21120.2380 Procedure for Biofire FilmArray Respiratory Panel and Pneumonia Panel

Copy of version 9.0 (approved and current)

Last Approval or Periodic Review Completed	14-May-2021
Next Periodic Review Needed On or Before	14-May-2022
Effective Date	24-May-2021

Controlled Copy ID 313829

Location Client Request

Organization Eurofins - Viracor

Comments for version 9.0
Updated the resulting section to include (b) (4) (NCE# CA-03191)

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	(b) (6)	14-May-2021 10:58	9.0	(b) (6) (b) (6)	
Approval	(b) (6)	14-May-2021 10:44	9.0	(b) (6) (b) (6)	
Approval	(b) (6)	12-May-2021 16:30	9.0	(b) (6) (b) (6)	
Approval	(b) (6)	12-May-2021 15:07	9.0	(b) (6) (b) (6)	
Approval	(b) (6)	10-Mar-2021 14:18	8.0	(b) (6) (b) (6)	

Approval	(b) (6)	28-Sep-2020 18:13	8.0	(b) (6) (b) (6)
Approval	(b) (6)	28-Sep-2020 9:22	8.0	(b) (6) (b) (6)
Approval	(b) (6)	25-Sep-2020 15:30	8.0	(b) (6) (b) (6)
Approval	(b) (6)	30-Mar-2020 20:40	7.0	(b) (6) (b) (6)
Approval	(b) (6)	25-Mar-2020 13:25	7.0	(b) (6)
Approval	(b) (6)	24-Mar-2020 18:45	7.0	(b) (6) (b) (6)
Periodic review	(b) (6)	17-Feb-2020 8:16	6.0	(b) (6) (b) (6)
Approval	(b) (6)	25-Feb-2019 20:39	6.0	(b) (6) (b) (6)
Approval	(b) (6)	20-Feb-2019 8:37	6.0	(b) (6)

				(b) (6)
Approval	(b) (6)	01-Feb-2019 11:27	5.0	(b) (6) (b) (6)
Approval	(b) (6)	01-Feb-2019 10:52	5.0	(b) (6) (b) (6)
Periodic review	(b) (6)	09-Jan-2019 13:50	4.0	(b) (6) (b) (6)
Periodic review	(b) (6)	05-Feb-2018 8:32	4.0	(b) (6) (b) (6)
Approval	(b) (6)	06-Apr-2017 8:37	4.0	(b) (6) (b) (6)
Approval	(b) (6)	05-Apr-2017 12:37	4.0	(b) (6) (b) (6)
Approval	Lab Operations Director	04-Apr-2017 9:32	4.0	Scott Mather

				Scott Mattivi
Periodic review	(b) (6)	07-Dec-2016 10:29	3.0	(b) (6)
Approval	(b) (6)	14-Dec-2015 12:42	3.0	(b) (6) (b) (6)
Approval	(b) (6)	14-Dec-2015 11:40	3.0	(b) (6) (b) (6)
Approval	Lab Operations Director	11-Dec-2015 15:36	3.0	 Scott Mattivi
Approval	(b) (6)	07-Aug-2015 17:12	2.0	(b) (6) (b) (6)
Approval	Lab Operations Director	07-Aug-2015 17:05	2.0	 Scott Mattivi
Approval	(b) (6)	07-Aug-2015 16:05	2.0	(b) (6) (b) (6)
Periodic review	(b) (6)	20-May-2015 14:10	1.0	(b) (6)

Approval	(b) (6)	25-Mar-2014 8:15	1.0	(b) (6) (b) (6)
Approval	Lab Operations Director	23-Mar-2014 7:55	1.0	 Scott Mattivi
Approval	(b) (6)	21-Mar-2014 14:29	1.0	(b) (6) (b) (6)

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
9.0	Approved and Current	Major revision	03-May-2021	24-May-2021	Indefinite
8.0	Retired	Major revision	25-Sep-2020	05-Oct-2020	24-May-2021
7.0	Retired	Major revision	24-Mar-2020	06-Apr-2020	05-Oct-2020
6.0	Retired	Major revision	19-Feb-2019	27-Feb-2019	06-Apr-2020
5.0	Retired	Major revision	01-Feb-2019	04-Feb-2019	27-Feb-2019
4.0	Retired	Major revision	03-Apr-2017	09-Jan-2019	04-Feb-2019
3.0	Retired	Major revision	21-Oct-2015	15-Dec-2015	07-Apr-2017
2.0	Retired	Major revision	07-Aug-2015	10-Aug-2015	15-Dec-2015
1.0	Retired	Initial version	18-Mar-2014	25-Mar-2014	10-Aug-2015

Linked Documents

- 21120.2381 Biofire FilmArray Panel Worksheet

Table of Contents

INTENDED USE

FilmArray® Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with the FilmArray Instrument for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections..

FilmArray® Pneumonia Panel (Pneumo) is a multiplexed nucleic acid test intended for use with the FilmArray Instrument for the simultaneous qualitative and semi-quantitative detection and identification of multiple respiratory viral and bacterial nucleic acids in sputum-like specimens(induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimen (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infections.

