Protocols for Laboratory Verification of Performance of the BioFire® FilmArray® Pneumonia Panel

Laboratory Protocols for Use with a ZeptoMetrix NATtrol™ Verification Panel

Purpose

The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, establishes quality standards for all laboratory testing to ensure the accuracy and reliability of patient test results, regardless of where the test is performed. The CLIA regulations include a requirement for verifying the performance specifications of unmodified, moderate complexity tests cleared or approved by the FDA.

This document provides examples of verification procedures to assist your laboratory in developing a protocol for the verification of the BioFire Pneumonia Panel performance on BioFire® FilmArray® Systems as required by CLIA. Two possible verification schemes, compatible with the BioFire Pneumonia Panel, have been designed using non-clinical specimens. Each verification scheme provides positive and negative tests for each organism detected by the BioFire Pneumonia Panel, as well as semi-quantitative bin results for bacterial interpretations to demonstrate the ability to distinguish between relative abundance levels in a single test. This scheme may be easily modified or expanded to meet specific criteria.

Day-to-day variation is evaluated by testing each sample on two separate days. To evaluate user-to-user variation, multiple laboratory technicians may test the same sample. In addition, testing patient samples representative of the different types expected to be tested by the laboratory (ex. Sputum, ETA, BAL) for verification of the performance of the BioFire Pneumonia Panel should be done under the guidance of the Laboratory Director, but is not described here.

As per the CLIA regulation, the Laboratory Director is ultimately responsible for ensuring that verification procedures meet the appropriate standards for CLIA and applicable laboratory accrediting agencies.

BioFire Intended Use

The BioFire Pneumonia Panel is a multiplexed nucleic acid test intended for use with BioFire® FilmArray® 1.5, BioFire® FilmArray® 2.0, or BioFire® FilmArray® Torch systems for the simultaneous detection and identification of 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

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mini-BAL) obtained from individuals suspected of lower respiratory tract infections.

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 acids 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		
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 complete intended use statement and additional information about the use of the BioFire® FilmArray® System can be found in the *BioFire® FilmArray® Pneumonia Panel Instructions for Use.*

Performance Verification: Overview

Two different examples of performance verification procedures are described. Both procedures evaluate the performance of each assay on the BioFire® FilmArray® Pneumonia Panel using samples in the presence of synthetic or clinical matrix background. A Synthetic Matrix Protocol describes the verification of the BioFire Pneumonia Panel performance in either a synthetic background (Negative) provided with the ZeptoMetrix NATtrol control organisms or in Artificial Brochoalveolar Lavage Matrix (aBAL). Preparation of aBAL is described in the Performance Verification: Protocols section below. A Clinical Matrix Protocol evaluates the performance of each assay on the BioFire Pneumonia Panel in a clinical specimen matrix (induced or expectorated sputum, endotracheal aspirates or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL). These protocols are examples of procedures to assist your laboratory in developing a protocol for the verification of BioFire Pneumonia Panel performance on BioFire Systems.

Note: It is important to characterize aBAL or clinical matrix specimens for Pneumonia Panel targets by screening the specimen on the BioFire Pneumonia Panel prior to starting the verification procedure. The optimal clinical matrix specimen will be negative for all analytes tested on the BioFire Pneumonia Panel.

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A BioFire® FilmArray® System is defined as all BioFire® FilmArray® Instruments or modules that are connected to and controlled by a single computer system. If the laboratory director chooses not to perform the entire verification protocol on each individual instrument, it is advised that test replicates are evenly distributed among the instruments or modules.

The procedures have been designed to take advantage of the multiplex nature of the BioFire® FilmArray® Pneumonia Panel. Verification testing efficiency is maximized by evaluating multiple target organisms in a single test run. Each procedure described below will generate multiple positive and negative detections for each of the BioFire Pneumonia Panel assays. In addition, semi-quantitative bacteria are reported with relative bin values of 10^4, 10^5, 10^6, or $\geq 10^7$ copies/mL. The protocols described will generate detections in high bins (10^6-$\geq 10^7$) and low bins (10^4-10^5) to demonstrate the ability to differentiate organism levels in a single test run. The procedures were developed using a Pneumonia Verification Panel available from ZeptoMetrix™ Corporation, Buffalo, NY (NATPPA-BIO + NATPPQ-BIO).

