spiked at various factors of LoD. If the stock concentration of organism did not allow for spiking at the highest level, the highest achievable level was used. For bacteria reported with binned values, specimens were spiked at various concentrations starting just below and then spanning the reported levels (i.e. 10^3 to ≥10^7 copies per milliliter (mL)).

Specimens were prepared and randomized at BioFire such that the analyte status of each contrived specimen was unknown to the users performing the testing. BAL and sputum specimens were analyzed separately; however, the preparation and testing for both matrices were identical. Contrived specimens were frozen, then distributed to prospective study sites and tested according to the prospective clinical study protocol alongside clinical (non-contrived) specimens.

The positive percent agreement (PPA) and negative percent agreement (NPA) for the FilmArray Pneumonia Panel *plus* assays were determined using standard binomial sampling statistics. In this study, a success was defined as agreement between the known composition of the contrived specimen and the

FilmArray Pneumonia Panel *plus* result; i.e., a positive FilmArray Pneumonia Panel *plus* result for spiked samples (True Positive, TP) and a negative FilmArray Pneumonia Panel *plus* result for un-spiked samples (True Negative, TN).

The results of the 1225 specimens tested in this study are summarized in Table 41 for BAL and Table 42 for sputum below.

The majority of analytes in both specimen types met the performance goals of 90% PPA with an 80% lower bound of the 95% CI and 98% NPA with a 95% lower bound of the 95% CI. The exceptions being influenza A spiked into BAL and *Klebsiella aerogenes* spiked into BAL and sputum. Influenza A spiked in BAL demonstrated 86% PPA in part due to two missed detections at 0.2 × LoD and two additional missed detections at 2 × LoD from a strain that may have been under-quantified. However, FilmArray performance goals for influenza A in BAL were achieved in the archived study. *Klebsiella aerogenes* spiked in both sample types demonstrated 85.5% PPA in part due to five missed detections in BAL and four missed detections in sputum at a range of concentrations from an *Klebsiella aerogenes* strain that demonstrated poor reactivity with the FilmArray Pneumonia Panel *plus*.

Samples spiked with bacterial analytes just below the 10^4 copies/mL binned value (*i.e.*, near 1.00E+03), and samples spiked with other analytes below their LoD (*i.e.*, near 0.2 × LoD), produced the expected unreliable detection.

Table 41. FilmArray Pneumonia Panel *plus* Performance of Contrived BAL Specimens

Analyte	Sensitivity/PPA			Specificity/NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Middle East Respiratory Syndrome Coronavirus	50/50	100	92.9-100%	604/604	100	99.4-100%
Bacteria						
Acinetobacter calcoaceticus-baumannii complex	47/50	94.0	83.8-97.9%	598/598	100	99.4-100%
Klebsiella aerogenes[a]	47/55	85.5	73.8-92.4%	592/594	99.7	98.8-99.9%
Klebsiella oxytoca	46/50	92.0	81.2-96.8%	604/604	100	99.4-100%
Proteus spp.	48/50	96.0	86.5-98.9%	603/603	100	99.4-100%
Serratia marcescens	49/50	98.0	89.5-99.6%	604/604	100	99.4-100%
Streptococcus pyogenes	49/50	98.0	89.5-99.6%	597/597	100	99.4-100%
Atypical Bacteria						
Chlamydia pneumoniae	47/50	94.0	83.8-97.9%	604/604	100	99.4-100%
Legionella pneumophila	50/50	100	92.9-100%	599/599	100	99.4-100%
Mycoplasma pneumoniae	48/50	96.0	86.5-98.9%	603/604	99.8	99.1-100%
Viruses						
Adenovirus	50/53	94.3	84.6-98.1%	568/569	99.8	99.0-100%
Human metapneumovirus	50/50	100	92.9-100%	597/598	99.8	99.1-100%
Influenza A[b]	43/50	86.0	73.8-93.0%	585/585	100	99.3-100%
Influenza B[c]	47/50	94.0	83.8-97.9%	588/589	99.8	99.0-100%
Antibiotic Resistance Markers						
CTX-M	130/130	100	97.1-100%	323/324	99.7	98.3-100%
IMP	45/45	100	92.1-100%	412/412	100	99.1-100%
KPC	53/53	100	93.2-100%	400/400	100	99.1-100%
NDM	53/53	100	93.2-100%	404/404	100	99.1-100%

Analyte	Sensitivity/PPA			Specificity/NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
OXA-48 like	53/53	100	93.2-100%	307/307	100	98.8-100%
VIM	58/58	100	93.8-100%	399/399	100	99.0-100%

[a] Five FN specimens were spiked with a *K. aerogenes* (previously *E.* aerogenes) strain (ATCC, 29751) that demonstrated poor reactivity with the FilmArray Pneumonia Panel *plus* (see Table 47).

[b] Two FN specimens were spiked with an influenza A strain that may have been under-quantified

[c] Three FN specimens were spiked with an influenza B strain that may have been under-quantified

Table 42. FilmArray Pneumonia Panel *plus* Performance of Contrived Sputum Specimens

Analyte	Sensitivity/PPA			Specificity/NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Middle East Respiratory Syndrome Coronavirus	49/49	100	92.7-100%	521/521	100	99.3-100%
Bacteria						
Klebsiella aerogenes[a]	47/55	85.5	73.8-92.4%	513/513	100	99.3-100%
Streptococcus pyogenes	48/50	96.0	86.5-98.9%	516/516	100	99.3-100%
Atypical Bacteria						
Chlamydia pneumoniae	49/50	98.0	89.5-99.6%	521/521	100	99.3-100%
Legionella pneumophila	50/50	100	92.9-100%	521/521	100	99.3-100%
Mycoplasma pneumoniae	48/50	96.0	86.5-98.9%	521/521	100	99.3-100%
Viruses						
Adenovirus	50/52	96.2	87.0-98.9%	494/494	100	99.2-100%
Human metapneumovirus	51/51	100	93.0-100%	520/520	100	99.3-100%
Influenza A[b]	47/50	94.0	83.8-97.9%	517/521	99.2	98.0-99.7%
Influenza B[c]	48/51	94.1	84.1-98%	516/517	99.8	98.9-100%
Antibiotic Resistance Markers						
CTX-M	121/122	99.2	95.6-99.9%	289/290	99.7	98.1-99.9%
IMP	43/44	97.7	88.2-99.6%	381/381	100	99.0-100%
KPC	54/54	100	93.4-100%	360/361	99.7	98.4-100%
NDM	53/53	100	93.2-100%	372/372	100	99.0-100%
OXA-48 like	51/51	100	93.0-100%	232/232	100	99.0-100%
VIM	56/56	100	93.6-100%	369/369	100	99.0-100%

[a] Four FN specimens were spiked with a *K. aerogenes* (previously *E.* aerogenes) strain (ATCC, 29751) that demonstrated poor reactivity with the FilmArray Pneumonia Panel *plus* (see Table 47).

[b] Two FN specimens were spiked with an influenza A strain that may have been under-quantified

[c] Two FN specimens were spiked with an influenza B strain that may have been under-quantified

Testing of Polymicrobial Contrived Specimens

Additionally, two sets of individual BAL (N=60) and sputum (N=60) specimens were multi-spiked with randomized low, medium and high relative concentrations of either *A. baumannii*, *E. cloacae*, and *E. coli* or *K. oxytoca*, *P. mirabilis*, and *S. marcescens*. As shown in Table 43 and Table 44, the majority of the spiked organisms were reported at the expected relative low, medium, or high bin level by the FilmArray Pneumonia Panel *plus*. In four BAL specimens, *E. cloacae* was intended to be spiked at a medium level but was reported in a in a high (≥10^7) bin. Also, one specimen spiked with a high level of *P. mirabilis* was not detected (i.e. a false negative result for *P. mirabilis*).

Table 43. Polymicrobial Sputum Specimen Results

Organism Spiked Into Sputum					
		FilmArray Result			Total
		Low	Medium	High	
Spike Level	Low (10^4 copies/mL)	60	0	0	60
	Medium ($10^{5.5}$ copies/mL)	0	60	0	60
	High (10^7 copies/mL)	0	0	60	60

Table 44. Polymicrobial BAL Specimen Results

Organism Spiked Into BAL					
		FilmArray Result			Total
		Low	Medium	High	
Spike Level	Low (10^4 copies/mL)	60	0	0	60
	Medium ($10^{5.5}$ copies/mL)	0	56	4[a]	60
	High (10^7 copies/mL)	0	0	59	59[b]

[a]Quantified at the bin boundary and reported as>=10^7
[b]One false negative result

Selected Analytical Studies

Limit of Detection

A limit of detection (LoD) was established for atypical bacteria and viruses detected by the FilmArray Pneumonia Panel *plus*. LoD was estimated by testing dilutions of contrived BAL or sputum samples containing known concentrations of organisms. Confirmation of LoD was achieved by testing at least 20 replicates per samples type on FilmArray, FilmArray 2.0 and FilmArray Torch systems (60 replicates total per sample type). LoD concentration was confirmed when the analyte was detected in at least 95% of the replicates tested.

The confirmed LoD for each atypical bacterium or virus (including a LoD for more than one isolate of the more genetically diverse viruses) is listed in Table 45. LoD concentration is based on quantification of each culture in viable units ($TCID_{50}$/mL or CFU/mL) and a corresponding molecular LoD concentration (DNA or RNA copies/mL) is provided based on quantitative real-time or digital PCR.

Table 45. Summary of Limit of Detection (LoD) for FilmArray Pneumonia *plus* Atypical Bacteria and Viruses

Analyte	Isolate Strain/Serotype/Source ID	LoD Concentration[a]	
		Viable Units	Molecular (DNA or RNA)
Atypical Bacteria			
Chlamydia pneumoniae	**TW183** ATCC VR-2282	5.0E-01 $TCID_{50}$/mL[b]	3.3E+02 copies/mL[b]
Legionella pneumophila	**Philadelphia-1** ATCC 33152	5.0E+02 CFU/mL	1.6E+03 copies/mL
Mycoplasma pneumoniae	**M129** Zeptometrix 0801579	7.5E+01 $TCID_{50}$/mL[b]	3.5E+03 copies/mL[b]
Viruses			
Middle East Respiratory Coronavirus	**EMC/2012** BEI NR-50171 (heat inactivated)	5.0E+01 $TCID_{50}$/mL[b]	3.2E+03 copies/mL[b]
Adenovirus	**Species A (A18)** ATCC VR-19	5.0E+01 $TCID_{50}$/mL	9.2E+03 copies/mL
	Species B (B3) Zeptometrix 0810062CF	1.0E+00 $TCID_{50}$/mL	1.8E+03 copies/mL
	Species C (C2) ATCC VR-846	5.0E+00 $TCID_{50}$/mL	7.5E+03 copies/mL
	Species D (D37) Zeptometrix 0810119CF	2.5E-01 $TCID_{50}$/mL[b]	2.9E+03 copies/mL[b]
	Species E (E4) Zeptometrix 0810070CF	1.0E-01 $TCID_{50}$/mL[b]	3.5E+04 copies/mL[b]
	Species F (F41) ATCC VR-930	5.0E+00 $TCID_{50}$/mL	5.5E+03 copies/mL
Coronavirus	**229E** ATCC VR-740	5.0E-01 $TCID_{50}$/mL	8.1E+01 copies/mL
	HKU1 Clinical Specimen[d]	-	1.0E+04 copies/mL
	NL63 BEI NR-470	2.5E+00 $TCID_{50}$/mL[c]	5.4E+02 copies/mL[c]
	OC43 ATCC VR-759	5.0E+02 $TCID_{50}$/mL[c]	9.3E+03 copies/mL[c]
Human Metapneumovirus	**16 Type A1** Zeptometrix 0810161CF	5.0E+01 $TCID_{50}$/mL	5.9E+03 copies/mL
Human Rhinovirus/ Enterovirus	**Rhinovirus Type 1A** Zeptometrix 810012CFN	1.5E+01 $TCID_{50}$/mL[b]	6.6E+03 copies/mL[b]
	Echovirus 6 Zeptometrix 0810076CF	1.0E+02 $TCID_{50}$/mL	5.7E+02 copies/mL

Analyte	Isolate Strain/Serotype/Source ID	LoD Concentration[a]	
		Viable Units	Molecular (DNA or RNA)
Influenza A	**H1N1pdm09** **A/SwineNY/03/09** Zeptometrix 0810249CF	2.5E+00 $TCID_{50}$/mL[c]	1.7E+03 copies/mL[c]
	H3N2 **A/Port Chalmers/1/73** ATCC VR-810	1.0E+00 $TCID_{50}$/mL[b]	2.1E+02 copies/mL[b]
Influenza B	**B/FL/04/06** Zeptometrix 0810255CF	5.0E+00 $TCID_{50}$/mL[c]	4.2E+02 copies/mL[c]
Parainfluenza Virus	**Type 1** Zeptometrix 0810014CF	2.5E+01 $TCID_{50}$/mL	5.2E+03 copies/mL
	Type 2 Zeptometrix 0810015CF	2.5E+01 $TCID_{50}$/mL[c]	1.5E+03 copies/mL[c]
	Type 3 Zeptometrix 0810016CF	2.5E+01 $TCID_{50}$/mL[c]	3.8E+02 copies/mL[c]
	Type 4A Zeptometrix 0810060CF	2.5E+02 $TCID_{50}$/mL	8.1E+03 copies/mL
Respiratory Syncytial Virus	**Type A** Zeptometrix 0810040ACF	1.0E+00 $TCID_{50}$/mL	4.3E+02 copies/mL

[a] The listed concentration was confirmed with ≥95% detection on each FilmArray system in artificial BAL (aBAL) and/or sputum.

[b] LoD confirmation (≥95% detection) was achieved at a 2 to 5-fold lower concentration in aBAL.

[c] LoD confirmation (≥95% detection) was achieved at a 2 to 5-fold lower concentration in sputum.

[d] No cultured isolates of Coronavirus HKU1 were available for testing.

Note: LoD concentrations of the cultured viruses and the obligate intracellular atypical bacteria (*C. pneumoniae* and *M. pneumoniae*) are provided in units of $TCID_{50}$ (50% Tissue Culture Infectious Dose). $TCID_{50}$ is an indirect measure of viral or bacterial concentration based on infectivity and cytotoxicity and will therefore vary considerably depending on technique and methodology (including cell type, culture media and conditions, cytotoxicity of the virus, etc.). It is not appropriate to make determinations on relative sensitivity of different molecular assays for detection of viruses and bacteria based on LoD values measured in $TCID_{50}$/mL. Concentrations are also presented in copies/mL based upon independent quantitative PCR assays (qPCR) or digital PCR. Note that the accuracy of qPCR assays may also be affected by assay conditions, the standard reference material, and sequence variance between strains.