TEST INFORMATION

The FilmArray Respiratory Panel and Pneumonia Panel pouch is a closed system disposable that houses all the chemistry required to isolate, amplify and detect nucleic acid from multiple respiratory pathogens within a single specimen. The rigid plastic component (fitment) of the FilmArray pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) which, through interactions with actuators and sensors in the FilmArray Instrument, are where the required chemical processes are carried out. The user of the FilmArray system loads the sample into the FilmArray pouch, places the pouch into the FilmArray Instrument, and starts the run. All other operations are automated. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by these tests. Positive results do not rule out co-infection with other organisms: the agent(s) detected by the FilmArray tests 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 respiratory tract infection.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray Panels cannot reliably differentiate them. A positive FilmArray Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g., cell culture or sequence analysis).

The following organism types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae.

The following organism types and subtypes are identified using the FilmArray Pneumo Panel: Adenovirus, Coronavirus Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B Parainfluenza Virus Respiratory Syncytial Virus, Chlamydia pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae. The following bacteria are reported semi-quantitatively with bins representing approximately 1.00E+04, 1.00E+05, 1.00E+06, or ≥1.00E+07 genomic copies of bacterial nucleic acid per milliter (copies/ mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria with in a specimen: Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae complex, Escherichia coli, Haemophilus influenza, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Moraxella catarrhalis, Proteus spp., Pseudomonas awruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae and Streptococcus pyogenes.

Test Codes: Respiratory Panel 30854
Pneumonia Panel 30856

METHOD PRINCIPLE

The following is an overview of the operations and processes that occur during a FilmArray run:

1. Nucleic Acid Purification - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes and the bead-beater apparatus can be heard as a high-pitched whine during the first minute of operation.

2. Reverse Transcription and 1st Stage Multiplex PCR - Since many pathogens identified by the FilmArray RP pouch are RNA viruses, a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.

3. 2nd Stage PCR - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen® Plus, BioFire Diagnostics, Inc.). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are 'nested' or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.

4. DNA Melting Analysis – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melting curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray Software automatically evaluates the data from replicate wells for each assay to report results.

SPECIMEN REQUIREMENTS

Patient Preparation

No special patient preparation is required for this assay.

Specimen Type and Handling

Minimum Sample Volume – 300 µL of sample is required for testing.

Transport and Storage –
NPS specimens for the Respiratory Panel that is received in VTM should be processed and tested as soon as possible. If storage is required, specimens in VTM can be held at room temperature (18–30 ºC) for up to 4 hours, at refrigerator temperature (2-8 °C) for up to 3 days, or at freezer temperature (-80 to -65 °C)for up to 30 days.

Sputum-like and BAL-like specimens for the Pneumonia Panel that are received should be processed and tested as soon as possible. If storage is required, specimens can be held at refrigerator temperature (2-8 °C) for up to 24 hours (b) (4)

REAGENTS AND MATERIALS

Lot numbers are tracked in accordance with 21120.572 *Verification and Qualification of Critical Laboratory Materials*. Reagents are used within kits only and lot numbers are not used interchangeably without prior approval from vendor.

Reagents included in the FilmArray RP and Pneumo kits are listed below.

Description	Source	Part/Cat No	Storage
FilmArray RP Kit	Biofire Diagnostics	RFIT-ASY-0124	Room temperature (15–25º C)
Individually packaged FilmArray RP pouches	Biofire Diagnostics	N/A	
Single-use (1.0 mL) Sample Buffer ampoules	Biofire Diagnostics	N/A	
Single-use pre-filled (1.5 mL) Hydration Injection vials (blue)	Biofire Diagnostics	N/A	
Individually packaged Transfer Pipettes	Biofire Diagnostics	N/A	
Single-use Sample Injection vials (red)	Biofire Diagnostics	N/A	
FilmArray Pneumo Kit	Biofire Diagnostics	RFIT-ASY-0144	Room temperature (15–25º C)
Individually packaged FilmArray Pneumo pouches	Biofire Diagnostics	N/A	
Single-use (1.0 mL) Sample Buffer ampoules	Biofire Diagnostics	N/A	
Single-use pre-filled (1.5 mL) Hydration Injection vials (blue)	Biofire Diagnostics	N/A	
Individually packaged Transfer Pipettes	Biofire Diagnostics	N/A	
Single-use Sample Injection vials (red)	Biofire Diagnostics	N/A	

Reagent Handling

- Store reagents at temperature conditions listed above when not in use. Exercise caution when handling components.
- Do not interchange kit components with different lot numbers.
- Avoid storage of any materials near heating or cooling vents or in direct sunlight.
- Always check the expiration date and do not use reagents beyond the expiration date printed on the pouch or kit.
- Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately (b) (4)).
- Once a pouch has been loaded, the test run should be started as soon as possible (within (b) (4) (b) (4)).

Reagent Preparation

- Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
- Remove the FilmArray pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.
- **NOTE**: If the vacuum seal of the pouch packaging is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps below. If hydration is successful, continue with the run. Although, if hydration fails, discard the pouch and use a new pouch to test the sample.