Clinical/patient samples may be used in place of or in addition to the verification schemes described here in order to assess clinical sensitivity/specificity and sample matrix effects as part of the performance verification of the BioFire Pneumonia Panel.

Table 1. Overview of Verification Protocols

Verification Protocol	Organisms per Pool	Number of Sample Pools	Replicates per Sample Pool	Pouches Required	Expected Positive Results	Expected Negative Results	Targeted Low Bin Results[a]	Targeted High Bin Results[b]	Approximate Days of Testing[c]
Example 1: Synthetic Matrix protocol	5 or 6	5	4	20	4 per organism	16 per organism	32	36	4
Example 2: Clinical Matrix protocol	5 or 6	5	4	20	4 per organism	16 per organism	32	36	4

[a] Targeted Low Bin Results represents bacterial detections in the semi-quantitative bins of 10^4-10^5 copies/mL.

[b] Targeted High Bin results represent bacterial detections in the semi-quantitative bins of 10^6-$\geq 10^7$ copies/mL.

[c] The approximate number of days for testing assumes a BioFire® FilmArray® System configured with one instrument/module.

Performance Verification: Materials

The following materials may be used to perform verification procedures:

Table 2. Recommended materials for verification protocol

Material	Part Number
BioFire® FilmArray® Pneumonia Panel Kit (30 tests per kit)	BioFire Diagnostics,LLC (RFIT-ASY-0144)
BioFire® FilmArray® Pneumonia Instruction for Use	BioFire Diagnostics,LLC (RFIT-PRT-0575)
BioFire® FilmArray® Pneumonia Panel Quick Guide	BioFire Diagnostics,LLC (RFIT-PRT-0368)
Control Organism[a]	ZeptoMetrix NATPPA-BIO and NATPPQ-BIO
5 mL sample tubes	Various manufacturers
Transfer pipettes	VWR Part # 13-711-43 (or similar)
Human genomic DNA (1mL of 0.2mg/mL) or equivalent[b]	Roche 11691112001

Sterile normal saline (0.85 - 0.9% sodium chloride)[b]	Medline PCS1650 or equivalent
10 mL sample tubes[b]	Various manufacturers

[a]Any appropriate source of organism may be used for verification of any or all of the assays in the BioFire® FilmArray® Pneumonia Panel. However, when alternate organism sources are used (i.e. not the ZeptoMetrix material), the sample volumes or pooling schemes suggested in the examples below may need to be adjusted.

[b]Optional; needed for preparation aBAL matrix

Performance Verification: Protocols

Synthetic Matrix Protocol

The Synthetic Matrix Protocol evaluates BioFire Pneumonia Panel performance in a synthetic matrix. Sample material (ZeptoMetrix NATPPA-BIO and NATPPQ-BIO) is pooled and added to an equal volume of synthetic matrix. The proposed organism pooling scheme (Table 3) should be followed to obtain the expected results for each assay in a time and resource-efficient manner.

Note: Dilution of ZeptoMetrix Pneumonia Verification Panel organisms beyond levels proposed in these guidelines may lead to inconsistent results and is not recommended.

The Synthetic Matrix Protocol can be followed to test 20 pooled samples, providing 4 positive results and 16 negative results per assay, as well as 32 low bin and 36 high bin detections. Sample distribution in the targeted low and high bins are approximate and bin variation may occur due to sampling differences and run variability. The pooling scheme provides sufficient volume for testing more samples if desired. The number of samples tested per day should be determined by the individual laboratory. The testing scheme can be modified to run more samples per day based on the number of instruments configured on the BioFire® FilmArray® System.

Note: Target bin levels are relative and may vary between test runs.