No assay-specific LoD concentrations were determined for the bacterial analytes. For bacteria, the FilmArray Pneumonia Panel *plus* reports a Detected result when the estimated bacterial nucleic acid abundance is ≥10^3.5 copies/mL, and the panel reports a Not Detected result if there is no amplification or the estimated bacterial nucleic acid abundance is <10^3.5 copies/mL. Each assay was determined to be linear in relation to input concentration (slope ≈ 1.0 and coefficient of determination (Adj R^2) >0.95) and estimates of nucleic acid abundance and corresponding bin results were determined to be accurate within 0.5-log_{10} copies/mL when compared to a copies/mL input concentration determined by digital PCR.

Antimicrobial resistance (AMR) genes are reported as Detected when an applicable bacterium is detected and the assay for the AMR gene is positive. No AMR gene assay-specific LoD concentrations were determined for the AMR gene, but positive AMR gene assay results were recorded in ≥95% of 90 replicates of applicable bacteria tested at concentrations of 1.0E+04 copies/mL or less in the precision evaluation (see Precision below).

Analytical Reactivity (Inclusivity) for MERS-CoV

Due to limited availability of well-characterized MERS-CoV strains, empirical testing of MERS-CoV strains for assessment of analytical reactivity was also limited (one cultured MERS-CoV strain tested in the LoD study, an external quality assessment (EQA) panel from Quality Control Molecular Diagnostics (QCMD), and seventeen MERS-CoV positive clinical specimens collected and archived from the 2015 outbreak in South Korea).

Table 46. Middle East Respiratory Syndrome Coronavirus Isolates Tested and Detected

Organism	Strain/Location/Year	Source	Test Concentration		Result
			(copies/mL)	xLoD	
Middle East Respiratory Syndrome Coronavirus	EMC/2012	BEI NR-50171[a]	3.2E+03	1x	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Detected
	unknown	Quality Control Molecular Diagnostics (QCMD) 2017 MERS-CoV External Quality Assessment (EQA)	various[b]		
	South Korea 2015	7 clinical BAL specimens	unknown		
		10 clinical sputum specimens			

[a]Organism obtained through BEI Resources, NIAID, NIH: Middle East Respiratory Syndrome Coronavirus (MERS-CoV), EMC/2012, Heat-Inactivated, NR-50171.
[b] FilmArray Pneumonia Panel *plus* results for MERS-CoV and other coronaviruses was concordant with the indicated panel content for all samples tested.

Analytical reactivity of the FilmArray Pneumonia Panel *plus* MERS-CoV assays was further assessed by conducting *in silico* analyses of all publicly available virus sequences (as of March 2018) of human and camel host origin.

Based on an *in silico* analysis of 230 publicly available MERS-CoV sequences of human host that align with the MERS1 (M gene) assay primers and 221 publicly available MERS-CoV sequences of human host that align with the MERS2 (E gene) assay primers, there is no evidence of sequence variants that would contribute to altered or impaired reactivity with the MERS1 assay, and only two sequences with a >400 bp deletion between ORF5 and the E protein that could prevent reactivity with the MERS2 assay. The two variant sequences were obtained from a specimen taken from a single patient, and wild-type virus was also identified in this patient[1].

FilmArray Pneumonia Panel plus MERS1 and MERS2 assay primer sequences were also aligned with 240 and 241 (respectively) publicly available MERS-CoV sequences from camels (the suspected animal host reservoir for the virus). This analysis revealed only five sequences under the MERS1 assay primers (5/240) and one sequence under the MERS2 assay primers (1/241) with a single base mismatch near the 3' end of a primer that could moderately impair reactivity and detection at low viral concentrations.

Analytical Reactivity (Inclusivity) for Other Analytes

Analytical reactivity of FilmArray Pneumonia Panel *plus* assays was evaluated via a combination of empirical (wet) testing and *in silico* analysis of sequences available in public databases. Testing was performed on a collection of more than 350 genetically diverse viruses, bacteria, and antimicrobial resistance genes. The tested isolates representing relevant species, subspecies, strains, serotypes, or genotypes as well as temporal and geographic diversity for each of the panel analytes. Each isolate was tested in triplicate at concentrations near LoD or the lowest reportable level for the analyte. *In silico* analyses of sequence data from was also used to make predictions of assay reactivity for less common strains or serotypes and AMR gene types that were not tested but that may be detected by the FilmArray Pneumonia Panel *plus* assays.

Atypical bacteria and viruses were tested and detected at concentrations within 3× LoD (Table 48 -Table 58). Bacteria were tested at a concentration of 1.0E+04 copies/mL (based on digital PCR of a single-copy

gene in the bacterial chromosome) and the majority of isolates (94.4%) were detected with the expected bin result (Table 59 - Table 73) and when the bacterium was detected, the appropriate associated AMR gene(s) were also detected (Table 74 - Table 81).

Limitations on assay reactivity (based on wet testing observations) with specific viral and bacterial isolates or sequences and AMR gene types or sequences are noted in Table 47. Most limitations are associated with single-base sequence variants under one or more assay primers. Additional predicted limitations on reactivity based on sequence analysis are provided in the analyte-specific tables below.

Note: FilmArray Pneumonia Panel plus Influenza A and Influenza B assays are predicted to react with attenuated viruses used in vaccines.

Table 47. Limitations on Analytical Reactivity of FilmArray Pneumonia Panel *plus* Assays

Limitation	Observed/Predicted Result[a]	Analyte	Strain/Isolate/Variant
Minor	**Detected** may be under-reported by one bin (≤10-fold)	*Enterobacter cloacae* complex	*Enterobacter hormaechei* (ATCC 49162)[a]
		Klebsiella pneumoniae group	*Klebsiella quasipneumoniae* subsp. *quasipneumoniae* (DSM 28211)[b]
		Moraxella catarrhalis	*Moraxella catarrhalis* (ATCC 23246)[c]
		Streptococcus pyogenes	*Streptococcus pyogenes* (ATCC 19615)
Major	**Detected** may be under-reported by two or more bins (>10-fold)	*Enterobacter cloacae* complex	*Enterobacter asburiae* (ATCC 35953, 35954, 35955, and 35957)[e]
		Klebsiella aerogenes	*Klebsiella (Enterobacter) aerogenes* (ATCC 29751)[d]
		mecA/C and MREJ	MREJ type xv
	Not Detected	*Acinetobacter calcoaceticus-baumannii* complex	*Acinetobacter nosocomialis* (ATCC 700472)[f]
		Pseudomonas aeruginosa	*Pseudomonas aeruginosa* (ATCC 25619)[g]
		mecA/C and MREJ	MREJ type xviii MREJ type xix

[a] Minor limitation observed for this isolate due to sequence variant under a primer. Similar limitation predicted for two *E. hormaechei* sequences (3.0%) from public databases.

[b] Minor limitation observed for this isolate due to sequence variant under a primer. Similar limitation predicted for one *K. quasipneumoniae* sequence (20.0%) from public databases. Additional minor or major limitation predicted for four *K. pneumoniae* sequences (0.3%) from public databases.

[c] Minor limitation observed for this isolate. Additional minor or major limitation predicted for two *M. catarrhalis* sequences (3.3%) from public databases.

[d] Major limitation observed or predicted for these isolates due to sequence variance under primer. Similar limitation predicted for five *E. asburiae* sequences (10.9%), eight *E. cloacae* sequences (2.2%), and two *E. ludwigii* sequences (16.7%) from public databases.

[e] Major limitation observed for this isolate due sequence variance under primers. Similar limitation predicted for six *K. aerogenes* sequences (4.3%) from public databases

[f] ATCC 700472 could not be confirmed as *A. nosocomialis* by sequence and may be a non-*Acinetobacter calcoaceticus-baumannii* complex species that has been mis-identified.

[g] Major limitation observed for this isolate due to sequence variant under a primer. Similar limitation predicted for one *P. aeruginosa* sequence (0.7%) from public databases.

Table 48. Adenovirus Isolates Tested and Detected

Organism	Species	Serotype [a]	Source [Strain/Location/Year]	Test Concentration		Result
				(copies/mL)	xLoD	
Adenoviruses	A	18	ATCC VR-19 [Washington D.C./1954]	9.2E+03	1x	Adenovirus Detected
		12	ATCC VR-863 [Huie/Massachusetts]	2.7E+04	3x	
		31	Zeptometrix 0810073CF	2.7E+04	3x	
	B	3	Zeptometrix 0810062CF	1.8E+03	1x	
		7	ATCC VR-7 [Gomen/California/1954]	5.3E+03	3x	
		7A	Zeptometrix 0810021CF	5.3E+03	3x	
		7d/d2	Univ of Iowa Research Foundation [Iowa/2001]	5.3E+03	3x	
		7h	Univ of Iowa Research Foundation [Iowa/1999]	5.3E+03	3x	
		11	ATCC VR-12 [Slobitski/Massachusetts]	5.3E+03	3x	
		14	ATCC VR-15 [De Wit/Netherlands/1955]	5.3E+03	3x	

Organism	Species	Serotype [a]	Source [Strain/Location/Year]	Test Concentration		Result
				(copies/mL)	xLoD	
		16	ATCC VR-17 [CH.79/Saudi Arabia/1955]	5.3E+03	3x	
		21	ATCC VR-1833 [128/Saudi Arabia/1956]	5.3E+03	3x	
		34	ATCC VR-716 [Compton/1972]	5.3E+03	3x	
		35	ATCC VR-718 [Holden]	5.3E+03	3x	
		50	ATCC VR-1602 [Wan/Amsterdam/1988]	5.3E+03	3x	
	C	2	ATCC VR-846 [Adenoid 6]	7.5E+03	1x	
		1	Zeptometrix 0810050CF	2.3E+04	3x	
		5	Zeptometrix 0810020CF	2.3E+04	3x	
		6	ATCC VR-6 [Tonsil 99]	2.3E+04	3x	
	D	37	Zeptometrix 08100119CF	5.8E+02	1x	
		8	Zeptometrix 0810069CF	1.7E+03	3x	
		20	Zeptometrix 0810115CF	1.7E+03	3x	
	E	4	Zeptometrix 0810070CF	1.7E+04	1x	
		4	ATCC VR-1572 [RI-67/Missouri/1952-1953]	1.0E+04	0.6x	
		4a	Univ of Iowa Research Foundation [S Carolina/2004]	1.0E+04	0.6x	
	F	41	ATCC VR-930 [Tak 73-3544/ Netherlands/1973]	5.5E+03	1x	
		40	NCPV 0101141v	1.6E+04	3x	
		40	Zeptometrix 0810084CF	1.6E+04	3x	
		41	Zeptometrix 0810085CF	1.6E+04	3x	

[a] *In silico* analysis of available sequences predicts that the FilmArray Pneumonia Panel *plus* will also react with Adenovirus B55, C57, all species D serotypes, and G52.

Table 49. Coronavirus Isolates Tested and Detected

Organism	Type	Source [Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
Coronavirus	229E	ATCC VR-740	8.1E+01	1x	Coronavirus Detected
		Zeptometrix 0810229CF	2.4E+02	3x	
	HKU1[a]	Clinical Specimen [Utah/2015]	1.0E+04	1x	
		Clinical Specimen [Detroit/2010]	3.0E+04	3x	
		Clinical Specimen [Utah/2015]	3.0E+04	3x	
		Clinical Specimen [Utah/2015]	3.0E+04	3x	
		Clinical Specimen [S Carolina/2010]	3.0E+04	3x	
	NL63	BEI NR-470[b] [Amsterdam/2003]	2.7E+02	1x	
		Zeptometrix 0810228CF	8.0E+02	3x	
	OC43	ATCC VR-759[c]	4.6E+03	1x	
		Zeptometrix 0810024CF	1.4E+04	3x	

[a] No cultured isolates of Coronavirus HKU1 were available for testing. Five clinical NPS specimens containing Coronavirus HKU1 were collected from different regions of the US in 2010 and 2015, quantified molecularly, and tested.

[b] Organism obtained through the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH: Human Coronavirus NL63, NR-470.

[c] Discontinued part #. See ATCC VR-1558.

Table 50. Human Metapneumovirus Isolates Tested and Detected

Organism	Genotype	Serotype	Source [Location/Year]	Test Concentration		Result
				($TCID_{50}$/mL)	xLoD	
Human Metapneumovirus	A1	16	Zeptometrix 0810161CF [Iowa10/2003]	5.0E+01	1x	Human Metapneumovirus Detected
		9	Zeptometrix 0810160CF [Iowa3/2002]	1.5E+02	3x	
	A2	20	Zeptometrix 0810163CF [Iowa14/2003]	1.5E+02	3x	
		27	Zeptometrix 0810164CF [Iowa27/2004]	1.5E+02	3x	
	B1	3	Zeptometrix0810156CF [Peru2/2002]	1.5E+02	3x	
		5	Zeptometrix 0810158CF [Peru3/2003]	1.5E+02	3x	
	B2	8	Zeptometrix 0810159CF [Peru6/2003]	1.5E+02	3x	
		4	Zeptometrix 0810157CF [Peru1/2002]	1.5E+02	3x	
		18	Zeptometrix 0810162CF [Iowa18/2003]	1.0E+02	3x	

Table 51. Human Rhinovirus and Enterovirus Isolates Tested and Detected

Species	Serotype	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
Human Rhinovirus[a]					
A	1	Zeptometrix 0810012CFN [1A]	2.2E+03	1x	Human Rhinovirus/ Enterovirus Detected
	2	ATCC VR-482 [HGP]	1.7E+03	3x	
	7	ATCC VR-1601 [68-CV11]	1.7E+03	3x	
	16	ATCC VR-283 [11757/Washington DC/1960]	1.7E+03	3x	
	34	ATCC VR-507[b] [137-3]	1.7E+03	3x	
	57	ATCC VR-1600 [Ch47]	1.7E+03	3x	
	77	ATCC VR-1187 [130-63]	1.7E+03	3x	

Species	Serotype	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
	85	ATCC VR-1195 [50-525-CV54]	1.7E+03	3x	
B	3	ATCC VR-483 [FEB]	1.7E+03	3x	
	14	ATCC VR-284 [1059/S Carolina/1959]	1.7E+03	3x	
	17	ATCC VR-1663 [33342/N Carolina/1959]	1.7E+03	3x	
	27	ATCC VR-1137 [5870]	1.7E+03	3x	
	42	ATCC VR-338 [56822]	1.7E+03	3x	
	83	ATCC VR-1193 [Baylor 7]	1.7E+03	3x	
Enterovirus					
A	Coxsackievirus 10	ATCC VR-168 [NY/1950]	1.7E+03	3x	Human Rhinovirus/ Enterovirus Detected
	Enterovirus 71	ATCC VR-1432 [H]	1.7E+03	3x	
B	Coxsackievirus A9	Zeptometrix 0810017CF	1.7E+03	3x	
	Coxsackievirus B3	Zeptometrix 0810074CF	1.7E+03	3x	
	Coxsackievirus B4	Zeptometrix 0810075CF	1.7E+03	3x	
	Echovirus 6	Zeptometrix 0810076CF	5.7E+02	1x	
	Echovirus 9	Zeptometrix 0810077CF	1.7E+03	3x	
	Echovirus 11	Zeptometrix 0810023CF	1.7E+03	3x	
C	Coxsackievirus A21	ATCC VR-850 [Kuykendall/California/1952]	1.7E+03	3x	
	Coxsackievirus A24	ATCC VR-583 [DN-19/Texas/1963]	1.7E+03	3x	
D	Enterovirus 68	ATCC VR-1823 [US/MO/2014-18947]	1.7E+03	3x	

[a] The concentration used for Human Rhinovirus isolate testing was based on 3× the Enterovirus LoD concentration (5.7E+02 copies/mL).