CALIBRATORS AND STANDARDS

Calibrators:
Refer to SOP: 21120.2081 *BioFire Film Array Instrument Operation, Maintenance, and Calibration* for any calibration or maintenance procedures required.

Standards:
N/A, qualitative assay

QUALITY CONTROL

The quality control program for this test is established in accordance with SOP *Analytical Quality Control: Quality Control Procedures*.

Description	Source	Part/Cat No	Storage
(b) (4)			

Run Control Procedure
Two process controls are included in each pouch:

1. **RNA Process Control**
The RNA Process Control assay targets an RNA transcript from the yeast Schizosaccharomyces pombe. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR and DNA melting. A positive control result indicates that all steps carried out in the FilmArray pouch were successful.

2. **PCR2 Control**

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.

Both control assays must be positive for the test run to pass. When either control fails, the Controls field of the test report (upper right hand corner) will display Failed and all results will be listed as Invalid. If the controls fail, the sample should be retested using a new pouch.

(b) (4) Control Procedure

(b) (4)
For the Respiratory Panel (b) (4)
(b) (4)
For the Pneumonia Panel (b) (4)
(b) (4) .

Acceptance Criteria/Repeat Criteria

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch controls were successful.	None	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls failed.	Repeat the test using a new pouch.	Accept the results of the repeat testing. If the error persists, contact technical support for further instruction.
Invalid	The controls are invalid because the run failed. (typically a software or hardware error)	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator's Manual or contact technical support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument. If the error occurred in the first 30 seconds of the run, the same pouch may be used for the repeat test (within 60 minutes of pouch loading) using the same instrument or another instrument, as available. If the error occurred later in the run or you are unsure when the error occurred, return to the original sample to load a new pouch. Repeat the test with the new pouch on the same instrument or another instrument, as available.	Accept the valid results of the repeat testing. If the error persists, contact technical support for further instruction.

Proficiency Testing

These tests shall be challenged by in-house and/or external proficiency testing (b) (4)

EQUIPMENT AND SUPPLIES

Description
FilmArray Instrument or FilmArray Torch Instrument
Vortex
FilmArray Pouch Loading Station

Preventative Maintenance

Follow maintenance procedures for equipment as included in the following SOP 21120.2081 *BioFire Film Array Instrument Operation, Maintenance, and Calibration* or 21120.7712 *BioFire FilmArray Torch Operation Maintenance and Calibration*.

Environmental Conditions

See FilmArray Instrument Operator's Manual or FilmArray Torch Operator's Manual for environmental conditions required for operation.

PROCEDURE

Pouch Preparation

1. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Remove the FilmArray pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

> **NOTE:** If the vacuum seal of the pouch packaging is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps below. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

3. Place the FilmArray Pouch into the FilmArray Pouch Loading Station. To do so, hold the pouch so that the barcoded label is upright and readable, and then slide the flexible film portion of the pouch into the loading station. In the correct configuration, the inlet ports on both ends of the rigid plastic part of the pouch will point up, and the red and blue labels on the pouch will align with the red and blue arrows on the FilmArray Pouch Loading Station.
4. Place a blue-capped Hydration Injection Vial in the blue well of the FilmArray Pouch Loading Station.
5. Place a red-capped Sample Injection Vial in the red well of the FilmArray Pouch Loading Station.

Pouch Hydration

1. Twist and lift the Hydration Injection Vial, leaving the blue cap in the well of the Loading Station.
2. Insert the cannula tip into the port in the pouch located directly below the blue arrow of the Loading Station. Push down forcefully in a firm and quick motion until you hear a "pop" and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the pouch has been hydrated by flipping the barcode label down and checking to see that fluid has entered the reagent wells (at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the port was broken, or retrieve a new pouch and repeat the process.

Respiratory Panel Sample Loading

1. Hold the Sample Buffer ampoule so that the tip is facing up. Do not touch the tip of the ampoule as it could introduce contamination.

2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
3. Invert the ampoule over the red-capped Sample Injection Vial. Grip the bottom of the ampoule, dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided.
4. Using the Transfer Pipette provided in the test kit, draw sample (NPS in VTM) to the third line (approximately 0.3 mL).
    a. Add sample to the red Sample Injection Vial (do not mix).
    b. Tightly close the lid of the Sample Injection Vial.
    c. Discard the Transfer Pipette in a biohazard waste container.
    d. If any specimen anomalies are observed, document observations on worksheet.
5. Remove the Sample Injection vial from the Loading Station and gently invert the vial at least three times to mix.
6. Return the Sample Injection Vial to the Loading Station.
7. Slowly twist the Sample Injection Vial to loosen it from the red cop and pause for 3-5 seconds. Lift the Sample Injection Vial, leaving the red cap in the well of the Loading Station.
8. Insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the FilmArray Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
9. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 2 of the Pouch Hydration section.
10. Dispose of injection vials in an appropriate biohazard sharps container.
11. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the FilmArray Pouch Loading Station.

