IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LABRADOR DIAGNOSTICS LLC, Plaintiff, v. BIOFIRE DIAGNOSTICS, LLC and BIOMERIEUX S.A., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

LABRADOR DIAGNOSTICS LLC'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Labrador Diagnostics LLC ("Labrador"), by and through its undersigned counsel, pleads the following against BioFire Diagnostics, LLC ("BioFire") and bioMerieux S.A. ("bioMerieux") (collectively, "Defendants") and alleges as follows:

THE PARTIES

1. Plaintiff Labrador is a Delaware limited liability company duly organized and existing under the laws of the State of Delaware.

2. On information and belief, Defendant BioFire is a corporation duly organized and existing under the laws of the State of Delaware. On information and belief, Defendant BioFire is a wholly owned subsidiary of Defendant bioMerieux S.A.

3. On information and belief, Defendant bioMerieux S.A. is a foreign corporation, formed under the laws of France.

JURISDICTION AND VENUE

4. This is an action arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Defendant BioFire because on information and belief BioFire manufactures infringing products that are and have been used, offered for sale, sold, and/or purchased in the District of Delaware, and BioFire has committed, and continues to commit, acts of infringement in the District of Delaware, has conducted business in the District of Delaware, and/or has engaged in continuous and systematic activities in the District of Delaware. For example, upon information and belief, Defendant BioFire makes, uses, offers for sale, sells, and induces and contributes to the infringement of its products known as the BioFire FilmArray System, BioFire FilmArray 2.0, BioFire FilmArray EZ, BioFire FilmArray Torch, BioFire FilmArray pouches and/or panels ("pouches"), and BioFire FilmArray software running on computers (individually and in combination the "Accused Products") in this District. Further, Defendant BioFire has submitted itself to the jurisdiction of this Court by electing to incorporate in the State.

6. This Court has personal jurisdiction over Defendant bioMerieux because on information and belief bioMerieux directly or indirectly through control of its subsidiary BioFire manufactures infringing products that are and have been used, offered for sale, sold, and purchased in the District of Delaware, and bioMerieux has directly or indirectly through control of its subsidiary BioFire committed, and continues to commit, acts of infringement in the District of

Delaware, has directly or indirectly through control of its subsidiary BioFire conducted business in the District of Delaware, and/or has engaged in continuous and systematic activities in the District of Delaware.

7. For example, upon information and belief, Defendant bioMerieux through its subsidiary Defendant BioFire submitted FilmArray pouches, to be used in conjunction with the FilmArray 2.0, FilmArray EZ, and/or FilmArray Torch as part of the FilmArray System in an infringing manner, to the FDA for FDA clearance. *See, e.g.*, bioMerieux Website, "bioMerieux submits for FDA Clearance of the BIOFIRE® FILMARRAY® Pneumonia Panel," April 19, 2018, https://www.biomerieux.com/en/biomerieux-submits-fda-clearance-biofirer-filmarrayr-pneumonia-panel; bioMerieux Website, "bioMerieux submits enhanced BIOFIRE® BCID2 Panel for FDA clearance," January 13, 2020, https://www.biomerieux.com/en/biomerieux-submits-enhanced-biofirer-bcid2-panel-fda-clearance.

8. As an additional example, upon information and belief, Defendant bioMerieux advertises use of the Accused Products on its website and in its literature for use in the United States in an infringing manner for example, by advertising its FDA status, (*see, e.g.*, *id.*; bioMerieux 2018 Annual Report at, e.g., 16, available at https://www.biomerieux.com/sites/corporate/files/biomerieux_annual_report_2018.pdf), and providing contact information for the purchase of the Accused Products.

9. As a further example, upon information and belief, Defendant bioMerieux has pervasive control over the activities of its subsidiary Defendant BioFire. As one illustration, Defendant bioMerieux directs and controls the infringing activities of its subsidiary Defendant BioFire as shown, for example, by its referral to the Accused Products as "our [bioMerieux's]

BIOFIRE® product line" as "a clear growth driver that has propelled bioMerieux to the position of market leader." *Id*. at 2.

10. As a yet further example of bioMerieux's pervasive control over the activities of its subsidiary Defendant BioFire, upon information and belief, Defendant bioMerieux directs and controls the infringing activities of its subsidiary Defendant BioFire by its direct control of BioFire senior management. In particular, Randy Rasmussen is both the "CEO of BioFire Diagnostics and Executive VP Molecular Biology of bioMerieux." *See, e.g.*, bioMerieux Website, https://www.biomerieux-diagnostics.com/biomerieux-submits-enhanced-biofirer-bcid2-panel-fda-clearance. On an affiliated US website, bioMerieux lists Mr. Rasmussen among its "Corporate Governance" leaders, noting that "The Management Committee is responsible for putting bioMerieux's strategy into effect: overseeing strategic projects, deciding on priorities and implementing the necessary resources within the Company's various divisions." bioMerieux USA Website, "About bioMerieux: Corporate Governance," https://www.biomerieux-usa.com/about-us/corporate-governance. The "Corporate Governance" group of bioMerieux also lists Kirk Ririe as "Corporate VP, Chief Innovative Officer." *Id*. On information and belief, Mr. Ririe is also a co-founder of BioFire and identifies as the "CEO" at BioFire Diagnostics. *See* LinkedIn, Kirk Ririe, https://www.linkedin.com/in/kirk-ririe-81692bb.