Pooled samples may be stored overnight (or up to 3 days) at refrigeration temperature (2–8°C) for subsequent testing to evaluate day-to-day variation. To evaluate user-to-user variation, multiple laboratory technicians may perform testing.

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Table 3. Proposed Organism Pooling Scheme

Organism	Target Bin Level[a]	Approximate Organism Volume	Approximate Volume of Synthetic or Clinical Matrix	Approximate Final Volume of Pool
Pool 1				
Acinetobacter baumanni	Low	0.2 mL		
Enterobacter cloacae	High	0.2 mL		
Escherichia coli (IMP)	Low	0.2 mL	1.2 mL	2.4 mL
Klebsiella pneumoniae Z138 (OXA-48-like, CTX-M)	High	0.2 mL		
Proteus mirabilis	Low	0.2 mL		
Serratia marcescens	High	0.2 mL		
Pool 2				
Klebsiella aerogenes (aka Enterobacter aerogenes)	High	0.2 mL		
Klebsiella oxytoca	Low	0.2 mL		
Klebsiella pneumoniae KPC-2 (KPC)	High	0.2 mL	1.0 mL	2.0 mL
Pseudomonas aeruginosa (VIM)	Low	0.2 mL		
Streptococcus pyogenes	High	0.2 mL		
Pool 3				
Haemophilus influenzae	High	0.2 mL		
Klebsiella pneumoniae Z460 (NDM/ CTX-M)	High	0.2 mL		
Moraxella catarrhalis	Low	0.2 mL	1.2 mL	2.4 mL
Staphylococcus aureus (*mecA/C* and MREJ)	High	0.2 mL		
Streptococcus agalactiae	Low	0.2 mL		
Streptococcus pneumoniae	Low	0.2 mL		
Pool 4				
Adenovirus Type 31	N/A	0.2 mL		
Coronavirus NL63	N/A	0.2 mL		
Influenza A H3	N/A	0.2 mL	1.2 mL	2.4 mL
Parainfluenza virus Type 1	N/A	0.2 mL		
Respiratory Syncytial Virus (RSV) A2	N/A	0.2 mL		
Legionella pneumophila	N/A	0.2 mL		
Pool 5				
Adenovirus Type 3	N/A	0.2 mL		
Human Metapneumovirus 8	N/A	0.2 mL		
Human Rhinovirus 1 A	N/A	0.2 mL	1.2 mL	2.4 mL
Influenza B	N/A	0.2 mL		
Chlamydia pneumoniae	N/A	0.2 mL		
Mycoplasma pneumoniae	N/A	0.2 mL		

[a]Target bin levels are relative and may vary between test runs. Low Bin results refer to relative abundance of 10^4-10^5 copies/mL; High Bin results refer to relative abundance of 10^6-$\geq 10^7$ copies/mL.

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Technical Note
BioFire Diagnostics, LLC
www.BioFireDX.com

QS-339B-01

Synthetic Matrix Protocol Example

The estimated total time for completion for this verification example is 4 days for a BioFire® FilmArray® System configured with 1 instrument/module. A proposed organism pooling scheme is presented above in Table 3. Refer to Figure 1 for the suggested workflow.

Note: It is important to prepare only the number of sample pools that will be tested within 3 days of preparation. The suggestion to prepare 3 sample pools is based on testing up to 6 pouches per day. The number of samples prepared may be increased or decreased based on the laboratory's work schedule and number of instruments connected within a BioFire System.

Day 1

1. Organize materials needed (Table 2). If using Artificial Brochoalveolar Lavage Matrix (aBAL) - follow the optional protocol below to prepare the synthetic matrix before starting Step 2.