Pneumonia Panel Sample Loading

1. Hold the Sample Buffer ampoule so that the tip is facing up. Do not touch the tip of the ampoule as it could introduce contamination.
2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
3. Invert the ampoule over the red-capped Sample Injection Vial. Grip the bottom of the ampoule, dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided.
4. Using the Sample Swab provided in the test kit, thoroughly stir the BAL-like or sputum-like specimen for about 10 seconds.
    a. Place the swab end into the Sample Injection Vial then break off the swab handle.
    b. Tightly close the lid of the Sample Injection Vial.
    c. If any specimen anomalies are observed, document observations on worksheet.
5. Remove the Sample Injection vial from the Loading Station and gently invert the vial at least three times to mix.
6. Return the Sample Injection Vial to the Loading Station.
7. Slowly twist the Sample Injection Vial to loosen it from the red cop and pause for 3-5 seconds. Lift the Sample Injection Vial, leaving the red cap in the well of the Loading Station.

8. Insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the FilmArray Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint "pop" and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
9. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 2 of the Pouch Hydration section.
10. Dispose of injection vials in an appropriate biohazard sharps container.
11. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the FilmArray Pouch Loading Station.

Using the FilmArray Instrument to Perform the Test

The FilmArray Software includes a step-by-step on-screen instructions that guide the operator through performing a run.

1. Ensure that the FilmArray Instrument has been powered on and software is launched.
2. Follow on-screen instruction and procedure described in the Operator's Manual to place the pouch in an instrument, enter pouch, sample and operator information.
3. Insert the loaded FilmArray pouch into the instrument.

   Position the pouch so that the array is on the right with the film directed downward into the instrument. The red and blue labels on the FilmArray pouch should align with the red and blue arrows on the FilmArray Instrument. There is a 'click' when the FilmArray pouch has been placed securely in the instrument. If inserted correctly, the pouch barcode is visible. If the FilmArray pouch is not completely in place, the instrument will not continue to the next step.

   NOTE: If the pouch does not slide into the instrument easily, gently push the lid of the instrument back to be sure that it is completely open.
4. Scan the barcode on the FilmArray pouch using the barcode scanner.
   Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the rectangular barcode located on the FilmArray pouch. The information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields.

   NOTE: The barcode cannot be scanned prior to placing the pouch in the instrument. A "Cannot scan now" message will be displayed.
5. Enter the Sample ID.

   The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
6. If necessary, select a protocol from the Protocol drop down list.
7. Insert the pouch into the instrument.
8. Enter a user name and password in the Name and Password fields.
9. Click Start Run.

   Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

   NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first minute of operation.

10. When the run is finished, follow the on-screen instructions to remove the pouch.
11. Immediately discard the pouch in a biohazard container.

Data Analysis

Results are automatically displayed in the report section of the screen.
Select Print to print the report, or Save to save the report as a file.

CALCULATIONS

Manual Calculations:

There are no calculations for this assay

RESULT REPORTING AND REPEAT CRITERIA

When 2nd stage PCR is complete, the FilmArray Instrument performs a high resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see FilmArray Operator's Manual). The FilmArray Software then performs several analyses and assigns a final assay result.

Analysis of melting curves. The FilmArray Software evaluates the DNA melting curve for each well of the 2nd stage PCR array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve. The Tm value is then compared against the expected Tm range for the assay. If the software determines that the melt is positive and the melt peak falls inside the assay-specific Tm range, the curve is called positive. If the software determines that the melt is negative or is not in the appropriate Tm range, the curve is called negative.

Analysis of replicates: Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, *and* the Tm for at least two of the three positive curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

RP Organism Interpretation: For most organisms detected by the FilmArray RP, the organism is considered to be Detected if a single corresponding assay is positive. For example, Human Metapneumovirus will have a test report result of Human Metapneumovirus Detected if at least two of the three replicates of the one Human Metapneumovirus assay have similar positive melt peaks with Tm values that are within the assay-specific Tm range. The test results for Adenovirus, the Human Rhinovirus/Enterovirus group, and Influenza A depend on the interpretation of results from several assays. Interpretation and follow-up testing for these three results are provided below.

- Rhinovirus/Enterovirus Group

  The FilmArray RP pouch contains six different assays (HRV1, HRV2, HRV3, HRV4, Entero 1, Entero 2) for the detection of Rhinoviruses and Enteroviruses. Though these viruses are both very diverse, they are also closely related. Therefore, the six assays are not able to reliably differentiate Rhinovirus and Enterovirus. The FilmArray Software interprets each of the six assays independently (as described above) and the results are combined as a final test result for the virus(es).

  If any of the six assays are positive, the test report result will be Human Rhinovirus/Enterovirus Detected.

  If all six assays are negative, the test report result will be Human Rhinovirus/Enterovirus Not Detected.

A positive FilmArray RP Human Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g., viral culture or sequence analysis).

NOTE: Despite the names, the HRV (1-4) and Entero (1-2) assays are not specific for detection of Human Rhinovirus or Enterovirus, respectively. Individual assay results cannot be used to differentiate these two viruses.