[b] Discontinued part #; see ATCC VR-1365.

Table 52. Influenza A Isolates Tested and Detected

Organism	Subtype	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/ mL)	xLoD	
Influenza A	**Human**				Influenza A Detected
	H1N1	ATCC VR-219 [NWS/1933]	3.1E+02	3x	
		ATCC VR-95 [PR/8/1934a]	1.0E+03	1.5x[a]	
		ATCC VR-96 [Wiess/1943]	3.1E+02	3x	
		ATCC VR-97 [FM/1/1947]	3.1E+02	3x	
		ATCC VR-98 [Mal/302/1954]	3.1E+02	3x	
		ATCC VR-546 [Denver/1/1957]	3.1E+02	3x	
		Zeptometrix 0810036CF [New Caledonia/20/1999]	3.1E+02	3x	
		Zeptometrix 0810036CFN [Solomon Islands/3/2006]	3.1E+02	3x	
		Zeptometrix 0810244CF [Brisbane/59/2007]	3.1E+02	3x	
	H1N2	BEI NR-3478[b] [Kilbourne F63 A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA)]	3.1E+02	3x	
	H1N1pdm09	Zeptometrix 0810249CF [SwineNY/03/2009]	6.6E+02	1x	
		Zeptometrix 0810109CFJ [Canada/6294/2009]	3.1E+02	3x	
		Zeptometrix 0810165CF [California/07/2009]	3.1E+02	3x	
		Zeptometrix 0810166CF [Mexico/4108/2009]	3.1E+02	3x	
		BEI NR-19823[c] [Netherlands/2629/2009]	3.1E+02	3x	
		BEI NR-42938[d] [Georgia/F32551/2012]	3.1E+02	3x	
		BEI NR-44345[e] [Hong Kong/H090-761-V1(0)/2009]	1.0E+03	1.5x[a]	
	H3N2	ATCC VR-810 [Port Chalmers/1/1973]	1.0E+02	1x	
		ATCC VR-776 [Alice (live attenuated vaccine)]	3.1E+02	3x	
		Zeptometrix 0810238CF [Texas /50/2012]	3.1E+02	3x	
		ATCC VR-547 [Aichi/2/1968]	3.1E+02	3x	
		ATCC VR-544 [Hong Kong/8/1968]	3.1E+02	3x	
		ATCC VR-822 [Victoria/3/1975]	3.1E+02	3x	
		Zeptometrix 0810252CF [Wisconsin/67/2005]	3.1E+02	3x	
		Zeptometrix 0810138CF [Brisbane/10/2007]	3.1E+02	3x	
	H3N2v	ODHL1 [Ohio/2012]	3.1E+02	3x	
	Avian				
	H2N2	BEI NR-2775[f] [Japan/305/1957]	3.1E+02	3x	
	H2N3	MRIGlobal[g] [Mallard/Alberta/79/2003]	3.1E+02	3x	
	H5N1	MRIGlobal[g] [Chicken/Yunnan/1251/2003]	3.1E+02	3x	
	H5N2	MRIGlobal[g] [Northern pintail/Washinton/40964/2014]	3.1E+02	3x	
	H5N3	BEI NR-9682[h] [Duck/Singapore/645/97]	3.1E+02	3x	
	H5N8	MRIGlobal[g] [Gyrfalcon/Washing-ton/41088-6/2014]	3.1E+02	3x	
	H7N7	MRIGlobal[g] [Netherlands/219/2003]	3.1E+02	3x	
	H7N9	MRIGlobal[g] [Anhui/01/2013]	3.1E+02	3x	
	H10N7	BEI NR-2765[i] [Chicken/Germany/N/49]	3.1E+02	3x	
	Swine				

Organism	Subtype	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
	H1N1 Swine	ATCC VR-333 [Swine/Iowa/15/1930]	3.1E+02	3x	
		ATCC VR-99 [Swine/1976/1931]	3.1E+02	3x	

[a] 1.5x the LoD for Influenza A H1N1pdm09 Zeptometrix 0810109CFN [SwineNY/03/2009] (6.6E+02 copies/mL).

[b] Genomic RNA obtained through BEI Resources NAID, NIH: Kilbourne F63: A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA) (H1N2), Reassortant NWS-F, NR-9677.

[c] Virus obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Netherlands/2629/2009 (H1N1)pdm09, NR-19823

[d] Virus obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Georgia/F32551/2012 (H1N1)pdm09, NR-42938.

[e] Virus obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Hong Kong/H090-761-V1(0)/2009 (H1N1)pdm09, NR-44345.

[f] Genomic RNA obtained through BEI Resources, NIAID, NIH: Genomic RNA from Influenza A Virus, A/Japan/305/1957 (H2N2), NR-2775.

[g] Isolate provided and tested by MRI Global, Kansas City, MO.

[h] Genomic RNA obtained through BEI Resources, NIAID, NIH: Genomic RNA from Influenza A Virus, A/duck/Singapore/645/1997 (H5N3), Wild Type, NR-9682.

[i] Genomic RNA obtained through BEI Resources, NIAID, NIH: Genomic RNA from Influenza A Virus, A/chicken/Germany/N/1949 (H10N7), NR-2765.

Table 53. Influenza B Isolates Tested and Detected

Organism	Lineage	[Strain/Location/Year], Source	Test Concentration		Reported Result
			(copies/mL)	xLoD	
Influenza B	N/A	ATCC VR-101 [Lee/1940]	6.3E+02	3x	Influenza B Detected
		ATCC VR-102 [Allen/1945]	6.3E+02	3x	
		ATCC VR-103 [GL/1739/1954]	6.3E+02	3x	
		ATCC VR-296 [1/Maryland/1959]	6.3E+02	3x	
		ATCC VR-295 [2/Taiwan/1962]	6.3E+02	3x	
		ATCC VR-786 [Brigit/Russia/1969]	6.3E+02	3x	
	Victoria	ATCC VR-823 [5/Hong Kong/1972]	6.3E+02	3x	
		Zeptometrix 0810258CF [2506/Malaysia/2004]	6.3E+02	3x	
		CDC 2005743348 [1/Ohio/2005]	6.3E+02	3x	
	Yamagata	Zeptometrix 0810256CF [07/Florida/2004]	6.3E+02	3x	
		Zeptometrix 0810255CF [04/Florida/2006]	2.1E+02	1x	
		Zeptometrix 0810241CF [1/Wisconsin/2010]	6.3E+02	3x	
		Zeptometrix 0810239CF [2/Massachusetts/2012]	6.3E+02	3x	

Table 54. Parainfluenza Virus Isolates Tested and Detected

Organism	Type	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
Parainfluenza Virus	1	Zeptometrix 0810014CF	5.2E+03	1x	Parainfluenza Virus Detected
		BEI NR-48680[a] [FRA/29221106/2009]	1.6E+04	3x	
		ATCC VR-94 [C-35/Washington DC/1957]	1.6E+04	3x	
	2	Zeptometrix 0810015CF	1.5E+03	1x	
		ATCC VR-92 [Greer/Ohio/1955]	8.9E+02	0.6x	
	3	Zeptometrix 0810016CF	1.9E+02	1x	
		BEI NR-3233[b] [NIH 47885, Wash/47885/57]	5.7E+02	3x	
		ATCC VR-93 [C-243/Washington DC/1957]	5.7E+02	3x	
	4	Zeptometrix 0810060CF	8.1E+03	1x	
		ATCC VR-1378 [M-25/1958]	2.4E+04	3x	
		Zeptometrix 0810060BCF	2.4E+04	3x	
		ATCC VR-1377 [CH-19503/Washington DC/1962]	2.4E+04	3x	

[a] Virus obtained through BEI Resources, NIAID, NIH: Human Parainfluenza Virus 1, HPIV1/FRA/29221106/2009, NR-48680.

[b] Virus obtained through BEI Resources, NIAID, NIH: Human Parainfluenza Virus 3, NIH 47885, NR-3233.

Table 55. Respiratory Syncytial Virus Isolates Tested and Detected

Organism	Type	Source [Strain/Location/Year]	Test Concentration		Result
			(copies/mL)	xLoD	
Respiratory Syncytial Virus	A	Zeptometrix 0810040ACF [2006]	4.3E+02	1x	Respiratory Syncytial Virus Detected
		ATCC VR-26 [Long/Maryland/1956]	1.3E+03	3x	
		ATCC VR-1540 [A2/Melbourne/1961]	1.3E+03	3x	
	B	Zeptometrix 0810040CF [Ch-93 (18)-18]	1.3E+03	3x	
		ATCC VR-1400 [WV/14617/1985]	1.3E+03	3x	
		ATCC VR-955 [9320/Massachusetts/1977]	1.3E+03	3x	
		ATCC VR-1580 [18537/Washington DC/1962]	1.3E+03	3x	

Table 56. *Chlamydia pneumoniae* Isolates Tested and Detected

Organism	Source [Strain]	Test Concentration		Result
		(copies/mL)	xLoD	
	ATCC VR-2282 [TW-183/Taiwan/1965]	6.7E+01	1x	

Organism	Source [Strain]	Test Concentration		Result
		(copies/mL)	xLoD	
Chlamydia pneumoniae	ATCC VR-1310 [CWL-029]	2.0E+02	3x	*Chlamydia pneumoniae* Detected
	ATCC VR-1360 [CM-1/Georgia]	2.0E+02	3x	
	ATCC 53592 [AR-39/Seattle/1983]	2.0E+02	3x	

Table 57. *Legionella pneumophila* Isolates Tested and Detected

Species/Subspecies	Serogroup	Source [Strain]	Test Concentration		Result
			(CFU/mL)	xLoD	
L. pneumophila	1	ATCC 33152 [Philadelphia-1]	5.0E+02	1x	*Legionella pneumophila* Detected
	3	ATCC 33155 [Bloomington-2]	1.5E+03	3x	
L. pneumophila subsp. *fraseri*	4	ATCC 33156 [Los Angeles-1]	1.5E+03	3x	
	5	ATCC 33216 [Dallas 1E]	1.5E+03	3x	
L. pneumophila subsp. *pascullei*	5	ATCC 33737 [U8W]	1.5E+03	3x	
L. pneumophila subsp. *pneumophila*	10	ATCC 43283 [Leiden 1]	1.5E+03	3x	
	14	ATCC 43703 [1169-MN-H]	1.5E+03	3x	

Table 58. *Mycoplasma pneumoniae* Isolates Tested and Detected

Organism	Type	Source [Strain]	Test Concentration		Result
			(copies/mL)	xLoD	
Mycoplasma pneumoniae	1	Zeptometrix 0801579 [M129]	1.2E+03	1x	*Mycoplasma pneumoniae* Detected
		ATCC 29342 [M129-B7]	3.5E+03	3x	
		ATCC 29085 [PI 1428]	3.5E+03	3x	
	2	ATCC 15531-TTR [FH strain of Eaton Agent [NCTC 10119]]	3.5E+03	3x	
		ATCC 15492 [Mac]	3.5E+03	3x	
	unknown	ATCC 15293 [M52]	3.5E+03	3x	
		ATCC 15377 [Bru]	3.5E+03	3x	
		ATCC 39505 [Mutant 22]	3.5E+03	3x	
		ATCC 49894 [UTMB-10P]	3.5E+03	3x	

Table 59. *Acinetobacter calcoaceticus-baumannii* complex Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
A. baumannii	ATCC 9955 [6-561]	1.0E+04	*Acinetobacter calcoaceticus-baumannii* complex Detected
	ATCC 19606 [2208 Type strain]	1.0E+04	
	ATCC 17961 [CDC 7788]	1.0E+04	
	AR-Bank #0033	1.0E+04	
	GRE 1153064	1.0E+04	
	GRE 1062081	1.0E+04	
A. calcoaceticus	ATCC 51432	1.0E+04	
	ATCC 23055 [46]	1.0E+04	
	ATCC 14987 [HO-1]	1.0E+04	
A. calcoaceticus subsp. *anitratus*	ATCC 15308 [NCTC 7844]	1.0E+04	
A. pittii	ATCC 19004 [57.071.228]	1.0E+04	
A. nosocomialis [a]	ATCC 17903 [NCTC 8102]	1.0E+04	
A.seifertii	CCUG 34785	1.0E+04	

[a] *A. nosocomialis* ATCC 700472 was not detected at any concentration. Sequencing suggests the isolate may be mis-identified.

Table 60. Isolates *Enterobacter cloacae* Complex Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
E. cloacae	ATCC 49141 [AmMs 204]	1.0E+04	*Enterobacter cloacae* complex Detected
	ATCC BAA-1143 [Entb 55M]	1.0E+04	
	ATCC BAA-2341 [1101152]	1.0E+04	
	AR-Bank #0154	1.0E+04	
	NCTC 13464	1.0E+04	
E. cloacae subsp. cloacae	ATCC 13047 [Type Strain]	1.0E+04	
E. cloacae subsp. dissolvens	ATCC 23373D[a] [ICPB ED105]	1.0E+04	
E. asburiae	ATCC 35953[b] [CDC 1497-78 Type Strain]	1.0E+06[b]	
	ATCC 35957[b] [CDC 570-83]	1.0E+06[b]	
E. hormaechei	ATCC 49162[b] [CDC 992-77]	1.0E+05[b]	
	ATCC BAA-2082	1.0E+04	
E. kobei	CCUG 59410	1.0E+04	
E. ludwigii	CCUG 23050	1.0E+04	

[a] Genomic DNA from *E. cloacae* subsp. *dissolvens*.

[b] See Table 47 for limitation.

Table 61. *Escherichia coli* Isolates and Cross-Reactive Species Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Reported Result
E. coli	ATCC 25922 [FDA strain Seattle 1946]	1.0E+04	*Escherichia coli* Detected
	ATCC 43888 [CDC B568-73]	1.0E+04	
	AR-Bank #0061	1.0E+04	
	AR-Bank #0086	1.0E+04	
	AR-Bank #0137	1.0E+04	
	AR-Bank #0150	1.0E+04	
	AR-Bank #0162	1.0E+04	
	GRE 1062016	1.0E+04	
	GRE 1252008	1.0E+04	
	GRE 1252009	1.0E+04	
	GRE 1256018	1.0E+04	
	Zeptometrix 0801905 [Z136]	1.0E+04	
	ATCC 29930 [WRAIR I virulent]	1.0E+04	

Table 62. *Haemophilus influenzae* Isolates Tested and Detected

Organism	Serotype	Source [Strain/Location/Year]	Test concentration (copies/mL)	Result
H. influenzae[a]	Type a	ATCC 9006 [AMC 36-A-3 [610, PCM 2436]]	1.0E+04	*Haemophilus influenzae* Detected
	Type b	ATCC 10211 [AMC 36-A-1 [572]], Biotype 1	1.0E+04	
	Type c	ATCC 49699 [C 9007]	1.0E+04	
	Type d	ATCC 9008 [AMC 36-A-6 [611]]	1.0E+04	
	Type e	ATCC 8142 [AMC 36-A-7 [595, NCTC 8472]]	1.0E+04	
	Type f	ATCC 700223 [GA1264]	1.0E+04	
	Biogroup aegyptius	ATCC 11116 [180-a [NCTC 8502]]	1.0E+04	
	Non-typeable	ATCC 51907 [Rd [KW20]]	1.0E+04	

NOTE: The Hinfluenzae assay will not react with strains that do not carry the hpd gene[2].