2. Prepare one sample pool (i.e. pool #1) from ZeptoMetrix NATPPQ-BIO and NATPPA-BIO control material. Organism vials should be well mixed prior to preparing each pool. Refer to Table 3 for example organism pooling schemes and specific volumes for each pool.

    a. Transfer 1.2 mL (or 1.0 mL for pool 2) of Synthetic Matrix (either ZeptoMetrix Negative or aBAL) into a tube large enough to hold the entire organism pool volume (at least 3 mL).
    b. Use a transfer pipette to remove the entire contents of the ZeptoMetrix organism vial (approximately 0.2 mL) and transfer to the larger tube containing Synthetic Matrix.
    c. Repeat with the second (and subsequent) organisms to combine the appropriate organisms for each pool into a single tube (approximately 2.0 mL total volume for five organisms or 2.4 mL for six organisms).
    d. Ensure the pooled sample is well mixed prior to removing a sample for testing.
    e. Refrigerate samples (2–8°C) for up to 3 days for the evaluation of day-to-day variation.

3. Prepare and test 2 samples from a single pool (i.e. pool 1). The duplicate samples should be tested in a single day by different users.

Note: For each sample, follow instructions in the *BioFire® FilmArray® Pneumonia Panel Instructions for Use* and the *BioFire® FilmArray® Pneumonia Panel Quick Guide* for pouch preparation, pouch hydration, sample loading, and sample testing.

4. Repeat Steps 2 and 3 for remaining sample pools to be tested that day.

Note: The proposed organism pooling scheme (Table 3) provides sufficient material for running samples as described in Figure. 1. The volume is sufficient for testing more samples if desired.

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Day 2

To evaluate day-to-day variation, test the remaining volume of the sample pools prepared on Day 1 by repeating Step 3 above.

Day 3

Prepare 2 new sample pools (i.e. pools #4 and #5) as described in Step 2. Test samples according to Step 3 above.

Day 4

To evaluate day-to-day variation, test the samples prepared on Day 3 by repeating Step 2 and 3 above.

Optional Protocol: Preparation of Artificial Brochoalveolar Lavage Matrix (aBAL)

1. Thoroughly decontaminate the work area with 10% bleach followed by water wipes.
2. Prepare a 20 ng/uL solution of Human genomic DNA (hgDNA) by adding 1.0 mL hgDNA stock solution (0.2mg/mL) to 9 mL sterile saline in a 10 mL tube.
3. Mix by vortexing or inversion.
4. Characterize aBAL matrix by running a BioFire® FilmArray® Pneumonia Panel test prior to performing verification schemes. The BioFire Pneumonia Panel should test negative for all analytes on the panel.
5. Aliquots of aBAL matrix may be stored refrigerated at 4°C for up to 3 days or stored frozen at ≤ -70°C.

Note: It is important to characterize aBAL or clinical matrix specimens for Pneumonia Panel targets by screening the specimen on the BioFire Pneumonia Panel prior to starting the verification procedure. The optimal clinical matrix specimen will be negative for all analytes tested on the BioFire Pneumonia Panel.

Figure 1. Workflow for Synthetic Matrix Protocol

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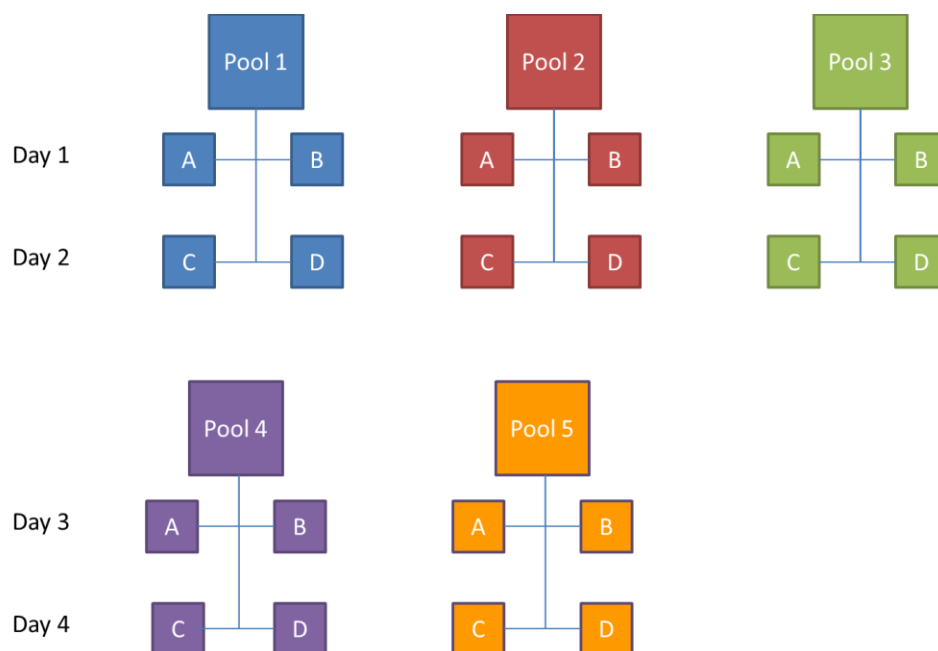
Clinical Matrix Protocol