- Adenovirus

The FilmArray RP pouch contains two different assays (Adeno, Adeno2) for the detection of Adenovirus. The FilmArray Software interprets each of these assays independently (as described above) and the results are combined as a final test result for the virus.

If either or both assays are positive, the test report result will be Adenovirus Detected.

If both the Adeno and Adeno2 assays are negative, the test report result will be Adenovirus Not Detected.

- Influenza A

The assays in the FilmArray RP are designed to both detect Influenza A and to differentiate commonly occurring hemagglutinin subtypes. To accomplish this, the FilmArray RP uses two Influenza A assays, (FluA-pan-1 and FluA-pan-2) and three subtyping assays directed at the hemagglutinin gene (FluA-H1-pan, FluA-H1-2009 and FluA-H3). The FluA-H1-pan assay is designed to detect both Influenza A H1 and the Influenza A H1-2009 variant. Each of the individual assays is interpreted independently (as described above) and the test result reported for Influenza A is based on the combined results of the five assays as outlined in Table 1.

In general, Influenza A is determined to be Detected if at least one of the two FluA-pan assays is positive and a subtyping assay is also positive.

If neither of the FluA-pan assays is positive, but a subtyping assay is positive, then the result is considered Equivocal for that specific subtype and the sample should be retested.

If one of the FluA-pan assays is positive and none of the subtyping assays are positive, the result is Equivocal for Influenza A and the specimen should be retested. All Equivocal results should be retested.

Table 1: Possible Assay Results for Influenza A and the Corresponding Interpretation

Assay / Final Result	FluA-pan Assays (n=2)	FluA-H1-pan	FluA-H1-2009	FluA-H3	Required Follow-up
Influenza A Not Detected	Negative	Negative	Negative	Negative	None
Influenza A H1	**≥1 positive**	**Positive**	Negative	Negative	
Influenza A H3	**≥1 positive**	Negative	Negative	**Positive**	
Influenza A H1-2009	**≥1 positive**	Any result	**Positive**	Negative	
Influenza A H1 and Influenza A H3	**≥1 positive**	**Positive**	Negative	**Positive**	Multiple infections are possible but rare [a], retest to confirm result [b]
Influenza A 2009 H1 and Influenza A H3	**≥1 positive**	Any result	**Positive**	**Positive**	

Assay / Final Result	FluA-pan Assays (n=2)	FluA-H1-pan	FluA-H1-2009	FluA-H3	Required Follow-up
Influenza A (no subtype detected)	**2 positive**	Negative	Negative	Negative	See below
Influenza A Equivocal	**1 positive**	Negative	Negative	Negative	Retest
Influenza A H1 Equivocal	Negative	**Positive**	Negative	Negative	
Influenza A H3 Equivocal	Negative	Negative	Negative	**Positive**	
Influenza A H1-2009 Equivocal	Negative	Any result	**Positive**	Negative	

[a] The FilmArray RP system can simultaneously detect multiple Influenza viruses contained in the FluMist® nasal Influenza vaccine (see "Interference" section below).
[b] Repeated multiple positives should be further confirmed by other FDA cleared Influenza subtyping tests.

- Influenza A (no subtype detected)

  If both of the Flu A-pan assays are positive, but none of the hemagglutinin subtyping assays are positive, then the interpretation is Influenza A (no subtype detected). This result could occur when the titer of the virus in the specimen is low and not detected by the subtyping assays. This result could also indicate the presence of a novel Influenza A strain. In both cases, the sample in question should be retested.
  If the retest provides a different result, test the sample a third time to ensure the accuracy of the result.
  If the retest provides the same result, then the function of the RP pouches should be verified by testing with appropriate external control materials (known positive samples for Influenza A H1, Influenza A H3 and Influenza A H1-2009), and a negative control should also be run to test for PCR-product contamination.
  If the FilmArray RP accurately identifies the external and negative controls, contact the appropriate public health authorities for confirmatory testing.

- Biopharma sample interpretation

  For Biopharma samples - if the initial result is Equivocal or Influenza A (no subtype detected), repeat testing. If retesting does not confirm the initial result, report all Influenza A analytes (Influenza A, Influenza A subype H1, Influenza A subype H1/2009, Influenza A subtype H3) as **See Comment**. Use comment "Result Inconclusive. Sample quantity not sufficient for additional confirmation testing". If retesting does confirm Equivocal or Influenza A (no subtype detected), report all Influenza A analytes as **See Comment**, then add either "Equivocal" or "No subtype detected" in the Comment field.

Pneumonia Panel Organism Interpretation: Analysis of assay results for Bacteria. The assays in the FilmArray Pneumonia Panel for detection of bacteria that are reported semi-quantitatively are designed to amplify genes that are present in single copies within the chromosome of the target bacterium and are used to estimate genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen. The FilmArray Software calculates an approximate value for each gene target based on real-time PCR amplification data relative to the QSM (internal reference of known quantity). Assays with no measurable amplification or a value below 1.00E+3.5 copies/mL are called negative. Assays with a value equal to or greater than 1.00E+3.5 copies/mL are called positive.