Table 63. Klebsiella (*Enterobacter) aerogenes* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
K. aerogenes[a]	ATCC 13048 [NCTC 10006]	1.0E+04	*Klebsiella aerogenes* Detected
	AR-Bank #0062	1.0E+04	
	AR-Bank #0074	1.0E+04	
	AR-Bank #0161	1.0E+04	
	GRE 1254066	1.0E+04	
	ATCC 29751[a] [MULB-250]	1.0E+07[b]	

[a] Previously known as *Enterobacter aerogenes*

[b] See Table 47 for limitation.

Table 64. *Klebsiella oxytoca* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
K. oxytoca	ATCC 13182 [479-2 Type strain]	1.0E+04	*Klebsiella oxytoca* Detected
	ATCC 43086 [Pasco 201]	1.0E+04	
	ATCC 49131 [AmMS 101]	1.0E+04	
	ATCC 700324 [LBM 90.11.033]	1.0E+04	
	ATCC 8724 [NRRL B-199]	1.0E+04	
	AR-Bank #0147	1.0E+04	
	JMI 2523	1.0E+04	
	JMI 2661	1.0E+04	
	JMI 7818	1.0E+04	
	JMI 10678	1.0E+04	
	JMI 14611	1.0E+04	
	GRE 1254054	1.0E+04	

Table 65. *Klebsiella pneumoniae* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
K. pneumoniae	ATCC BAA-1705 [ART 2008133]	1.0E+04	*Klebsiella pneumoniae* Detected
	AR-Bank #0068	1.0E+04	
	AR-Bank #0075	1.0E+04	
	AR-Bank #0076	1.0E+04	
	AR-Bank #0079	1.0E+04	
	AR-Bank #0080	1.0E+04	
	AR-Bank # 0097	1.0E+04	

Organism	Source [Strain]	Test concentration (copies/mL)	Result
	AR-Bank #0107	1.0E+04	
	AR-Bank #0153	1.0E+04	
	GRE 1062084	1.0E+04	
	GRE 1355030	1.0E+04	
	JMI 328	1.0E+04	
	JMI 766	1.0E+04	
	NCTC 13465	1.0E+04	
	Zeptometrix 0801886	1.0E+04	
K. pneumoniae subsp. ozaenae	ATCC 11296 [AMC 35-E-5]	1.0E+04	
K. pneumoniae subsp. pneumoniae	ATCC 13883 [NCTC 9633]	1.0E+04	
K. pneumoniae subsp. rhinoscleromatis	ATCC 13884 [NCTC 5046]	1.0E+04	
K. quasipneumoniae subsp. quasipneumoniae	DSM 28211[a] [01A030, SB11]	1.0E+05[a]	
K. quasipneumoniae subsp. simipneumoniae	DSM 28212 [07A044, SB30]	1.0E+04	
K. variicola	ATCC BAA-830 [F2R9]	1.0E+04	

[a] See Table 47 for limitation.

Table 66. *Moraxella catarrhalis* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
M. catarrhalis	ATCC 25238 [Ne 11]	1.0E+04	*Moraxella catarrhalis* Detected
	ATCC 25240 [N9]	1.0E+04	
	ATCC 8176 [20]	1.0E+04	
	ATCC 23246 [a] [NCTC 4103]	1.0E+05[a]	
	ATCC 49143 [Am MS 116]	1.0E+04	

[a] See Table 47 for limitation.

Table 67. *Proteus* spp. Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
P. mirabilis	ATCC 29906 [1003]	1.0E+04	*Proteus* spp. Detected
	ATCC 33583 [571101]	1.0E+04	
	ATCC 35659 [LRA 08 01 73]	1.0E+04	
	AR-Bank #0156	1.0E+04	
	AR-Bank #0159	1.0E+04	
	GRE 1254053	1.0E+04	
P. hauseri	ATCC 13315 [NCTC 4175 Strain Lehmann]	1.0E+04	
	ATCC 700826 [CDC 1732-80]	1.0E+04	
P. penneri	ATCC 33519 [Type Strain CDC 1808-73]	1.0E+04	
	ATCC 35197 [CDC 1655-67]	1.0E+04	
P. vulgaris	ATCC 29905	1.0E+04	
	ATCC 33420	1.0E+04	
	ATCC 27973 [CDC 1787-64-SC1]	1.0E+04	

Table 68. *Pseudomonas aeruginosa* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
P. aeruginosa[a]	ATCC 10145 [MDB strain BU 277 type strain]	1.0E+04	*Pseudomonas aeruginosa* Detected
	ATCC BAA-1744 [109246]	1.0E+04	
	ATCC 19429 [NCTC 6750]	1.0E+04	
	ATCC 27853 [Boston 41501]	1.0E+04	
	AR-Bank #0054	1.0E+04	
	AR-Bank #0092	1.0E+04	
	AR-Bank #0100	1.0E+04	
	AR-Bank #0103	1.0E+04	
	AR-Bank #0111	1.0E+04	
	Creighton University PS28	1.0E+04	
	NCTC 13437	1.0E+04	

[a] *P. aeruginosa* ATCC 25619 was not detected at any concentration tested. See Table 47 for limitation.

Table 69. *Serratia marcescens* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
S. marcescens	ATCC 13880 [Type strain]	1.0E+04	*Serratia marcescens* Detected
	ATCC 27137 [CDC 3100-71]	1.0E+04	

Organism	Source [Strain]	Test concentration (copies/mL)	Result
	ATCC 43297 [3G]	1.0E+04	
	ATCC BAA-885 [Type strain KRED]	1.0E+04	
	GRE 1659005	1.0E+04	
	GRE 1659004	1.0E+04	
	JMI 697	1.0E+04	

Table 70. *Staphylococcus aureus* Isolates Tested and Detected

Organism	Source [Strain] (PFGE Type if applicable)	Test concentration (copies/mL)	Result
S. aureus	***Staphylococcus aureus* representing PFGE Types USA100-USA1200**		*Staphylococcus aureus* Detected
	NARSA NRS705 [PFGE USA100]	1.0E+04	
	NARSA NRS701 [PFGE USA200]	1.0E+04	
	ATCC BAA-1717 [PFGE USA300]	1.0E+05[a]	
	NARSA NRS683 [PFGE USA300]	1.0E+04	
	NARSA NRS662 [PFGE USA300]	1.0E+04	
	NARSA NRS707 [PFGE USA300]	1.0E+04	
	ATCC BAA-1707 [PFGE USA400]	1.0E+04	
	NARSA NRS691 [PFGE USA500]	1.0E+04	
	NARSA NRS648 [PFGE USA600]	1.0E+04	
	NARSA NRS689 [PFGE USA700]	1.0E+04	
	NARSA NRS668 [PFGE USA800]	1.0E+04	
	ATCC BAA-1749 [PFGE USA900 96:308]	1.0E+04	
	ATCC BAA-1759 [PFGE USA900 N7129]	1.0E+04	
	ATCC BAA-1700 [PFGE USA1000]	1.0E+04	
	BEI NR-46081 [PFGE USA1100 HIP12899]	1.0E+04	
	ATCC BAA-1765 [PFGE USA1200 102-04]	1.0E+04	
	ATCC BAA-1691 [Not USA100-1100]	1.0E+04	
	Methicillin Sensitive *Staphylococcus aureus* (MSSA)		
	ATCC 10832 [Wood 46]	1.0E+04	
	ATCC 14154 [Rose]	1.0E+04	
	ATCC 12600 [NCTC Type strain]	1.0E+04	
	ATCC 25923 [Seattle/1945]	1.0E+04	
	ATCC 29213 [Wichita]	1.0E+04	
	ATCC BAA-2421 [Mass/2010]	1.0E+04	
	Rennes 1060728	1.0E+04	
	GRE 1062519 [SCC*mec* Type: III / MREJ xix][b]	1.0E+04	
	Borderline Resistant *Staphylococcus aureus* (BORSA)		
	SUN1 [Sunnybrook]	1.0E+04	
	Methicillin Resistant *Staphylococcus aureus* (MRSA)		
	ATCC 43300 [F182 Kansas / SCC*mec* Type: II]	1.0E+04	
	ATCC BAA-2422 [Worcester MA/2010 / SCC*mec* Type: II]	1.0E+04	
	ATCC BAA-1720 [MRSA252 / SCC*mec* Type: II / PFGE USA200]	1.0E+04	
	NARSA NRS745 [CA-629 / SCC*mec* Type: V]	1.0E+04	
	ATCC BAA-38 [E2125 / SCC*mec* Type: I]	1.0E+04	
	NARSA NRS686 [MREJ type i]	1.0E+04	
	ATCC BAA-44 [HPV107 / SCC*mec* Type: I / PFGE: Iberian]	1.0E+04	
	ATCC BAA-41 [NYBK2464 / SCC*mec* Type: II / PFGE 100]	1.0E+04	
	NARSA NRS385 [MREJ type ii]	1.0E+04	
	ATCC BAA-42 [HDE288 / SCCmec: Type VI / PFGE 800]	1.0E+04	
	ATCC BAA-39 [HUSA304 / SCC*mec* Type: III]	1.0E+04	
	ATCC BAA-40 [CPS22 / SCC*mec* Type: III]	1.0E+04	
	GRE 1062264 [SCC*mec* Type: IV / MREJ type iv]	1.0E+04	
	GRE 1055015 [SCC*mec* Type: IVa / MREJ type vi]	1.0E+04	
	GRE 0759084 [SCC*mec* Type: IV / MREJ type v]	1.0E+04	
	GRE 0860042 [SCC*mec* Type: III / MREJ type vii]	1.0E+04	
	GRE 1052034 [MREJ ix]	1.0E+04	
	GRE 1151100 [SCC*mec* Type: IV / MREJ type xi]	1.0E+04	
	GRE 0960006 [MREJ type xii]	1.0E+04	
	GRE 1055017 [SCC*mec* Type: IVa / MREJ type xiii]	1.0E+04	
	GRE 0759163 [MREJ type xiv]	1.0E+04	
	GRE 1062373 [MREJ type xv]	1.0E+04	
	GRE 1057114 [MREJ type xvii]	1.0E+04	
	GRE 1062292 [MREJ type xviii]	1.0E+04	
	Methicillin Resistant Staphylococcus aureus (MRSA) - *mecC*+		
	ATCC BAA-2312 [M10/0061 / SCC*mec* Type: XI / *mecC*]	1.0E+04	
	ATCC BAA-2313 [M10/0148 / SCC*mec* Type: XI / *mecC*]	1.0E+04	

[a] *Staphylococcus aureus* ATCC BAA-1717 was not detected at 1.0E+04 copies/mL but was detected at 1.0E+05 copies/mL with accurate bin results. No limitation on reactivity could be identified based on the isolate sequence.

[b] MREJ type xix characterized as MSSA.[3]

Table 71. *Streptococcus agalactiae* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
S. agalactiae	NCTC 8017 [MK 104 P]	1.0E+04	*Streptococcus agalactiae Detected*
	ATCC 13813 [Ia/c Type Strain]	1.0E+04	
	ATCC 12403 [III Typing Strain D136C]	1.0E+04	
	ATCC 12386 [Grouping strain O90R]	1.0E+04	
	ATCC BAA-611 [V 2603 V/R]	1.0E+04	
	ATCC BAA-2669 [VIII 5030-08]	1.0E+04	
	Clinical Isolate [Utah/2010/CI03]	1.0E+04	

Table 72. *Streptococcus pneumoniae* Isolates Tested and Detected

Organism	Serotype	Source [Strain]	Test concentration (copies/mL)	Result
S. pneumoniae	3	ATCC 6303	1.0E+04	*Streptococcus pneumoniae* Detected
	5	ATCC BAA-341 [SPN1439-106]	1.0E+04	
	11A	NCTC 11900 [Gorman]	1.0E+04	
	14	ATCC 700672 [VH14]	1.0E+04	
	19A	ATCC 700673 [Hungary 19A-6]	1.0E+04	
	Non-capsulated	ATCC BAA-255 [R6]	1.0E+04	
	unknown	ATCC BAA-1409 [62076]	1.0E+04	

Table 73. *Streptococcus pyogenes* Isolates Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
S. pyogenes	ATCC 12344 [Typing strain T1, NCIB 11841, SF 130]	1.0E+04	*Streptococcus pyogenes* Detected
	ATCC 12348 [Typing strain S43 Type 6]	1.0E+04	
	ATCC 12384 [Typing strain C203 Type 3]	1.0E+04	
	ATCC 19615[a] [Bruno]	1.0E+06[a]	
	ATCC 700294 [SF370; M1 GAS [M-type 1 T-type 1]]	1.0E+05[b]	
	ATCC 49399 [QC A62]	1.0E+04	
	ATCC BAA-595 [MGAS 315, serotype M3]	1.0E+04	
	ATCC BAA-947 [MGAS 5005, serotype M1]	1.0E+04	

[a] See Table 47 for limitation.

[b] *Streptococcus pyogenes* ATCC 700294 was detected in 3/5 replicates at 1.0E+04 copies/mL with 10^4 copies/mL bin results and 3/3 replicates at 1.0E+05 copies/mL with 10^5 copies/mL bin results. No limitation on reactivity could be identified based on isolate sequence.

The following tables (Table 74 - Table 81) describe the reactivity of the AMR genes assays with different AMR gene types in various host bacteria. Results are shown for the isolates tested as well as predictions of reactivity with untested AMR gene types based on *in silico* analysis of sequences retrieved from public databases from June 2016 to Sept 2016.