The Clinical Matrix Protocol evaluates BioFire® FilmArray® Pneumonia Panel performance in a clinical specimen matrix. The laboratory will require a clinical specimen (induced or expectorated sputum, endotracheal aspirates or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) appropriate for the laboratory's verification needs and in a volume sufficient for testing as described in Table 3. The number of different sample types to be tested is up to the discretion of the laboratory director; multiple specimens may be used, if necessary. Clinical specimens should be screened in the BioFire Pneumonia Panel in order to characterize the sample.

Note: It is important to characterize aBAL or clinical matrix specimens for Pneumonia Panel targets by screening the specimen on the BioFire Pneumonia Panel prior to starting the verification procedure. The optimal clinical matrix specimen will be negative for all analytes tested on the BioFire Pneumonia Panel.

Sample material (ZeptoMetrix NATPPA-BIO and NATPPQ-BIO) is pooled and added to an equal volume of clinical matrix. The proposed organism pooling scheme (Table 3) should be followed to obtain the expected results for each assay in a time and resource-efficient manner. Specimen consistency may make accurate measurement difficult, but care should be taken to try to add the volume indicated.

Note: Dilution of ZeptoMetrix Pneumonia Verification Panel organisms beyond levels proposed in these guidelines may lead to inconsistent results and is not recommended.

The Clinical Matrix Protocol can be followed to test 20 pooled samples, providing 4 positive results and 16 negative results per assay, as well as 32 low bin and 36 high bin detections. Sample distribution in the targeted low and high bins are approximate and bin variation may occur due to sampling differences and run variability. The pooling scheme provides sufficient volume for testing more samples if desired. The number of samples tested per day should be determined by the individual laboratory. The testing scheme can be modified to run more samples per day based on the number of instruments configured on the BioFire® FilmArray® System.

Note: Target bin levels are relative and may vary between test runs.

Pooled samples may be stored overnight at refrigeration temperature (2–8°C) for subsequent testing to evaluate day-to-day variation; but all tests should be completed within a day. To evaluate user-to-user variation, multiple laboratory technicians may perform testing.

Note: Clinical specimens may contain inhibitors and enzymes which may degrade the organism mixture and lead to unpredictable results. It is important to prepare the organism pools and test samples within a day to achieve expected results.

Clinical Matrix Protocol Example

The estimated total time for completion for this verification example is 4 days for a BioFire System configured with 1 instrument/module. A proposed organism pooling scheme is presented above in Table 3. Refer to Figure 2 for the suggested workflow.

Note: It is important to prepare only the number of sample pools that will be tested within a day of preparation. The suggestion to prepare 3 sample pools is based on testing up to 6 pouches per day. The number of samples prepared may be increased or decreased based on the laboratory's work schedule and number of instruments connected within a BioFire System.

Day 1

1. Organize materials needed (Table 2.) Clinical specimens should be screened in the BioFire® FilmArray® Pneumonia Panel in order to characterize the sample prior to preparing pools.