Each positive and negative assay result is interpreted by the FilmArray Software to provide results for the identification of specific bacteria, atypical bacteria, viruses, and antimicrobial resistance (AMR) genes as shown in Table 2. Viracor does not report the AMR genes. For most analytes detected by the FilmArray Pneumonia Panel,

interpretations are based on the result of a single assay. However, results for Staphylococcus aureus, Adenovirus, and the AMR genes require interpretation based on more than one assay result, as discussed in the relevant sections below.

Table 2. Analytes Detected by the FilmArray Pneumonia Panel

Bacteria		
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*
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 (not reported)		
CTX-M	NDM	*mecA*/*C* and MREJ
IMP	OXA-48-like	
KPC	VIM	

- Interpretations and Semi-quantitative Bin Results for Bacteria:

  The FilmArray Pneumonia Panel provides a Detected or Not Detected result as well as a semi-quantitative bin result (1.00E+04 copies/mL, 1.00E+05 copies/mL, 1.00E+06 copies/mL or ≥1.00E+07 copies/mL) for most bacteria. The bin result represents the approximate number of specific bacterial genomes in the specimen and is intended to provide a simple assessment of relative abundance of nucleic acids from different bacteria in a lower respiratory specimen based on a molecular method.

  For bacteria, negative assays (no measurable amplification or value less than 1.00E+3.5 copies/mL) are reported as Not Detected. Positive assays are reported as Detected and a bin result is assigned based on the assay value. Each bin is defined by discrete upper and lower limits spanning a 1-log range of values (see Table 3) such that the bin result reflects the assay value within the nearest ±0.5-log.

Table 3. FilmArray Pneumonia Panel Bin Results for Bacteria

Assay Result		Reported Result and Bin Result
Negative OR	<1.00E+3.5	Not Detected
Positive AND	≥1.00E+3.5 - <1.00E+4.5 copies/mL	Detected: 1.00E+04
Positive AND	≥1.00E+4.5 - <1.00E+5.5 copies/mL	Detected: 1.00E+05
Positive AND	≥1.00E+5.5 - <1.00E+6.5 copies/mL	Detected: 1.00E+06
Positive AND	≥1.00E+6.5 copies/mL	Detected: >1.00E+05

- Staphylococcus aureus

  The FilmArray Pneumonia Panel pouch contains two different assays (Saureus1 and Saureus2) for the detection of *Staphylococcus aureus*. The FilmArray Software interprets each of these assays independently (as described above) and if one or a combination of the assays is positive, the result will be *Staphylococcus aureus* Detected with the appropriate bin result. If both assays are negative the result will be *Staphylococcus aureus* Not Detected.

NOTE: 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 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.

- Interpretations for Atypical Bacteria and Viruses:

  Results for most Atypical Bacteria and Viruses are reported as Detected or Not Detected based on an individual corresponding assay result. If the assay is positive the result will be Detected, and if the assay is negative, the result will be Not Detected. However, Adenovirus detection is reported based on the results of multiple assays, as described below.

  - Adenovirus

    The FilmArray Pneumonia Panel pouch contains three different assays (Adenovirus2, Adenovirus3, and Adenovirus7) for the detection of all species and serotypes of Adenovirus. The FilmArray Software interprets each of these assays independently (as described above) and the results are combined as a final result for the virus. If one or any combination of assays is positive, the result will be Adenovirus Detected. If all assays are negative, the result will be Adenovirus Not Detected.

(b) (4)

- Results will be entered manually into (b) (4) using the **Resp Panel > BioFire FilmArray Panel** Batch Template.
- Select “Add” to add a batch under BioFire FilmArray Panel Batch Template. Scan accessions into batch. Print worklist.
  - Results of Not Detected for each organism can be populated using the **Populate Default Results** on the Results tab in Result Entry by Batch.
  - Change populated default result to Detected for those organisms that are detected on the run summary.
- Review results and finish batch.
- Refer 21120.2363 *Operation of* (b) (4) *and Batch Release* for instructions on result entry and batch approval.

(b) (4)

- Verify results and comments in (b) (4) and approve batch.
- See 21120.2363 *Operation of* (b) (4) (b) (4) *and Batch Release* for instructions on result entry and batch approval.

EXPECTED VALUES AND REFERENCE RANGES

Expected Values: Refer to FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0103-01), BioFire Diagnostics, Inc. or FilmArray Pneumonia Panel Instruction Booklet (RFIT-ASY-0144, RFIT-ASY-0145). BioFire Diagnostics, Inc. for expected values associated with this test.

Alert Values and Critical Values: There are no Alert or Critical values currently associated with this assay.

CLINICAL SIGNIFICANCE

The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection if used in conjunction with other clinical and laboratory findings. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decision.

Positive results do not rule out bacterial infection, or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, radiography, etc.) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection.

PROCEDURE NOTES

Testing System Unavailable

Viracor Laboratories takes precautions to ensure that testing systems do not have prolonged outages by ensuring that we have redundant equipment for all of our testing platforms. In this case, there is not a second instrument and if the test system were to go down, specimens would be stored according to their individual storage requirements until such time as the testing system is back to operational status and testing may resume again. In extreme cases whereby an entire testing system is going to be completely down for an extended period of time of (b) (4), clients will be notified and alternative testing options, potentially at other facilities will be communicated to them where possible and at their discretion.