Table 74. Isolates Containing *mecA/C* and MREJ Tested and Detected

Organism	Source [Strain]	Test concentration (copies/mL)	Result
S. aureus	**Methicillin Sensitive *Staphylococcus aureus* (MSSA) containing SCCmec cassette (non-functional *mecA* variant)**		*mecA/C* and MREJ Detected
	ATCC BAA-2421 [Mass/2010]	1.0E+04	
	Methicillin Resistant *Staphylococcus aureus* (MRSA) (Characterized SCCmec Types)		
	NARSA NRS705 [NY-12 / SCC*mec* Type: II]	1.0E+04	
	NARSA NRS701 [MN-082 / SCC*mec* Type: II]	1.0E+04	
	ATCC BAA-1717 [TCH1516 / SCC*mec* Type: IVa]	1.0E+05[a]	
	NARSA NRS683 [GA-298 / SCC*mec* Type: IV]	1.0E+04	
	NARSA NRS662 [CO-34 / SCC*mec* Type: IV]	1.0E+04	
	NARSA NRS707 [NY-155 / SCC*mec* Type: IV]	1.0E+04	
	ATCC BAA-1707 [MW2 /SCC*mec* Type: IV]	1.0E+04	
	NARSA NRS691 [GA-62 /SCC*mec* Type: IV]	1.0E+04	
	NARSA NRS648 [CA-347 /SCC*mec* Type:II or IV]	1.0E+05[a]	
	NARSA NRS689 [GA-442 / SCC*mec* Type: IV]	1.0E+04	
	NARSA NRS668 [CO-72 / SCC*mec* Type: IV]	1.0E+04	
	ATCC BAA-1700 [HFH-33798 / SCC*mec* Type: IVb]	1.0E+04	

Organism	Source [Strain]	Test concentration (copies/mL)	Result
	BEI NR-46081[b] (NRSA NRS484) [HIP12899 / SCCmec Type: IV]	1.0E+05[a]	
	ATCC BAA-1691 [HFH-30137 / SCC*mec* Type: IV]	1.0E+04	
	ATCC 43300 [F182 Kansas / SCC*mec* Type: II]	1.0E+04	
	ATCC BAA-2422 [Worcester MA/2010 / SCC*mec* Type: II]	1.0E+04	
	ATCC BAA-1720 [MRSA252 / SCC*mec* Type: II]	1.0E+04	
	NARSA NRS745 [CA-629 / SCC*mec* Type: IV or V]	1.0E+04	
	Methicillin Resistant *Staphylococcus aureus* (MRSA) (Characterized MREJ Types)		
	ATCC BAA-38 [MREJ type i]	1.0E+04	
	NARSA NRS686 [MREJ type i]	1.0E+04	
	ATCC BAA-44 [MREJ type ii]	1.0E+04	
	ATCC BAA-41 [MREJ type ii]	1.0E+04	
	NARSA NRS385 [MREJ type ii]	1.0E+04	
	ATCC BAA-42 [MREJ type ii]	1.0E+04	
	ATCC BAA-39 [MREJ type iii]	1.0E+04	
	ATCC BAA-40 [MREJ type iv]	1.0E+04	
	GRE 1062264 [MREJ type iv]	1.0E+04	
	GRE 1055015 [MREJ type vi]	1.0E+04	
	GRE 0860042 [MREJ type vii]	1.0E+04	
	GRE 1052034 [MREJ type ix]	1.0E+04	
	GRE 1151100 [MREJ type xi]	1.0E+04	
	GRE 0960006 [MREJ type xii]	1.0E+04	
	GRE 1055017 [MREJ type xiii]	1.0E+04	
	GRE 0759163 [MREJ type xiv]	1.0E+04	
	GRE 1062373 [MREJ type xv][c]	1.0E+06[b]	
	GRE 1057114 [MREJ type xvii]	1.0E+04	
	GRE 1062292 [MREJ type xviii][c]	3.3E+08	*mecA/C* and MREJ Not Detected
	GRE 1062519 [MREJ type xix][cd]	1.0E+07	
	Methicillin Resistant *Staphylococcus aureus* (MRSA) (SCC*mec* Type: XI / *mecC* / *mecA*$_{LGA251}$ variants)		*mecA/C* and MREJ Detected
	ATCC BAA-2312 [M10/0061 / SCC*mec* Type: XI / *mecC*]	1.0E+04	
	ATCC BAA-2313 [M10/0148 / SCC*mec*:Type XI / *mecC*]	1.0E+04	
S. argenteus	**Methicillin Resistant *Staphylococcus argenteus***		
	DSM 28299 [MSHR-1132]	1.00E+05	

[a] mecA/C and MREJ assays positive in less than three replicates at 1.0E+04 copies/mL, no sequence based limitation on reactivity identified.

[b] Bacteria obtained through NARSA for distribution by BEI Resources, NIAID, NIH: *Staphylococcus aureus*, Strain HIP12899, NR-46081

[c] See Table 47 for limitation.

[d] MREJ type xix characterized MSSA.[3]

Table 75. *In Silico* Reactivity Predictions for *mecA/C* and MREJ

mecA/C[a,b]		MREJ[d]		
Detected	Reduced Reactivity or Not Detected	Detected	Reduced Reactivity or Not Detected	Unknown Reactivity (no sequences)
mecA in S. aureus[c]	mecA in some isolates of S. capitis, S. kloosii and S. vitulinus	MREJ i, iα – vii[e]	MREJ ix[f]	MREJ viii
		MREJ xi-xiv	MREJ xv[g]	MREJ x
mecC in S. aureus		MREJ xvi – xvii	MREJ xviii	
	mecC in S. sciuri	MREJ in S. argenteus	MREJ xix, xx[h]	
mecA and mecC in non-aureus staphylococci (including S. argenteus)			MREJ in non-aureus staphylococci and other species[d]	

[a] July 2016; analysis of 1,257 database *mecA* sequences from *S. aureus* and 14 *mecC* sequences from *S. aureus*, as well as *mecA* and *mecC* sequences from non-aureus staphylococci.

[b] *mecC* is also referenced as SCC*mec* XI and *mecA*$_{LGA251}$.

[c] Limited or reduced reactivity predicted for 2/1,257 *mecA* sequences from *S. aureus* (0.2%).

[d] June 2016; analysis of approximately 1,450 typed MREJ database sequences from *S. aureus* and untyped sequences from *S. aureus*, non-aureus staphylococci and non-staphylococcus species (*Bacillus cereus*, *bacillus thuringiensis*, *Macrococcus caseolyticus*, *Clostridium acidurici*, *and Rummeliibacillus stabekisii*).

[e] Limited or reduced reactivity predicted for 1/141 MREJ iii sequences (0.7%); normal reactivity observed for the isolate of MREJ iii tested (see Table 74).

[f] Limited or reduced reactivity predicted for 2/8 MREJ ix sequences (25.0%); normal reactivity observed for the isolate of MREJ ix tested (see Table 74).

[g] Reduced reactivity predicted by *in silico* analysis and observed with the isolate of MREJ xv tested (see Table 74).

[h] MREJ xix and xx were not included in the assay design because they were identified from methicillin-sensitive S. aureus[3]

Table 76. Isolates Containing the *bla*$_{CTX-M}$ gene Tested and Detected, and *In Silico* Reactivity Predictions

CTX-M Type	Organism	Source	Test concentration (copies/mL)	Result
CTX-M	E. coli	AR-Bank #0137[a]	1.0E+04	CTX-M Detected
	K. oxytoca	GRE 1254054	1.0E+04	
	K. pneumoniae	AR-Bank #0068 [a]	1.0E+04	
		AR-Bank #0153 [a]	1.0E+04	
		GRE 1355030	1.0E+04	
CTX-M-1	E. coli	AR-Bank #0162	1.0E+04	
CTX-M-2	*K. pneumoniae*	AR-Bank #0107	1.0E+04	
CTX-M-8	*K. aerogenes*	GRE 1254066	1.0E+04	
CTX-M-9	*E.coli*	AR-Bank #0086	1.0E+04	
	E.cloacae	NCTC 13464	1.0E+04	
CTX-M-14	*K. pneumoniae*	AR-Bank #0079	1.0E+04	
CTX-M-15	*E.coli*	Zeptometrix 0801905	1.0E+04	
CTX-M-22	*P. mirabilis*	GRE 1254053	1.0E+04	
CTX-M-25	*K. pneumoniae*	NCTC 13465	1.0E+04	

***In silico* Reactivity Predictions[a]**				
Detected		**Not Detected**	**Unknown Reactivity (no sequences)**	
CTX-M-1 – CTX-M-117	CTX-M-150	CTX-M-151	CTX-M-118	CTX-M-143
CTX-M-121 – CTX-M-126	CTX-M-152		CTX-M-119	CTX-M-145
CTX-M-129 – CTX-M-132	CTX-M-155 – CTX-M-177		CTX-M-120	CTX-M-146
CTX-M-134	CTX-M-179 – CTX-M-185		CTX-M-127	CTX-M-149
CTX-M-136 – CTX-M-139			CTX-M-128	CTX-M-153
CTX-M-141 – CTX-M-142			CTX-M-133	CTX-M-154
CTX-M-144			CTX-M-135	CTX-M-178
CTX-M-147 – CTX-M-148			CTX-M-140	

[a] July 2016; analysis of over 1,200 database CTX-M sequences (typed and untyped).

Table 77. Isolates Containing the *bla*$_{IMP}$ gene Tested and Detected, and *In Silico* Reactivity Predictions

IMP Type	Organism	Source	Test concentration (copies/mL)	Result
IMP	*K. aerogenes*	AR-Bank #0161	1.0E+04	IMP Detected
	E. coli	GRE 1062016	1.0E+04	
	K. pneumoniae	AR-Bank #0080	1.0E+04	
IMP-1[a]	*P. aeruginosa*	AR-Bank #0103	1.0E+04	
IMP-3[a]	*E. coli*	GRE 1252008	1.0E+04	
IMP-4	*A. baumannii*	GRE 1062081	1.0E+04	
IMP-8	*K. pneumoniae*	GRE 1062084	1.0E+04	
IMP-9	*E. coli*	GRE 1252009	1.0E+04	
IMP-14	*P. aeruginosa*	AR-Bank #0092	1.0E+04	

***In silico* Reactivity Predictions[b]**				
Detected			**Reduced Reactivity or Not Detected**	**Unknown Reactivity (no sequences)**
IMP-1 – IMP-30[a]	IMP-40 – IMP-45	IMP-58 – IMP- 60	IMP-31	IMP-36
			IMP-35	IMP-39
IMP-32 – IMP-34	IMP-48 – IMP-49			IMP-46
				IMP-47
IMP 37 – IMP-38	IMP-51 – IMP-56			IMP-50
				IMP-57

[a] Limited or reduced reactivity predicted for 1/36 (2.8%) of IMP-1 and 1/3 (33.3%) of IMP-3 sequences.

[b] June 2016; analysis of over 220 database IMP sequences (typed and untyped).

Table 78. Isolates Containing the *bla*$_{KPC}$ gene Tested and Detected, and *In Silico* Reactivity Predictions

KPC Type	Organism	Source	Test concentration (copies/mL)	Result
KPC	*E. cloacae*	ATCC BAA-2341	1.0E+04	KPC Detected
	E. hormaechi	ATCC BAA-2082	1.0E+04	
	P. mirabilis	AR-Bank #0156	1.0E+04	
	K. oxytoca	AR-Bank #0147	1.0E+04	
	K. pneumoniae	AR-Bank #0097	1.0E+04	
	K. oxytoca	JMI 2523	1.0E+04	
KPC-2	*K. oxytoca*	JMI 7818	1.0E+04	
	K. pneumoniae	Zeptometrix 0801886	1.0E+04	
	K. pneumoniae	JMI 328	1.0E+04	
	K. pneumoniae	ATCC BAA-1705	1.0E+04	

KPC-3	*S. marcescens*	JMI 697	1.0E+04	
	E. coli	AR-Bank #0061	1.0E+04	
	K. oxytoca	JMI 2661	1.0E+04	
KPC-4	*K. pneumoniae*	JMI 766	1.0E+04	
KPC-5	*P. aeruginosa*	Creighton University PS28	1.0E+04	
***In silico* Reactivity Predictions[a]**				
Detected			**Not Detected**	**Unknown Reactivity (no sequences)**
KPC-1-19	KPC-21-22	KPC-24-26	None	KPC-20

[a] August 2016; analysis of approximately 1,125 database KPC sequences (typed and untyped).

Table 79. Isolates Containing the *bla*$_{NDM}$ gene Tested and Detected, and *In Silico* Reactivity Predictions

(copies/mL)	xLoD	(copies/mL)	xLoD	(copies/mL)
NDM	*E. coli*	AR-Bank #0162	1.0E+04	NDM Detected
	K. pneumoniae	AR-Bank #0153	1.0E+04	
	K. pneumoniae	AR-Bank #0068	1.0E+04	
	P. mirabilis	AR-Bank #0159	1.0E+04	
NDM-1	*A. baumannii*	AR-Bank #0033	1.0E+04	
NDM-2	*A. baumannii*	GRE 1153064	1.0E+04	
NDM-5	*E. coli*	AR-Bank #0150	1.0E+04	
NDM-6	*E. coli*	AR-Bank #0137	1.0E+04	
***In silico* Reactivity Predictions[b]**				
Detected			**Not Detected**	
NDM-1[a]	NDM-7	NDM-13	None	
NDM-2	NDM-8	NDM-14		
NDM-3	NDM-9	NDM-15		
NDM-4	NDM-10	NDM-16		
NDM-5	NDM-11			
NDM-6	NDM-12			

[a] Limited or reduced reactivity is predicted for 3/430 NDM-1 sequences (0.7%).

[b] June 2016; analysis of 900 database NDM sequences (typed and untyped).

Table 80. Isolates Containing the *bla*$_{OXA-48}$ and like genes Tested and Detected, and *In Silico* Reactivity Predictions

OXA Type[a]	Organism	Source	Test concentration (copies/mL)	Result
OXA-48	*K. aerogenes*	AR-Bank #0074	1.0E+04	Gram negative & OXA-48-Like Detected
OXA-48-like	*S. marcescens*	GRE 1411136	1.0E+04	
	S. marcescens	GRE 1411137	1.0E+04	
OXA-162	*K. pneumoniae*	GRE 1355030	1.0E+04	
OXA-181	*K. pneumoniae*	AR-Bank #0068	1.0E+04	
OXA-232	*K. pneumoniae*	AR-Bank #0075	1.0E+04	
***In silico* Reactivity Predictions[a]**				
Detected			**Not Detected[b]**	
OXA-48	OXA-204	OXA-370	OXA-163[c]	OXA-438[c]
OXA-48-like	OXA-232	OXA-484	OXA-247[c]	OXA-439[c]
OXA-162	OXA-244	OXA-505	OXA-405[c]	
OXA-181	OXA-245		OXA-416	
OXA-199	OXA-252		OXA-436[c]	

[a] June 2016; analysis of 165 database OXA-48-like sequences (typed and untyped).

[b] Sequence analysis predicts that the listed OXA-48-like types will not be detected. Non-OXA-48-like types (e.g. OXA-23-like, OXA-40/24-like, OXA-51-like, and OXA-58-like, OXA-143a-like and OXA-143-like) will also not be detected.

[c] Deletion variants with altered carbapenem hydrolysis activity, as described for OXA-163[4].