2. Prepare one sample pool (i.e. pool #1) from ZeptoMetrix NATPPQ-BIO and NATPPA-BIO control material. Organism vials should be well mixed prior to preparing each pool. Refer to Table 3 for example organism pooling schemes and specific volumes for each pool.

   a. Transfer 1.2 mL (or 1.0 mL for pool 2) of clinical specimen matrix into a tube large enough to hold the entire organism pool volume (at least 3 mL). Care should be taken to transfer the correct volume. Organism to matrix ratios that differ from recommendations in Table 3 may affect detection results.
   b. Use a transfer pipette to remove the entire contents of the ZeptoMetrix organism vial (approximately 0.2 mL) and transfer to the larger tube containing clinical specimen matrix.
   c. Repeat with the second (and subsequent) organisms to combine the appropriate organisms for each pool into a single tube (approximately 2.0 mL total volume for five organisms or 2.4 mL for six organisms).
   d. Ensure the pooled sample is well mixed prior to removing a sample for testing.
   e. Refrigerate samples (2–8°C) for up to a day for the evaluation of day-to-day variation.

3. Prepare and test 2 samples from a single pool (i.e. pool 1). The duplicate samples should be tested in a single day by different users.

Note: For each sample, follow instructions in the *BioFire® FilmArray® Pneumonia Panel Instructions for Use* and the *BioFire® FilmArray® Pneumonia Panel Quick Guide* for pouch preparation, pouch hydration, sample loading, and sample testing.

4. Repeat Steps 2 and 3 for remaining sample pools to be tested that day.

Note: The proposed organism pooling scheme (Table 3) provides sufficient material for running samples as described in Figure. 2. The volume is sufficient for testing more samples if desired.

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Day 2

To evaluate day-to-day variation, test the remaining volume of the sample pools prepared on Day 1 by repeating Step 3 above.
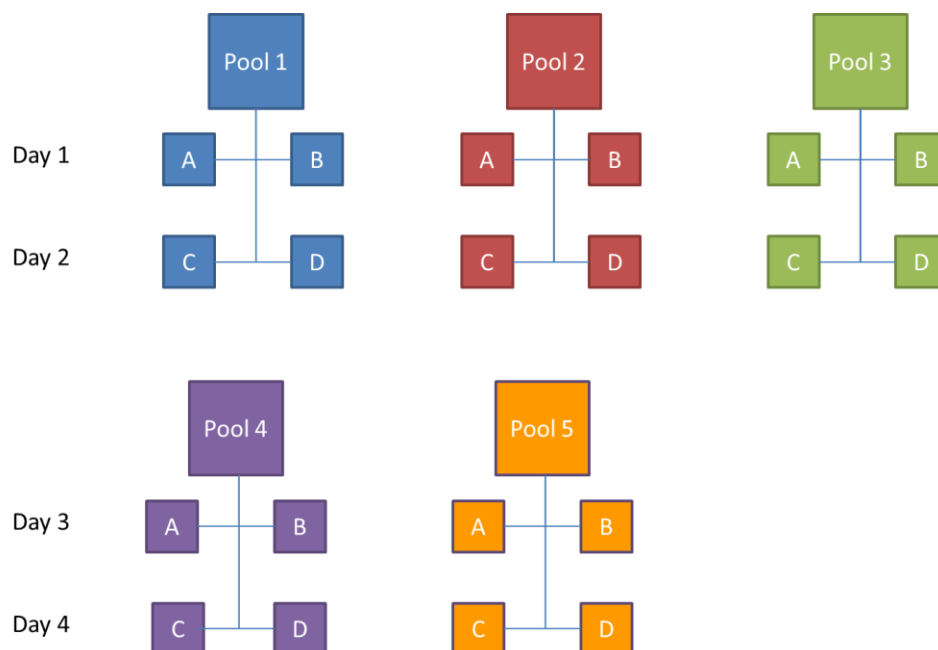
Day 3

Prepare 2 new sample pools (i.e. pools #4 and #5) as described in Step 2. Test samples according to Step 3 above.

Day 4

To evaluate day-to-day variation, test the samples prepared on Day 3 by repeating Step 2 and 3 above.

Figure 2. Workflow for Clinical Matrix Protocol

Expanding the protocols

The protocols described above can be expanded by increasing the number of tests from each of the organism pools. Each organism pool contains approximately 2 mL, which is enough material to complete many tests for each pool.