The RP assay has been approved by the FDA for testing of nasopharyngeal (NP) swabs.
The Pnuemonia Panel assay has been approved by the FDA for testing of sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL).

LIMITATIONS OF THE METHOD

Respiratory Panel

- This product can be used only with the FilmArray Instrument.
- This test is a qualitative test and does not provide a quantitative value for the organism(s) detected in the specimen.
- The performance of the test has been evaluated for use with human specimen material only.
- This test has not been validated for testing specimens other than nasopharyngeal swab (NPS) specimens in transport medium.
- The performance of this test has not been established for immunocompromised individuals.
- The performance of this test has not been established for patients without signs and symptoms of respiratory infection.
- Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- The effect of antibiotic treatment on test performance has not been evaluated.
- Viral and bacterial nucleic acids may persist in vivo independent of organism viability. Detection of organism target(s) does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.
- The detection of viral and bacterial nucleic acid is dependent upon proper specimen collection, handling, transportation, storage and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive or false negative values resulting from improperly collected, transported or handled specimens.

- A negative FilmArray RP result does not exclude the possibility of viral or bacterial infection. Negative test results may occur from the presence of sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antiviral/antibacterial therapy or levels of organism in the specimen that are below the limit of detection for the test. Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen.
- If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.
- False positive and false negative results can be the result of a variety of sources and causes, it is important that these results be used in conjunction with other clinical, epidemiological, or laboratory information. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate to low.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay.
- Observed and predicted cross-reactivity for BioFire RP is described in the Analytical Specificity section of the Instructions for Use booklet. Erroneous results due to cross-reactivity with organisms that were not evaluated or new variant sequences that emerge is also possible.
- The BioFire RP Adenovirus assay may show variable detection with non-respiratory serotypes within species A, D, F and G.
- The BioFire RP Influenza A subtyping assays target the Influenza A hemagglutinin (H) gene only. The BioFire RP does not detect or differentiate the Influenza A neuraminidase (N) gene.
- Clinical specificity was established when Influenza A H1-2009 (H1N1pdm09) was the predominant Influenza A virus in circulation. When other Influenza A viruses are emerging, clinical specificity may vary.
- A new influenza B subclade (B/Vicotoria V1A.3) emerged during the 2018-2019 influenza season. Mutations within this subclade have demonstrated a mile reduction in analytical sensitivity (estimated 10-100 fold difference in the limit of detection with this test, approximated to be near 2000 copies per mL) as compared to other Victoria strains. This variant was not circulating when analytical reactivity was initially evaluated for this panel.
- Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for Bordetella pertussis, Coronavirus 229E, Coronavirus OC43, Influenza A H1, Influenza A H3, Influenza A H1-2009, Influenza B, Mycoplasma pneumoniae, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4, were established primarily with retrospective clinical specimens. Performance characteristics for Chlamydophila pneumoniae were established primarily using contrived clinical specimens.
- The performance of this test has not been established for screening of blood or blood product.
- Recent administration of nasal influenza vaccines (e.g. FluMist) prior to NPS specimen collection could lead to accurate virus detection by the BioFire RP of the viruses contained in the vaccine, but would not represent infection by those agents.
- Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP cannot reliably differentiate them. A positive FilmArray RP Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g. cell culture or sequence analysis) if differentiation is required.
- The Coronavirus OC43 assay may cross-react with Coronavirus HKU1. As a result, when both HKU1 and OC43 are detected in the same patient specimen, the result may be due to assay cross-reactivity. A co infection with these two viruses is also possible.
- The BioFire RP may not be able to distinguish between existing viral strains and new variants as they emerge. For example, the BioFire RP can detect Influenza A H3N2v (first recognized in August, 2011), but will not be able to distinguish this variant from Influenza A H3N2 seasonal. If variant virus infection is suspected, clinicians should contact their state or local health department to arrange specimen transport and request a timely diagnosis at a state public health laboratory.
- BioFire RP detects a single-copy Pertussis Toxin promoter target (ptxP, present at one copy per cell) in B. pertussis. Other PCR tests for B. pertussis target the multi-copy IS481 insertion sequence (present in both B. pertussis and B. holmesii) and are therefore capable of detecting lower levels of B. pertussis (i.e. more sensitive)
    - BioFire RP should not be used if B pertusiss infection is specifically suspected; a B. pertussis molecular test that is FDA-cleared for use on patients suspected of having a respiratory tract infection attributable to B. pertussis only should be used instead.