Table 81. Isolates Containing the *bla*$_{VIM}$ gene Tested and Detected, and *In Silico* Reactivity Predictions

VIM Type	Organism	Source	Test concentration (copies/mL)	Result
VIM	*E. cloacae*	AR-Bank #0154	1.0E+04	VIM Detected
	P. aeruginosa	AR-Bank #0111	1.0E+04	
	K. pneumoniae	AR-Bank 0076	1.0E+04	
VIM-2	*P. aeruginosa*	AR-Bank #0100	1.0E+04	
VIM-4	*P. aeruginosa*	AR-Bank #0054	1.0E+04	
VIM-7	*E. coli*	GRE 1256018	1.0E+04	
VIM-10	*P. aeruginosa*	NCTC 13437	1.0E+04	
***In silico* Reactivity Predictions[b]**				
Detected			**Reduced Reactivity or Not Detected**	**Unknown Reactivity (no sequences)**

VIM-1 – VIM-20[a]	VIM-23 – VIM-47	VIM-49 – VIM-51	VIM-39	VIM-21
			VIM-45	VIM-22
			VIM-46	VIM-48

[a] Limited or reduced reactivity is predicted for 2/177 VIM-2 sequences (1.1%).

[b] September 2016; analysis of over 600 database VIM sequences (typed and untyped).

Analytical Specificity (Cross-Reactivity and Exclusivity)

There is a risk of false positive results due to non-specific amplification and/or cross-reactivity with organisms found in the respiratory tract. The potential for non-specific amplification and detection by the FilmArray Pneumonia Panel *plus* assays was evaluated by *in silico* analyses of available sequences and by empirical (wet) testing of high concentrations of organisms in contrived samples and the observed and predicted cross-reactivities for organisms closely related to those detected by the panel and unrelated organisms that may present in lower respiratory specimens summarized in Table 82. Erroneous results due to cross-reactivity with organisms that were not evaluated or new variant sequences that emerge is also possible.

On-panel organisms were tested to assess the potential for intra-panel cross-reactivity (Table 83). Off-panel organisms included species of the same genus or otherwise genetically related to organisms detected by the panel, as well as normal flora and pathogens that may be present in sputum-like and BAL-like specimens (Table 84). Antimicrobial resistance genes were also evaluated in conjunction with on and off panel host organisms.

The final concentration of analyte in the sample (typically ≥1.0E+07 CFU/mL for bacteria and fungi and ≥1.0E+05 $TCID_{50}$/mL for viruses) represented levels ~100 - 100,000 fold higher than the LoD or lowest reportable level of the FilmArray Pneumonia Panel *plus* assays.

Table 82. Observed and Predicted Cross-Reactivity of FilmArray Pneumonia Panel *plus* Assays

FilmArray Pneumonia Panel *plus* Result	Cross-Reactive Organism
Closely-Related Species	
Escherichia coli	*Escherichia fergusonii*[a]
	Shigella species *(S. boydii, S. dysenteriae, S. flexneri, S. sonnei)* [a]
Klebsiella oxytoca	*Klebsiella michiganensis*[a]
Staphylococcus aureus	*Staphylococcus argenteus*[b]
	Staphylococcus schweitzeri[c]
Pseudomonas aeruginosa	*Pseudomonas putida*[d]
Unrelated Species	
Human Rhinovirus/Enterovirus	*Bordetella* species[e]
Parainfluenza Virus[f]	*Aspergillus niger*
	Cryptococcus laurentii
	Cryptococcus uniguttulatus
Adenovirus	*Stenotrophomonas acidaminiphila*[g]
CTX-M[h]	*Acinetobacter schindleri* *Burkholderia vietnamiensis*[i]
Escherichia coli[j,k]	*Lelliottia amnigena (Enterobacter amnigenus)*
	Enterobacter kobei
	Enterobacter ludwigii
	Enterobacter cloacae

[a] Genetically or phenotypically indistinguishable and often misidentified by standard laboratory techniques. Detected at a concentrations ≥1.0E+04 copies/mL.

[b] Genetically or phenotypically indistinguishable and often misidentified by standard laboratory techniques. Detected at a concentrations ≥1.0E+05 copies/mL.

[c] Genetically or phenotypically indistinguishable and often misidentified by standard laboratory techniques. Detected at a concentrations ≥1.0E+06 copies/mL.

[d] Cross-reactivity possible at concentrations >1.0E+07 copies/mL.

[e] Cross-reactivity with *B. pertussis* confirmed at ≥1.0E+06 CFU/mL. Cross-reactivity with *B. parapertussis* and *B. bronchiseptica* was not observed at 1.0E+08 CFU/mL, but possible based on sequence analysis.

[f] Cross-reactivity was observed with *A. niger*, *C. laurentii* and *C. uniguttulatus* at concentrations >1.0E+06 copies/mL. Cross-reactivity with other *Cryptococcus* species may be possible based on sequence analysis.

[g] *S. acidaminiphila* has not been isolated from human clinical specimens, no cross-reactivity observed with other *Stenotrophomonas* species.

[h] Cross-reactive product observed only at concentrations >4.5E+07 CFU/mL and only reported if an applicable gram-negative bacterium is also detected.

[i] Not tested. Predicted by *in silico* analysis.

[j] If observed, results will be reported as *Escherichia coli* 10^4 copies/mL.

[k] Based on *in silico* analysis, cross-reactivity is also possible at high concentrations (>1.0E+07 copies/mL) of other *Enterobacter* species (*E. hormaechei, K. aerogenes, E. lingolyticus), Citrobacter freundii*, *Citrobacter koseri*, *Escherichia vulneris*, and *Leclercia adecaboxylata*.

Table 83. On Panel Organisms Tested for Evaluation of FilmArray Pneumonia Panel *plus* Analytical Specificity

False positive results were observed when testing the species shown in **bold**.

ON-PANEL			
Bacteria			
Acinetobacter baumannii	***Enterobacter kobei*** [a]	*Klebsiella quasipneumoniae*	*Pseudomonas aeruginosa*
Acinetobacter calcoaceticus	***Enterobacter ludwigii*** [a]	*Klebsiella variicola*	*Serratia marcescens*
Acinetobacter nosocomialis	*Escherichia coli*	*Moraxella catarrhalis*	*Staphylococcus aureus*
Acinetobacter pittii	*Haemophilus influenzae*	*Proteus hauseri*	*Streptococcus agalactiae*
Enterobacter asburiae	*Klebsiella aerogenes*	*Proteus mirabilis*	*Streptococcus pneumoniae*
Enterobacter cloacae	*Klebsiella oxytoca*	*Proteus penneri*	*Streptococcus pyogenes*
Enterobacter hormaechei	*Klebsiella pneumoniae*	*Proteus vulgaris*	
Atypical Bacteria			
Chlamydia pneumoniae	*Legionella pneumophila*	*Mycoplasma pneumoniae*	
Viruses			
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Coronavirus HKU1	Human Metapneumovirus	Parainfluenza Virus 2
Adenovirus B	Coronavirus NL63	Influenza A	Parainfluenza Virus 3
Adenovirus C	Coronavirus OC43	Influenza B	Parainfluenza Virus 4
Adenovirus E	Enterovirus	Parainfluenza Virus 1	Respiratory Syncytial Virus
Coronavirus 229E	Human Rhinovirus		
Antimicrobial Resistance Genes			
CTX-M (*Klebsiella oxytoca*)	KPC (*Klebsiella pneumoniae*)	OXA-48-like (*Serratia marcescens*)	*mecA* and MREJ (*Staphylococcus aureus*)
IMP (*Pseudomonas aeruginosa*)	NDM (*Acinetobacter baumannii*)	VIM (*Enterobacter cloacae*)	

[a] See Table 82 for cross-reactivity information.

Table 84. Off-Panel Bacteria Tested or Evaluated by In Silico Analysis for FilmArray Pneumonia Panel *plus* Analytical Specificity

False positive results were observed when testing the species shown in **bold**.

OFF-PANEL			
Bacteria			
Abiotrophia defectiva	***Escherichia fergusonii*** [a]	*Mycobacterium tuberculosis*	***Shigella boydii*** [a]
Achromobacter xylosoxidans	*Escherichia hermanii*	*Mycoplasma bovis*	***Shigella dysenteriae*** [a]
Acinetobacter haemolyticus	*Escherichia vulneris*	*Mycoplasma genitalium*	***Shigella flexneri*** [a]
Acinetobacter johnsonii	*Fluoribacter dumoffei*	*Mycoplasma hominis*	***Shigella sonnei*** [a]
Acinetobacter junii	*Fusobacterium varium*	*Mycoplasma orale*	***Staphylococcus argenteus*** [a]
Acinetobacter lwolfii	*Gemella morbillorum*	*Neisseria gonorrhoeae*	*Staphylococcus capitis*
Acinetobacter radioresistens	*Granulicatella adiacens*	*Neisseria lactamica*	*Staphylococcus caprae*
Acinetobacter schindleri [a]	*Haemophilus ducreyi*	*Neisseria meningitidis*	*Staphylococcus cohnii*
Acinetobacter ursingii	*Haemophilus haemolyticus*	*Neisseria mucosa*	*Staphylococcus haemolyticus*
Actinobacillus actinomycetemcomitans	*Haemophilus parahaemolyticus*	*Neisseria sicca*	*Staphylococcus epidermidis* (*mecA*)
Actinobacillus hominis	*Haemophilus parainfluenzae*	*Nocardia asteroides*	*Staphylococcus hominis*
Actinobacillus ureae	*Haemophilus parasuis*	*Nocardia brasilensis*	*Staphylococcus intermedius*
Actinomyces israelii	*Haemophilus sputorum*[b]	*Pantoea agglomerans*	*Staphylococcus lugdunensis*
Actinomyces naeslundii	*Hafnia alvei*	*Pasteurella multocida*	*Staphylococcus lutrae*
Bacillus cereus	*Hafnia paralvei*	*Pediococcus acidilactici*	*Staphylococcus pasteuri*
Bacteriodes fragilis	*Helicobacter pylori*	*Peptostreptococcus anaerobius*	*Staphylococcus pseudointermedius*
Bordatella bronchiseptica	*Kingella kingae*	*Pluralibacter gergoviae*	*Staphylococcus saprophyticus*
Bordatella parapertussis	***Klebsiella michiganensis*** [a]	*Porphyromonas gingivalis*	*Staphylococcus schleiferi*
Bordatella pertussis [a]	*Kluyvera intermedia*	*Prevotella intermedia*	***Staphylococcus schweitzeri*** [a]
Burkholderia cepacia	*Kluyvera ascorbata*	*Prevotella melaninogenica*	*Staphylococcus sciuri*
Burkholderia mallei	*Lactobacillus acidophilus*	*Prevotella oralis*	*Staphylococcus warneri*
Burkholderia multivorans	*Leclercia adecarboxylata*	*Propionibacterium acnes*	*Staphylococcus xylosus*
Burkholderia pseudomallei	*Legionella bozemanii*	*Providencia rettgeri* (OXA-48-like)	***Stenotrophomonas acidaminiphila*** [a]
Cardiobacterium hominis	*Legionella cincinnatiensis*	*Providencia stuartii*	*Stenotrophomonas maltophilia*
Cedecea davisae	*Legionella feeleii*	*Pseudomonas fluorescens*	*Stenotrophomonas nitritireducens*
Chlamydia trachomatis	*Legionella lansingensis*	*Pseudomonas luteola*	*Stenotrophomonas rhizophila*

OFF-PANEL			
Chlamydophila psittaci	*Legionella longbeachae*	*Pseudomonas nitroreducens*	*Streptococcus equi subsp. Zooepidemicus*
Citrobacter freundii (KPC)	*Legionella micdadei*	*Pseudomonas oryzihabitans*	*Streptococcus mitis*
Citrobacter koseri (OXA-48-like)	*Legionella wadsworthii*	*Pseudomonas pertucinogena*	*Streptococcus mutans*
Citrobacter sedlakii	*Lelliottia nimipressuralis*	***Pseudomonas putida*** [a] (IMP)	*Streptococcus oralis*
Citrobacter werkmanii (VIM)	***Lelliottia amnigena*** [a] *(Enterobacter amnigenus)*	*Pseudomonas stutzeri*	*Streptococcus parasanguinis*
Clostridium difficile	*Leuconostoc lactis*	*Ralstonia pickettii*	*Streptococcus pseudopneumoniae*
Clostridium perfringens	*Listeria monocytogenes*	*Raoultella ornithinolytica*	*Streptococcus salivarius*
Corynebacterium diptheriae	*Macrococcus caseolyticus*	*Raoultella planticola*	*Streptococcus sanguinis*
Corynebacterium genitalium	*Micrococcus luteus*	*Raoultella terrigena*	*Streptococcus tigurinus*
Corynebacterium pseudodiptherticum	*Moraxella equi*	*Rhodococcus equi*	*Streptomyces anulatus*
Corynebacterium urealyticum	*Moraxella lacunata*	*Rothia mucilaginosa*	*Treponema denticola*
Cronobacter sakazakii	*Moraxella lincolnii*	*Salmonella enterica* (CTX-M)	*Ureaplasma parvum*
Eikenella corrodens	*Moraxella nonliquiefaciens*	*Serratia fonticola*	*Ureaplasma urealyticum*
Enterobacter cancerogenus	*Morganella morganii* (NDM)	*Serratia liquefaciens*	*Vagococcus fluvialis*
Enterobacter massiliensis	*Mycobacterium africanum*[b]	*Serratia odorifera*	*Veillonella parvula*
Enterobacter soli	*Mycobacterium bovis*	*Serratia plymuthica*	*Yersinia enterocolitica*
Enterococcus faecium	*Mycobacterium capra*[c]*e*	*Serratia rubidaea*	*Yersinia pseudotuberculosis*
Enterococcus faecalis	*Mycobacterium microti*[b]		
Viruses			
Bocavirus	Hantavirus[b]	Human Papillomavirus (HPV)	Varicella zoster virus
Cytomegalovirus	Herpes simplex virus 1	Influenza C[b]	Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)
Epstein Barr virus	Human Immunodeficiency Virus (HIV)	Mumps virus	
German Measles Virus (Rubella)	Measles Virus (Rubeola)		
Fungi/Yeast			
Aspergillus flavus	*Coccidioides posadasii*	*Fusarium kyushense*	*Pneumocystis carinii*
Aspergillus fumigatus	*Cryptococcus albidus*	*Histoplasma capsulatum*[c]	*Pneumocystis jirovecii*
Aspergillus niger [a]	*Cryptococcus gattii*	*Paecilomyces variottii*	*Pneumocystis murina*
Aspergillus terreus	***Cryptococcus laurentii*** [a]	*Paracoccidodes brasiliensis*[b]	*Rhizopus microsporus*
Blastomyces dermatitidis	*Cryptococcus neoformans*	*Penicillium chrysogenum*[c]	*Scedosporium apiospermum*
Candida albicans	***Cryptococcus uniguttalatus*** [a]	*Penicillium marneffei*	*Scedosporium prolificans*
Candida glabrata	*Filobasidium capsuligenum*		
Antimicrobial Resistance Genes			
AmpC (*Klebsiella (Enterobacter) aerogenes*)	OXA-24/40 (non-48-like) (*Acinetobacter baumannii*)	SME (*Serratia marcescens*)	TEM (*Escherichia coli*)
CMY (II) (*Escherichia coli*)	SHV (*Klebsiella pneumoniae*)	SPM (*Pseudomonas aeruginosa*)	VAN (*Staphylococcus aureus*)
ompK36 [SHV-12, OMPC]a (*Klebsiella pneumoniae*)	*SCCmec* variant lacking *mecA* or *mecC* (*Staphylococcus aureus*)[d]		

[a] See Table 82 for cross-reactivity information.