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Verification of Loaner, Repaired, and Permanent Replacement Instruments

If it becomes necessary to verify the performance of a loaner, repaired, or permanent replacement instrument, the following protocol may serve as a guideline but should be verified by the Laboratory Director.

1. Select a few specimens and/or proficiency samples (any combination of positives and negatives) previously tested on the BioFire® FilmArray® Pneumonia Panel. The Laboratory Director should determine the appropriate number of samples to test. Proficiency samples should not be pooled or diluted.
2. Select a set of controls that verify detection of all targets on the BioFire Pneumonia Panel.
3. Test the selected specimens/samples/controls on the loaner, repaired, or permanent replacement instrument and document the results.

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team for assistance.

BioFire Technical Support
Email: support@biofiredx.com
Phone: +1-801-736-6354, select Option 5

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System Serial # _____

BioFire® FilmArray® Pneumonia Panel, Kit Part #: _____

Lot #: _____

Organism/Sample Source and Lot #: _____

Verification Record: Bacteria Reported in Bins

Organism	Representative Strains	System Serial #	Was the Organism Detected?	# of Positives	# of Negatives	Bin (copies/mL) Low Bin # 10^4	Low Bin # 10^5	High Bin # 10^6	High Bin #≥10^7	# Days Tested	# Users	Matrix Type Tested	Patient Samples Tested?
Bacteria													
Acinetobacter calcoaceticus-baumanni complex			□ Yes / □ No										
Enterobacter cloacae complex			□ Yes / □ No										
Escherichia coli (with IMP call)			□ Yes / □ No										
Haemophilus influenzae			□ Yes / □ No										
Klebsiella aerogenes (aka *Enterobacter aerogenes*)			□ Yes / □ No										
Klebsiella oxytoca			□ Yes / □ No										
Klebsiella pneumoniae group	KPC-2 (with KPC call)		□ Yes / □ No										
	Z138 (with CTX-M and OXA-48 like calls)		□ Yes / □ No										
	Z460 (with CTX-M and NDM calls)		□ Yes / □ No										
Moraxella catarrhalis			□ Yes / □ No										
Proteus spp.			□ Yes / □ No										
Pseudomonas aeruginosa (with VIM call)			□ Yes / □ No										
Serratia marcescens			□ Yes / □ No										
Staphylococcus aureus (with *mecA/C* and MR			□ Yes / □ No										
Streptococcus agalactiae			□ Yes / □ No										
Streptococcus pneumoniae			□ Yes / □ No										
Streptococcus pyogenes			□ Yes / □ No										
Subtotal of Bin Detections at 10^4, 10^5, 10^6 and ≥10^7				N/A	N/A					N/A	N/A	N/A	N/A
Total number of Positives, Negatives, and High and Low Bin Detections				#Positives	#Negatives	Low Bin Total		High Bin Total					

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System Serial # _____

BioFire® FilmArray® Pneumonia Panel, Kit Part #: _____

Lot #: _____

Organism/Sample Source and Lot #: _____

Verification Record: Atypical Bacteria and Viruses

Organism	Representative Strains	System Serial #	Was the Organism Detected?	Number of Positives	Number of Negatives	Bin (copies/mL)				# Days Tested	# Users	Matrix Type Tested	Patient Samples Tested?
						# 10^4	# 10^5	# 10^6	# >10^7				
Atypical Bacteria													
Chlamydia pneumoniae			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Legionella pneumophila			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Mycoplasma pneumoniae			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Viruses													
Adenovirus	Type 3		☐ Yes ☐ No			N/A	N/A	N/A	N/A				
	Type 31		☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Coronavirus			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Human Metapneumovirus			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Human Rhinovirus/Enterovirus			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Influenza A			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Influenza B			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Parainfluenza virus			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Respiratory Syncytial Virus			☐ Yes ☐ No			N/A	N/A	N/A	N/A				
Total number of Positives and Negatives						N/A	N/A	N/A	N/A	N/A	N/A		N/A

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