- Due to lower sensiviity, the BioFire B. pertussis assay is less susceptible than IS481 assays to the detection of very low levels of contaminating B. pertussis vaccine material. However care must always be taken to avoid contamination of specimens with vaccine material as higher levels may still lead to false positive results with the BioFire RP test)
- The IS481 sequence is also present B. holmesii and to a lesser extent in B. bronchiseptica, wherease the BioFire RP2.1 assay (ptxP) was designed to be specific for B. pertussis. However, the BioFire RP Bordetella pertussis (ptxP) assay can also amplify pertussis toxin pseudogene sequences when present in B. bronchiseptica and B. parapertussis. Cross-reactivity was observed only at high concentrations (e.g. >/=1.2E+09 CFU/mL).

Pneumonia Panel:

- For prescription use only.
- The FilmArray Pneumonia Panel has not been validated for testing of specimens other than unprocessed sputum-like and BAL-like specimens.
- Contact or treatment of specimens with decontaminating agents (bleach, MycoPrep (NaOH and NALC), 2% NaOH and 5% Oxalic acid) can cause false negative results (see Interference section).
- The performance of FilmArray Pneumonia Panel has not been established for specimens collected from individuals without signs and/or symptoms of lower respiratory infection.
- The performance of the FilmArray Pneumonia Panel has not been established for monitoring treatment of infection.
- The effect of antibiotic treatment on test performance including semi-quantitative bin results has not been specifically evaluated.
- Viral and bacterial nucleic acids may persist in vivo independent of organism viability. Detection of organism target(s) does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.
- The FilmArray Pneumonia Panel results for bacteria are provided as a qualitative Detected/Not Detected result with an associated semi-quantitative bin result of 10^4, 10^5, 10^6, or ≥10^7 copies of genomic nucleic acid per milliliter of specimen. An exact quantitative value is not provided. The semi-quantitative (copies/mL) bin result does not distinguish between nucleic acid from live or dead bacteria.
- A negative FilmArray Pneumonia Panel result does not exclude the possibility of viral or bacterial infection. Negative test results may occur from the presence of sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antiviral/antibacterial therapy or levels of organism in the specimen that are below the limit of detection for the test or below the reportable level for bacterial analytes. Negative results should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
- Concomitant culture of specimens is required with the FilmArray Pneumonia Panel. Culture is needed for recovery of isolates and antimicrobial susceptibility testing, as well as further speciation of genus, complex, or group level results (if desired).
- Due to the genetic similarity between human rhinovirus and enterovirus, the FilmArray Pneumonia Panel cannot reliably differentiate them. A FilmArray Pneumonia Panel Human Rhinovirus/Enterovirus Detected result should be followed-up using an alternate method (e.g. cell culture or sequence analysis) if differentiation between the viruses is required.
- The in silico analyses performed to predict amplification and detection of organisms and antimicrobial resistance genes were based on a comparison of target gene sequences available in GenBank to FilmArray Pneumonia Panel primer sequences. In silico analyses were performed between January 2016 and January 2018. Entries of new sequences added to the database after these dates have not been evaluated. Additional limitations on reactivity may be identified as new sequence data are deposited and/or as new sequence variants emerge.
- Based on in silico analysis, the MREJ assay (which is only reported if Staphylococcus aureus is detected and the mecA/C assay is also positive) is predicted to have impaired reactivity or to be non-reactive with MREJ types ix, xv and xviii, as well as types xix and xx (associated with methicillin-sensitive S. aureus; MSSA), and MREJ sequences annotated from non-aureus Staphyloccoccus species and non-Staphyloccci such as Bacillus cereus, Bacillus thuringiensis, Macrococcus caseolyticus, Clostridium acidurici, and Rummeliibacillus stabekisii.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate to low.

- Performance characteristics for influenza A were established during the 2016-2017 influenza season. When other novel influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
- Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for several analytes in one or both matrices were primarily established using archived and/or contrived specimens as detailed in the Clinical Performance section.

PERFORMANCE SPECIFICATIONS

Refer to FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0103-01), BioFire Diagnostics, Inc. or FilmArray Pneumonia Panel Instruction Booklet (RFIT-ASY-0144, RFIT-ASY-0145). BioFire Diagnostics, Inc. for performance specifications associated with this test.

SAFETY

The following personal protective equipment will be applied as directed in currently effective Safety SOPs, including but not limited to, gloves, masks, lab coats, face shields and eye protection.

Personnel executing these procedures must be trained on effective Safety SOPs as listed in *Safety Program*.

See Material Safety Data Sheet (MSDS) manual for further details regarding all agents in the kit.

RELATED DOCUMENTS

21120.2081 BioFire Film Array Instrument Operation, Maintenance, and Calibration
21120.7712 BioFire FilmArray Torch Operation Maintenance and Calibration
21120.369 Analytical Quality Control - Assay Calibration and Calibration Verification
21120.572 Verification and Qualification of Critical Laboratory Materials
21120.265 Safety Program

REFERENCES

FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0435-01), BioFire Diagnostics, Inc
FilmArray Pneumonia Panel Instruction Booklet (RFIT-ASY-0144, RFIT-ASY-0145). BioFire Diagnostics, Inc.
BioFire FilmArray Operator's Manual and BioFire FilmArray Torch Operator's Manual; this can be found at https://www.biofiredx.com/support/documents/

ATTACHMENTS

21120.2381 FilmArray Respiratory Panel Worksheet