[b] Analytical specificity was evaluated only by in silico analysis of whole genome or partial genome sequences in public databases. No cross-reactivity is predicted based on the sequences analyzed.

[c] Tested at a concentration less than 1.0E+07 CFU/mL and also evaluated by in silico analysis. Cross-reactivity was not observed in testing nor predicted based on the sequences analyzed.

[d] Methicillin-sensitive isolate of *S. aureus* (Rennes 1060728) that has MREJ sequence but no *mecA* or *mecC* gene (empty cassette). *Staphylococcus aureus* was reported as Detected and the *mecA/C* and MREJ result was Not Detected.

Precision (Reproducibility)

Precision (Reproducibility) testing was performed with contrived BAL samples over multiple days at three laboratory locations (sites) on a combination of FilmArray, FilmArray 2.0 and FilmArray Torch systems. The testing incorporated a range of potential variation introduced by operator, system, instrument or Torch module, concentration and reagent lot, for a total of 30 tests per system and 90 total replicates per sample/concentration.

Evaluation of the reproducibility of Detected/Not Detected results for atypical bacteria and viruses included samples containing combinations of five different analytes, at Negative, Low Positive (1×LoD), and Moderate Positive (3×LoD) concentrations. Negative results were obtained from samples that were not spiked with the analyte (see evaluation of precision for bacterial analytes below).

A summary of results (percent (%) agreement with the expected Detected or Not Detected result) for atypical bacteria and viruses (by site and system) is provided in Table 85.

Table 85. Reproducibility of FilmArray Pneumonia Panel *plus* Atypical Bacteria and Virus Results

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result			
			FilmArray	FilmArray 2.0	FilmArray Torch	All Sites/Systems [95% CI]
			Site A	Site B	Site C	
Atypical Bacteria						
Chlamydia pneumoniae	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**780/780** 100%	**780/780** 100%	**2,340/2,340** **100%** [99.8%-100%]
Legionella pneumophila Philadelphia-1 ATCC 33152	**Moderate Positive 3× LoD** 1.5E+03 CFU/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	Low Positive 1× LoD 5.0E+02 CFU/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	None (No Analyte)	**Not Detected**	**720/720** 100%	**720/720** 100%	**720/720** 100%	**2,160/2,160** **100%** [99.8%-100%]
Mycoplasma pneumoniae	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**780/780** 100%	**780/780** 100%	**2,340/2,340** **100%** [99.8%-100%]
Viruses						
Middle East Respiratory Syndrome Coronavirus	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**780/780** 100%	**780/780** 100%	**2,340/2,340** **100%** [99.8%-100%]
Adenovirus Species B Serotype 3 ZeptoMetrix 0810062CF	**Moderate Positive 3× LoD** 3.0E+00 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	Low Positive 1× LoD 1.0E+00 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	None (No Analyte)	**Not Detected**	**720/720** 100%	**720/720** 100%	**720/720** 100%	**2,160/2,160** **100%** [99.8%-100%]
Coronavirus	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**776/780** 99.5%	**780/780** 100%	**2,336/2,340** **99.8%** [99.6%-100%]
Human Metapneumovirus 16 Type A1 ZeptoMetrix 0810161CF	**Moderate Positive 3× LoD** 1.5E+02 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	Low Positive 1× LoD 5.0E+01 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**29/30** 96.7%	**30/30** 100%	**89/90** **98.9%** [94.0%-100%]
	None (No Analyte)	**Not Detected**	**720/720** 100%	**720/720** 100%	**720/720** 100%	**2,160/2,160** **100%** [99.8%-100%]
Human Rhinovirus/Enterovirus	**None** (No Analyte)	**Not Detected**	**779/780** 99.9%	**780/780** 100%	**779/780** 99.9%	**2,338/2,340** **99.9%** [99.7%-100%]
Influenza A H3N2 A/Port Chalmers/1/73 ATCC VR-810	**Moderate Positive 3× LoD** 1.5E+00 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90** **100%** [96.0%-100%]
	Low Positive 1× LoD 0.5E-01 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**29/30** 96.7%	**30/30** 100%	**89/90** **98.9%** [94.0%-100%]
	None (No Analyte)	**Not Detected**	**720/720** 100%	**720/720** 100%	**720/720** 100%	**2,160/2,160** **100%** [99.8%-100%]

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result			
			FilmArray	FilmArray 2.0	FilmArray Torch	All Sites/Systems [95% CI]
			Site A	Site B	Site C	
Influenza B	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**780/780** 100%	**780/780** 100%	**2,340/2,340 100%** [99.8%-100%]
Parainfluenza Virus Type 2 ZeptoMetrix 0810015CF	**Moderate Positive 3× LoD** 7.5E+01 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90 100%** [96.0%-100%]
	Low Positive 1× LoD 2.5E+01 $TCID_{50}$/mL	**Detected**	**30/30** 100%	**30/30** 100%	**30/30** 100%	**90/90 100%** [96.0%-100%]
	None (No Analyte)	**Not Detected**	**720/720** 100%	**720/720** 100%	**720/720** 100%	**2,160/2,160 100%** [99.8%-100%]
Respiratory Syncytial Virus	**None** (No Analyte)	**Not Detected**	**780/780** 100%	**780/780** 100%	**780/780** 100%	**2,340/2,340 100%** [99.8%-100%]

Precision for bacterial analytes was measured at each concentration as 1) precision of bin results and 2) reproducibility of analyte detection. When a sample containing one or more bacteria is tested repeatedly, the precision of the bin results (probability that each replicate will receive the same bin result) will vary based on the concentration of nucleic acid measured and the relation of that concentration to the limits of each bin. Bin precision may be as low as 50% for values at a bin limit and precision will increase (up to 90% or higher) as the distance of the measured value from a bin limit increases. The precision of FilmArray Pneumonia Panel *plus* bin results will follow the model illustrated in Figure 1:

- >90% at a bin center (Scenario 1)
- ~60 – 90% between a bin limit and bin center (Scenario 2)
- ~50% at bin limits (Scenario 3)

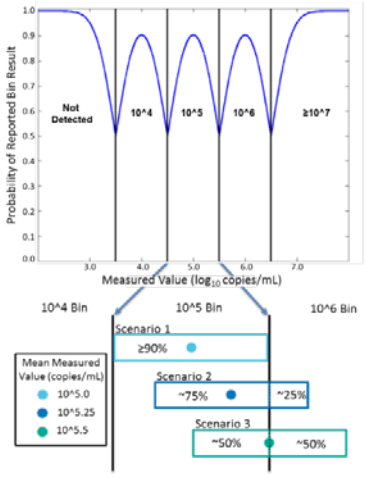

Figure 1. Model for Precision of FilmArray Pneumonia Panel *plus* Bin Results
Top: The probability of the same bin results for each replicate tested varies based on proximity of the measured value to a bin limit.
Bottom: Expected distribution of bin results at different mean measured values.

Samples containing bacteria and corresponding antimicrobial (AMR) genes were tested at six different concentrations over the reportable range and below. A summary of the bin precision (percent (%) of

replicates reported in each bin) and the reproducibility of detection is shown at each concentration tested in Table 86.

Table 86. Reproducibility of FilmArray Pneumonia Panel *plus* Bacterial Bin Results on FilmArray, FilmArray 2.0 and FilmArray Torch

Grey shading indicates the expected bin results based on the analyte concentration and bold font indicates the bin with the greatest percentage of results at each concentration.

Analyte	Concentration (log_{10} copies/mL)	% Replicates Reported in Each Bin Result					Total Detected
		≥10^7	10^6	10^5	10^4	ND	
Acinetobacter baumannii (NDM-1) AR-BANK#0033	**7.5**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.5	**87/90 (96.7%)**	3/90 (3.3%)	-	-	-	**90/90** 100%
	5.5	-	**82/90 (91.1%)**	8/90 (8.9%)	-	-	**90/90** 100%
	4.5	-	1/90 (1.1%)	**80/90 (88.9%)**	9/90 (10.0%)	-	**90/90** 100%
	3.5	-	-	1/90 (1.1%)	**74/90 (82.2%)**	15/90 (16.7%)	**75/90** 83.3%
	2.5	-	-	-	1/90 (1.1%)	**89/90 (98.9%)**	**1/90** 1.1%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Enterobacter cloacae (VIM) AR-BANK#0154	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	4/90 (4.4%)	**86/90 (95.6%)**	-	-	-	**90/90** 100%
	5.0	-	6/90 (6.7%)	**80/90 (88.9%)**	-	4/90 (4.4%)	**86/90** 95.6%
	4.0	-	-	6/90 (6.7%)	**83/90 (92.2%)**	1/90 (1.1%)	**89/90** 98.9%
	3.0	-	-	1/90 (1.1%)	4/90 (4.4%)	**85/90 (94.4%)**	**5/90** 5.6%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Escherichia coli (IMP) GRE 1062016	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	7/90 (7.8%)	**82/90 (91.1%)**	-	-	1/90 (1.1%)	**89/90** 98.9%
	5.0	-	10/90 (11.1%)	**80/90 (88.9%)**	-	-	**90/90** 100%
	4.0	-	-	12/90 (13.3%)	**77/90 (86.7%)**	1/90 (1.1%)	**89/90** 98.9%
	3.0	-	-	1/90 (1.1%)	15/90 (16.7%)	**74/90 (82.2%)**	**16/90** 17.8%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Haemophilus influenzae ATCC 10211	**7.0**	**89/90 (98.9%)**	1/90 (1.1%)	-	-	-	**90/90** 100%
	6.0	35/90 (48.9%)	**55/90 (61.1%)**	-	-	-	**90/90** 100%
	5.0	-	**49/90 (54.4%)**	40/90 (44.4%)	1/90 (1.1%)	-	**90/90** 100%
	4.0	-	-	41/90 (45.6%)	**49/90 (54.4%)**	-	**90/90** 100%
	3.0	-	-	-	42/90 (46.7%)	**48/90 (53.3%)**	**42/90** 46.7%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Klebsiella aerogenes (Enterobacter	**7.5**	**90/90 (100%)**	-	-	-	-	**90/90** 100%

Analyte	Concentration (log_{10} copies/mL)	% Replicates Reported in Each Bin Result					Total Detected
		≥10^7	10^6	10^5	10^4	ND	
aerogenes) ATCC 13048	**6.5**	**65/90 (72.2%)**	25/90 (27.8%)	-	-	-	**90/90** 100%
	5.5	-	**52/90 (57.8%)**	38/90 (42.2%)	-	-	**90/90** 100%
	4.5	-	-	38/90 (42.2%)	**51/90 (56.7%)**	1/90 (1.1%)	**89/90** 98.9%
	3.5	-	-	-	33/90 (36.7%)	**57/90 (63.3%)**	**33/90** 36.7%
	2.5	-	-	-	1/90 (1.1%)	**89/90 (98.9%)**	**1/90** 1.1%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Klebsiella oxytoca (CTX-M) GRE 1254054	**7.5**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.5	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	5.5	1/90 (1.1%)	**84/90 (93.3%)**	3/90 (3.3%)	-	2/90 (2.2%)	**88/90** 97.8%
	4.5	-	-	**89/90 (98.9%)**	-	1/90 (1.1%)	**89/90** 98.9%
	3.5	-	-	-	**90/90 (100%)**	-	**90/90** 100%
	2.5	-	-	1/90 (1.1%)	1/90 (1.1%)	**88/90 (97.8%)**	**2/90** 2.2%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Klebsiella pneumoniae (KPC) AR-BANK#0097	**7.00**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.00	12/90 (13.3%)	**78/90 (86.7%)**	-	-	-	**90/90** 100%
	5.00	-	15/90 (16.7%)	**75/90 (83.3%)**	-	-	**90/90** 100%
	4.00	-	-	23/90 (25.6%)	**66/90 (73.3%)**	1/90 (1.1%)	**89/90** 98.9%
	3.00	-	-	-	15/90 (16.7%)	**75/90 (83.3%)**	**15/90** 16.7%
	2.00	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Moraxella catarrhalis ATCC 8176	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	26/90 (28.9%)	**64/90 (71.1%)**	-	-	-	**90/90** 100%
	5.0	-	6/90 (6.7%)	**83/90 (92.2%)**	1/90 (1.1%)	-	**90/90** 100%
	4.0	-	-	4/90 (4.4%)	**86/90 (95.6%)**	-	**90/90** 100%
	3.0	-	-	-	4/90 (4.4%)	**86/90 (95.6%)**	**4/90** 4.4%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Proteus mirabilis ATCC 35659	**7.0**	**88/90 (97.8%)**	-	-	-	2/90 (2.2%)	**88/90** 97.8%
	6.0	27/90 (30.0%)	**63/90 (70.0%)**	-	-	-	**90/90** 100%
	5.0	-	26/90 (28.9%)	**64/90 (71.1%)**	-	-	**90/90** 100%
	4.0	-	-	14/90 (15.6%)	**75/90 (83.3%)**	1/90 (1.1%)	**89/90** 98.9%
	3.0	-	-	-	28/90 (31.1%)	**62/90 (68.9%)**	**28/90** 31.1%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%

Analyte	Concentration (log_{10} copies/mL)	% Replicates Reported in Each Bin Result					Total Detected
		≥10^7	10^6	10^5	10^4	ND	
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Pseudomonas aeruginosa ATCC 10145	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	20/90 (22.2%)	**70/90 (77.8%)**	-	-	-	**90/90** 100%
	5.0	-	24/90 (26.7%)	**66/90 (73.3%)**	-	-	**90/90** 100%
	4.0	-	-	16/90 (17.8%)	**74/90 (82.2%)**	-	**90/90** 100%
	3.0	-	-	-	14/90 (15.6%)	**76/90 (84.4%)**	**14/90** 15.6%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Serratia marcescens (OXA-48-like) GRE 1659005	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	2/90 (2.2%)	**88/90 (97.8%)**	-	-	-	**90/90** 100%
	5.0	-	7/90 (7.8%)	**83/90 (92.2%)**	-	-	**90/90** 100%
	4.0	-	-	6/90 (6.7%)	**83/90 (92.2%)**	1/90 (1.1%)	**89/90** 98.9%
	3.0	-	-	-	6/90 (6.7%)	**84/90 (93.3%)**	**6/90** 6.7%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Staphylococcus* aureus subsp. *aureus (*mecA/C* and MREJ) ATCC 43300	**7.0**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.0	-	**90/90 (100%)**	-	-	-	**90/90** 100%
	5.0	-	-	**90/90 (100%)**	-	-	**90/90** 100%
	4.0	-	-	-	**89/90 (98.9%)**	1/90 (1.1%)	**89/90** 98.9%
	3.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	2.0	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	2/1260 (0.2%)	**1258/1260 (99.8%)**	**2/1260** 0.2%
Streptococcus agalactiae ATCC 13813	**7.8**	**89/90 (98.9%)**	1/90 (1.1%)	-	-	-	**90/90** 100%
	6.8	**89/90 (98.9%)**	-	-	-	1/90 (1.1%)	**89/90** 98.9%
	5.8	-	**88/90 (97.8%)**	1/90 (1.1%)	1/90 (1.1%)	-	**90/90** 100%
	4.8	-	-	**89/90 (98.9%)**	1/90 (1.1%)	-	**90/90** 100%
	3.8	-	-	-	**86/90 (95.6%)**	4/90 (4.4%)	**86/90** 95.6%
	2.8	-	-	-	3/90 (3.3%)	**87/90 (96.7%)**	**3/90** 3.3%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Streptococcus pneumoniae ATCC 6303	**6.5**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	5.5	-	**90/90 (100%)**	-	-	-	**90/90** 100%
	4.5	-	-	**89/90 (98.9%)**	1/90 (1.1%)	-	**90/90** 100%
	3.5	-	-	-	**89/90 (98.9%)**	1/90 (1.1%)	**89/90** 98.9%

