



September 22, 2021

BioFire Diagnostics, LLC  
Kevin Bourzac  
Vice President, Regulatory & Clinical Affairs  
515 Colorow Drive  
Salt Lake City, Utah 84108

Re: K212727

Trade/Device Name: FilmArray Pneumonia Panel  
Regulation Number: 21 CFR 866.3985  
Regulation Name: Device To Detect And Identify Microorganisms And Associated Resistance Marker  
Nucleic Acids Directly In Respiratory Specimens  
Regulatory Class: Class II  
Product Code: QDP  
Dated: August 26, 2021  
Received: August 27, 2021

Dear Kevin Bourzac:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Maria I. Garcia -S**

Maria Ines Garcia, Ph.D.

Branch Chief

Division of Microbiology Devices

OHT7: Office of In Vitro Diagnostics  
and Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K180966

Device Name

FilmArray Pneumonia (PN) Panel

Indications for Use (Describe)

The FilmArray® Pneumonia Panel is a multiplexed nucleic acid test intended for use with FilmArray® 2.0 or 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 mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The following bacteria are reported semi-quantitatively with bins representing approximately  $10^4$ ,  $10^5$ ,  $10^6$ , or  $\geq 10^7$  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  $\geq 10^7$  copies/mL

- Acinetobacter calcoaceticus-baumannii complex
- Enterobacter cloacae complex
- Escherichia coli
- Haemophilus influenzae
- Klebsiella aerogenes
- Klebsiella oxytoca
- Klebsiella pneumoniae group
- Moraxella catarrhalis
- Proteus spp.
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Streptococcus pneumoniae
- Streptococcus pyogenes

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, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower 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 patient 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, 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 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 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 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, 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.**

---

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
*PRAStaff@fda.hhs.gov*

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**Special 510(k) Summary  
BioFire Diagnostics, LLC**

**FilmArray Pneumonia Panel**

**Introduction:**

Purpose

The content of this Special 510(k) submission is limited to obtaining FDA clearance for the FilmArray PN Panel (K180966) with modified labeling to address recent stability results of the adenovirus2 assay used for the detection of adenovirus C species.

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.

Background

Stability study results showed that the Adenovirus2 assay on the PN Panel exhibited an increased rate of unexpected Negative results in pouches that are more than 6 months from the date of manufacture (i.e. within 6 months of expiration). As a result of the stability testing, BioFire conducted a voluntary recall of the FilmArray PN Panel (Part No. RFIT-ASY-0144 and RFIT-ASY-0145) in June 2021 (refer to Recall Event 88117/ Z-2039-2021).

In addition, and as a corrective action, the FilmArray PN Panel 'Limitations' section in the Instructions for Use has been modified to include new limitations as well as an additional footnote on the analytical Limit of Detection (LoD) table (Table 62 in the Instructions for Use) that addresses the detection of adenovirus in the FilmArray PN Panel within 6 months of expiration.

**Submitted by:**

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

**Contact:**

Kevin Bourzac, Ph.D.  
Telephone: 801-736-6354, ext. 1358  
Fax: 801-588-0507  
Email: Kevin.bourzac@biofiredx.com

**Date Submitted:**

August 26, 2021

**Trade Name:**

FilmArray Pneumonia Panel

**Classification Name:**

Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens (21 CFR 866.3985)

**Predicate Device:**

K180966 – FilmArray Pneumonia (PN) Panel

**Intended Use:**

The FilmArray® Pneumonia Panel is a multiplexed nucleic acid test intended for use with FilmArray® 2.0 or 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 mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The following bacteria are reported semi-quantitatively with bins representing approximately  $10^4$ ,  $10^5$ ,  $10^6$ , or  $\geq 10^7$  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 $\geq 10^7$ copies/mL |                                    |                                 |
|--|------------------------------------|---------------------------------|
| <i>Acinetobacter calcoaceticus-baumannii</i> complex                               | <i>Klebsiella oxytoca</i>          | <i>Serratia marcescens</i>      |
| <i>Enterobacter cloacae</i> complex  | <i>Klebsiella pneumoniae</i> group | <i>Staphylococcus aureus</i>    |
| <i>Escherichia coli</i>  | <i>Moraxella catarrhalis</i>       | <i>Streptococcus agalactiae</i> |
| <i>Haemophilus influenzae</i>  | <i>Proteus spp.</i>                | <i>Streptococcus pneumoniae</i> |
| <i>Klebsiella aerogenes</i>  | <i>Pseudomonas aeruginosa</i>      | <i>Streptococcus pyogenes</i>   |

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

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

The detection and identification of specific viral and bacterial nucleic acids, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower 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 patient 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, 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 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 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 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, 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 (PN) Panel is designed to simultaneously identify 26 potential pathogens of lower respiratory tract infection (LRTI) and 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 with signs and/or symptoms of lower respiratory tract infection in a time (~1 hour) that allows the test results to be used in determining appropriate patient treatment and management. FilmArray PN Panel is compatible with BioFire Diagnostics’ (BioFire) PCR-based *in vitro* diagnostic FilmArray 2.0 (K143178) and FilmArray Torch (K160068) systems for infectious disease testing. A specific software module (i.e. FilmArray PN Panel pouch module) is used to perform FilmArray PN Panel testing on these systems.