Analyte	Concentration (log_{10} copies/mL)	% Replicates Reported in Each Bin Result					Total Detected
		≥10^7	10^6	10^5	10^4	ND	
	2.5	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	1.5	-	-	-	-	**90/90 (100%)**	**0/90** 0.0%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%
Streptococcus pyogenes ATCC 49399	**7.8**	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	6.8	**90/90 (100%)**	-	-	-	-	**90/90** 100%
	5.8	5/90 (5.6%)	**84/90 (93.3%)**	1/90 (1.1%)	-	-	**90/90** 100%
	4.8	-	4/90 (4.4%)	**86/90 (95.6%)**	-	-	**90/90** 100%
	3.8	-	-	3/90 (3.3%)	**87/90 (96.7%)**	-	**90/90** 100%
	2.8	-	-	-	16/90 (18.9%)	**74/90 (81.1%)**	**16/90** 17.8%
	None (No Analyte)	-	-	-	-	**1800/1800 (100%)**	**0/1800** 0.0%

The precision of the antimicrobial resistance (AMR) genes was measured as the reproducibility of analyte detection on each system and overall, presented in Table 87 as the percent of replicates that are detected at concentrations of the associated bacterium that are within the reportable range, or below the reportable range, as well as the percent agreement with the expected Not Detected result in unspiked samples.

Table 87. Reproducibility of FilmArray Pneumonia Panel *plus* Antimicrobial Resistance Gene Results on FilmArray, FilmArray 2.0 and FilmArray Torch

AMR Gene Organism	Concentration of Organism log_{10}	Expected Result	Agreement with the Expected Result			
			FilmArray	FilmArray 2.0	FilmArray Torch	All Systems/Sites [95% CI]
			Site A	Site B	Site C	
CTX-M *Klebsiella oxytoca* GRE 1254054	**Reportable Range (3.5 – 7.5)**	**Detected**	**150/150** 100%	**149/150**[a] 99.3%	**150/150** 100%	**449/450**[a] **99.8%** [98.8%-99.9%]
	Below Reportable Range (2.5)	Detected (Variable)	**0/30** 0.0%	**1/30** 3.3%	**0/30** 0.0%	**1/90** **1.1%** [0.03%-6.0%]
	None (No Analyte)	N/A or Not Detected	**600/600** 100%	**599/600** 99.8%	**600/600** 100%	1799/1800 99.9% [99.7%-100%]
IMP *Escherichia coli* GRE 1062016	**Reportable Range (4.0 – 7.0)**	**Detected**	**120/120** 100%	**120/120** 100%	**120/120** 100%	**360/360** **100%** [99.0%-100%]
	Below Reportable Range (2.0-3.0)	Detected (Variable)	**10/60** 16.7%	**9/60** 15.0%	**3/60** 5.0%	**22/180** **12.2%** [7.8%-17.9%]
	None (No Analyte)	N/A or Not Detected	**600/600** 100%	**600/600** 100%	**600/600** 100%	**1800/1800** **100%** [99.8%-100%]
KPC *Klebsiella pneumoniae* AR-Bank#0097	**Reportable Range (4.0 – 7.0)**	**Detected**	**120/120** 100%	**119/120**[b] 99.2%	**120/120** 100%	**359/360**[b] **99.7%** [98.5%-100%]
	Below Reportable Range (2.0 – 3.0)	Detected (Variable)	**14/60** 23.3%	**12/60** 20.0%	**9/60** 15.0%	**35/180** **19.4%** [13.9%-25.0%]
	None (No Analyte)	N/A or Not Detected	600/600 100%	600/600 100%	600/600 100%	**1800/1800** **100%** [99.8%-100%]
***mecA/C* and MREJ** *Staphylococcus aureus* ATCC 43300	**Reportable Range (4.0 – 7.0)**	**Detected**	**119/120**[b] 99.2%	**118/120**[b] 98.3%	**120/120** 100%	**357/360**[b] **99.2%** [97.6%-99.8%]
	Below Reportable Range	Detected (Variable)	**0/60** 0.0%	**0/60** 0.0%	**0/60** 0.0%	**0/180** **0%**

AMR Gene Organism	Concentration of Organism log_{10}	Expected Result	Agreement with the Expected Result			
			FilmArray Site A	FilmArray 2.0 Site B	FilmArray Torch Site C	All Systems/Sites [95% CI]
	(2.0 – 3.0)					[0.0%-2.0%]
	None (No Analyte)	N/A or Not Detected	**420/420** 100%	**420/420** 100%	**420/420** 100%	**1260/1260** **100%** [99.7%-100%]
NDM *Acinetobacter baumannii* AR-Bank#0033	**Reportable Range (3.5 – 7.5)**	**Detected**	**150/150** 100%	**149/150**[a] 99.3%	**150/150** 100%	**449/450**[a] **99.8%** [98.8%-100%]
	Below Reportable Range (2.5)	Detected (Variable)	**1/30** 3.3%	**1/30** 3.3%	**0/30** 0.0%	**2/90** **2.2%** [0.3%-7.8%]
	None (No Analyte)	N/A or Not Detected	**599/600** 99.8%	**600/600** 100%	**600/600** 100%	**1799/1800** **99.9%** [99.7%-100%]
OXA-48-like *Serratia marcescens* GRE 1659005	**Reportable Range (4.0 – 7.0)**	**Detected**	**120/120** 100%	**119/120**[b] 99.2%	**120/120** 100%	**359/360**[b] **99.70%** [98.5%-100%]
	Below Reportable Range (2.0 – 3.0)	Detected (Variable)	**14/60** 23.3%	**12/60** 20.0%	**9/60** 15.0%	**35/180** **19.4%** [13.9%-26.0%]
	None (No Analyte)	N/A or Not Detected	**598/600** 99.7%	**600/600** 100%	**600/600** 100%	**1798/1800** **99.9%** [99.6%-100%]
VIM *Enterobacter cloacae* AR-BANK#0154	**Reportable Range (4.0 – 7.0)**	**Detected**	**120/120** 100%	**120/120** 100%	**120/120** 100%	**360/360** **100%** [99.0%-100%]
	Below Reportable Range (2.0 – 3.0)	Detected (Variable)	**10/60** 16.7%	**9/60** 15.0%	**3/60** 5.0%	**22/180** **12.2%** [7.8%-17.9%]
	None (No Analyte)	N/A or Not Detected	**599/600** 99.8%	**600/600** 100%	**600/600** 100%	**1799/1800** 99.9% [99.7%-100%]

[a] CTX-M and NDM Not Detected results observed at the corresponding bacterial concentration of 4.5 log_{10} copies/mL.

[b] KPC, *mecA/C* and MREJ, and OXA-48-like Not Detected results observed at the corresponding bacterial concentration of 4.0 log_{10} copies/mL.

Interference

Potentially interfering substances that could be present in BAL-like or sputum-like specimens or that may be introduced during specimen collection and testing were evaluated for their effect on FilmArray Pneumonia Panel *plus* performance. Substances included endogenous substances that may be found in specimens at normal or elevated levels (e.g. blood, mucus/mucin, human genomic DNA), various commensal or infectious microorganisms, medications, a variety of sample processing substances and substances used to clean, decontaminate, or disinfect work areas. The performance of the FilmArray Pneumonia Panel *plus* has not been established with all potentially interfering medications for the treatment of lower respiratory tract infections. The effect of interfering substances has only been evaluated for those listed in Table 88. Interference from substances that were not evaluated could lead to erroneous results.

Each substance was added to contrived samples containing representative qualitatively reported organisms and representative organisms with bin reporting. Qualitatively reported organisms were at concentrations near (2-3×) LoD and those with bin reporting were present at 4.0 log_{10} (copies/mL) (e.g. in the lowest reported bin). The concentration of substance added to the samples (Table 88) was equal to or greater than the highest level expected to be in BAL-like or Sputum-like specimens.

Four of the evaluated substances were found to interfere with the ability of the FilmArray Pneumonia Panel *plus* to report accurate analyte results; Bleach, MycoPrep, 2% NaOH, and 5% Oxalic acid. Each of these substances contain chemicals known to react with nucleic acids, altering their chemical structure.

The interference observed was related to the inability to detect the chemically modified nucleic acids. Treatment of specimens with these substances prior to FilmArray Pneumonia Panel *plus* testing may result in loss of analyte detection, therefore samples that have been in contact with these substances should not be tested using the FilmArray Pneumonia Panel *plus*. None of the other substances were shown to interfere with the FilmArray Pneumonia Panel *plus* results, however, testing of specimens that have been centrifuged or pre-treated by addition of enzyme, media, mucolytic agent, or decontaminating substances is not recommended..

Table 88. Evaluation of Potentially Interfering Substances on the FilmArray Pneumonia

Substance	Concentration Tested	Testing Outcome
Endogenous Substances		
Blood	10% v/v	No Interference
Albumin	60 mg/mL	No Interference
HCl (gastric acid)	5 mmol/L	No Interference
Hemoglobin	2 mg/mL	No Interference
Human Cells (K-562 cell line)	3.8E+06 cells/mL	No Interference
Immunoglobulins (IgG)	60 mg/mL	No Interference
Mucin	16 mg/mL	No Interference
Exogenous Substances		
Albuterol (bronchodilator)	1.7 µmol/L	No Interference
Benzocaine (Orajel)	1.0 % w/v	No Interference
Epinephrine (hormone, bronchodilator)	8.3 µg/mL	No Interference
Galphimia glauca (Homeopathic remedy)	1.0 % w/v	No Interference
Guaifenesin (expectorant)	15.2 mmol/L	No Interference
Lidocaine	5.1 mmol/L	No Interference
Menthol and cetylpyridinium chloride (Cepacol Mouthwash)	1.0% v/v	No Interference
Mupirocin (antibiotic)	6.0 ng/mL	No Interference
Nicotine	6.2 µmol/L	No Interference
Pentamidine (antimicrobial)	1.5 mg/mL	No Interference
Phenylephrine hydrochloride (decongestant)	0.3 mg/mL	No Interference
Tobramycin sulfate (antibiotic)	30 mg/mL	No Interference
Zanamivir (influenza antiviral)	426 ng/mL	No Interference
Competitive Microorganisms		
Actinobacillus actinomycetecomitans	3.8E+07 CFU/mL	No Interference
Aspergillus fumigatus	5.5E+07 CFU/mL	No Interference
Burkholderia cepacia	1.7E+07 CFU/mL	No Interference
Cryptococcus neoformans	2.5E+05 CFU/mL	No Interference
Enterovirus D68	1.4E+06 copies/mL	No Interference
Haemophilus influenzae	1.8E+07 CFU/mL	No Interference
Legionella pneumophila	8.1E+06 CFU/mL	No Interference
Respiratory Syncytial Virus	3.5E+04 copies/mL	No Interference
Staphylococcus epidermidis	1.9E+07 CFU/mL	No Interference
Streptococcus mutans	5.9E+06 CFU/mL	No Interference
Streptococcus pyogenes	5.5E+06 CFU/mL	No Interference
Varicella Zoster Virus	8.7E+07copies/mL	No Interference
Disinfection/Cleaning Substances		
Reagent Alcohol	7.0%	No Interference
Bleach	1.0% v/v (600 ppm chlorine)	**Interference Observed** [a]
Sample Processing Materials [a]		
Copan Snotbuster (active ingredient DTT)	50.0% v/v	No Interference
Sputolysin (active ingredient DTT)	50.0% v/v	No Interference
SPUTASOL (active ingredient DTT + salts)	50.0% v/v	No Interference
MycoPrep (active ingredient NaOH + NALC)	50.0% v/v	**Interference Observed** [b]
NaOH (decontaminant)	1.0%	**Interference Observed** [b]
Oxalic Acid (decontaminant)	2.5%	**Interference Observed** [b]

[a] FilmArray Pneumonia Panel *plus* testing of lower respiratory specimens that have been processed or treated with these or other substances (e.g. trypsin) has not been validated and is not recommended.

[b] Pouch controls passed but Not Detected results were reported for one or more analytes after incubation of the sample with substance. Substance(s) are known to chemically interact with and damage nucleic acids (DNA and/or RNA) to prevent amplification.

External Control Material

External Controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Molecular grade water or saline can be used as an external negative control. Previously characterized positive samples or negative samples spiked with well characterized organisms can be used as external positive controls.

Alternatively, Maine Molecular Quality Controls, Inc. provides an external positive and negative assayed quality control panel designed to monitor the performance of in vitro laboratory nucleic acid testing procedures for the detection of FilmArray Pneumonia Panel *plus* assays on the FilmArray®, FilmArray® 2.0 or the FilmArray® Torch Systems. The FilmArray Pneumonia Panel/Pneumonia Panel *plus* Control is composed of synthetic nucleic acid specifically designed for and intended to be used solely with the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel *plus*. This material is composed of synthetic nucleic acid specific for all analytes targeted by the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel *plus* assays, including a MERS-CoV synthetic nucleic acid of less than 500 bases. The material is provided as a liquid in a stabilizing matrix. To use the product, the operator opens the tube and uses the Sample Swab to deliver the same volume of material as in the actual test, and otherwise runs the test according to protocol. This control is shipped and stored at -20°C. This product is not intended to replace manufacturer internal controls provided with the test system.

The MMQCI external control material is available for purchase directly from:

Maine Molecular Quality Controls, Inc.
23 Mills Brook Road
Saco, Maine 04072
Phone: (207) 885-1072
http://www.mmqci.com

FilmArray® Pneumonia/Pneumonia *plus* Control M340

It is ultimately the responsibility of each laboratory to determine the frequency of external control testing with the FilmArray Pneumonia Panel *plus* as part of the laboratory's Quality Control program.

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