| Bacteria – Quantitative Results                      | Antimicrobial Resistance Genes  |
|--|---|
| <i>Acinetobacter calcoaceticus-baumannii</i> complex | <i>bla</i> <sub>CTX-M</sub> (Extended spectrum beta-lactamase (ESBL)) |
| <i>Enterobacter cloacae</i> complex                  | <i>bla</i> <sub>IMP</sub> (Carbapenem resistance)                     |
| <i>Escherichia coli</i>                              | <i>bla</i> <sub>KPC</sub> (Carbapenem resistance)                     |
| <i>Haemophilus influenzae</i>                        | <i>mecA/mecC</i> and MREJ (Methicillin resistance)                    |
| <i>Klebsiella aerogenes</i>                          | <i>bla</i> <sub>NDM</sub> (Carbapenem resistance)                     |
| <i>Klebsiella oxytoca</i>                            | <i>bla</i> <sub>Oxa48-like</sub> (Carbapenem resistance)              |
| <i>Klebsiella pneumoniae</i> group                   | <i>bla</i> <sub>VIM</sub> (Carbapenem resistance)                     |
| <i>Moraxella catarrhalis</i>                         | <b>Viruses</b>  |
| <i>Proteus</i> spp.                                  | Adenovirus  |
| <i>Pseudomonas aeruginosa</i>                        | Coronavirus   |
| <i>Serratia marcescens</i>                           | Human Metapneumovirus   |
| <i>Staphylococcus aureus</i>                         | Human Rhinovirus/Enterovirus  |
| <i>Streptococcus agalactiae</i>                      | Influenza A   |
| <i>Streptococcus pneumoniae</i>                      | Influenza B   |
| <i>Streptococcus pyogenes</i>                        | Parainfluenza Virus   |
| <b>Bacteria (Atypical) - Qualitative Results</b>     | Respiratory Syncytial Virus   |
| <i>Chlamydia pneumoniae</i>                          |   |
| <i>Legionella pneumophila</i>                        |   |
| <i>Mycoplasma pneumoniae</i>                         |   |

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 PN Panel 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 instrument contains a coordinated system 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 single plex 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 feature of the FilmArray PN Panel is the reporting of organism abundance for common bacteria in discrete bins representing  $10^4$ ,  $10^5$ ,  $10^6$ , and  $\geq 10^7$  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.

**Device Comparison:**

Table 1 outlines the similarities and differences between the two panels.

**Table 1 Comparison of the FilmArray PN with modified labeling to the current FilmArray PN Panel.**

| Element            | Modified Device:<br>FilmArray PN Panel (with modified labeling)  | Predicate:<br>FilmArray PN Panel<br>(K180966) |
|--------------------|--|---|
| Organisms Detected | Bacteria: <i>Acinetobacter calcoaceticus-baumannii</i> complex, <i>Enterobacter aerogenes</i> , <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i> , <i>Haemophilus influenzae</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella</i> | Same  |

| Element                   | Modified Device:<br>FilmArray PN Panel (with modified labeling)  | Predicate:<br>FilmArray PN Panel<br>(K180966) |
|---------------------------|--|---|
|                           | <p><i>pneumoniae</i> group, <i>Moraxella catarrhalis</i>, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>, <i>Serratia marcescens</i>, <i>Staphylococcus aureus</i>, <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i></p> <p>Atypical Bacteria: <i>Chlamydia pneumoniae</i>, <i>Legionella pneumophila</i>, <i>Mycoplasma pneumoniae</i></p> <p>Antimicrobial Resistance Genes: CTX-M, IMP, KPC, <i>mecA/C</i> + MREJ, NDM, Oxa48-like, VIM</p> <p>Viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza virus, Respiratory Syncytial virus</p> |   |
| Analyte                   | DNA/RNA  | Same  |
| Specimen Types            | Positive blood culture samples containing gram-positive or gram-negative bacteria and/or yeast.  | Same  |
| Technological Principles  | Nested multiplex PCR followed by high resolution melting analysis to confirm the identity of amplified product.  | Same  |
| Instrumentation           | Single instrument FilmArray 2.0 System, or FilmArray Torch System  | Same  |
| Time to result            | About 1 hour   | Same  |
| Test Interpretation       | Automated test interpretation and report generation. User cannot access raw data.  | Same  |
| Sample Preparation Method | Sample Processing is automated in the FilmArray PN pouch.  | Same  |
| Reagent Storage           | Reagents are stored at room temperature.   | Same  |
| Shelf-Life                | 12 months from Date of Manufacture (DOM)*  | 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  |

\* LoD for adenovirus species C is 10 – 100 x impaired when pouches are within 6 months of expiration

The purpose of this submission is to modify the labeling of the FilmArray PN Panel to include the following limitations in the Instructions for Use:

17. There is an increased risk of false negative Adenovirus results for adenovirus species C when using a pouch that is within 6 months of the expiration date due to a 10-100 x loss in sensitivity (i.e. impairment leading to an increase in the LoD). The test performance is not impacted if kits are more than 6 months from expiration date. Performance for other adenovirus species is not impacted.
18. If using a pouch that is within 6 months of expiration when a patient is suspected of adenovirus C infection, confirm all negative Adenovirus results using another method prior to reporting the result, or alternatively, do not report a negative Adenovirus result.

An additional footnote in the Analytical LoD (Table 62) of the Instructions for Use will also be included.

**Conclusion:**

The fundamental scientific technology, performance, and risk of the FilmArray PN Panel is unchanged from the legally marketed FilmArray PN Panel. There is no change to the product itself, only to the labeling (Instructions for Use). Therefore, the modified FilmArray PN Panel performs as well as the predicate device.