11. Defendant bioMerieux has additionally availed itself of the privileges of this Court. For example, bioMerieux has sought to enforce patent rights against an alleged infringer in this District. *See bioMerieux, S.A. v. Hologic Inc.*, Case No. 1:18-cv-00021-LPS. The trial was completed only days ago, on February 25, 2020, and is currently undergoing post-trial motions.

12. Under 28 U.S.C. §§ 1391(b)-(d) and 1400(b), venue is proper in this judicial district as to Defendant BioFire because at least BioFire resides within this District, as it is incorporated

in the State of Delaware. Further, on information and belief, venue is additionally proper because Defendant BioFire has committed acts of infringement within this judicial district giving rise to this action.

13. Further, under 28 U.S.C. §§ 1391(b)-(d), venue is proper in this judicial district as to Defendant bioMerieux because bioMerieux is a foreign corporation and, as described above, is subject to this Court's jurisdiction.

FIRST CLAIM

(Infringement of U.S. Patent No. 8,283,155)

14. Labrador re-alleges and incorporates herein by reference Paragraphs 1-13 of its Complaint.

15. The '155 Patent, entitled "Point-of-Care Fluidic Systems and Uses Thereof," was duly and lawfully issued on October 9, 2012. A true and correct copy of the '155 Patent is attached hereto as Exhibit 1.

16. The '155 Patent has been in full force and effect since its issuance. Labrador owns by assignment the entire right, title, and interest in and to the '155 Patent, including the right to seek damages for past, current, and future infringement thereof.

17. The '155 Patent relates generally to "the field of medical devices," including "portable medical devices that allow real-time detection of analytes from a biological fluid." Ex. 1 at Abstract.

18. Labrador is informed and believes, and on that basis alleges, that Defendants individually and collectively[1] have infringed and, unless enjoined will continue to infringe, one or

[1] All reference to Defendants or Defendants' products refer to the Defendants individually and collectively and to products over which the Defendants individually and collectively control.

more claims of the '155 Patent, in violation of 35 U.S.C. § 271, by, among other things, making, using, offering to sell, and selling within the United States, and/or supplying or causing to be supplied in or from the United States, without authority or license, the Accused Products for use in an infringing manner.

19. The Accused Products embody at least claim 1 of the '155 Patent, literally or under the doctrine of equivalents, as set forth below. The further descriptions below, which are based on publicly available information, are preliminary examples and are non-limiting. On information and belief, the FilmArray 2.0, FilmArray EZ, and FilmArray Torch devices operate, together with the FilmArray pouches and software, similarly as pertinent to the non-limiting examples set forth below. On information and belief, the FilmArray EZ operates in substantially the same manner as the FilmArray 2.0, and as such is not separately addressed below. For the purposes of infringement, Plaintiff Labrador's non-limiting examples relating to the FilmArray 2.0 are equally applicable to the FilmArray EZ, albeit with use of at least the RP EZ Panel designed for use with the FilmArray EZ. *See* BioFire Diagnostics Website, https://www.biofiredx.com/products/the-filmarray-panels/filmarray-respiratory-panel-ez/.

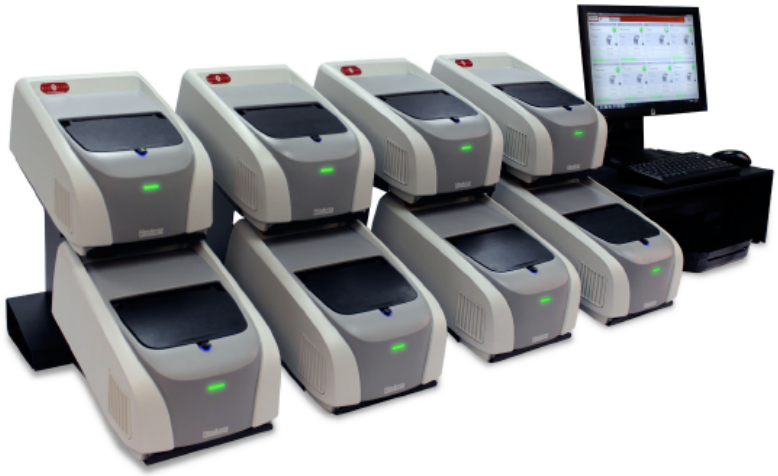
"1. A two-way communication system for detecting an analyte in a bodily fluid from a subject, comprising:"

20. Defendants' FilmArray 2.0 and Torch systems are each two-way communication systems for detecting an analyte in a bodily fluid from a subject.

21. Defendants' FilmArray 2.0 Instrument connected to a computer running FilmArray software, together with FilmArray pouches, is a system. This system is referred to herein as the "FilmArray 2.0 System."

22. The FilmArray 2.0 System is a two-way communication system. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

The FilmArray 2.0 system is composed of one to eight FilmArray 2.0 instruments connected to a computer running FilmArray software. The FilmArray software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.



23. Defendant's FilmArray Torch Module connected to a FilmArray Torch System Base, together with FilmArray pouches, is a system. This system is referred to herein as the "FilmArray Torch System."

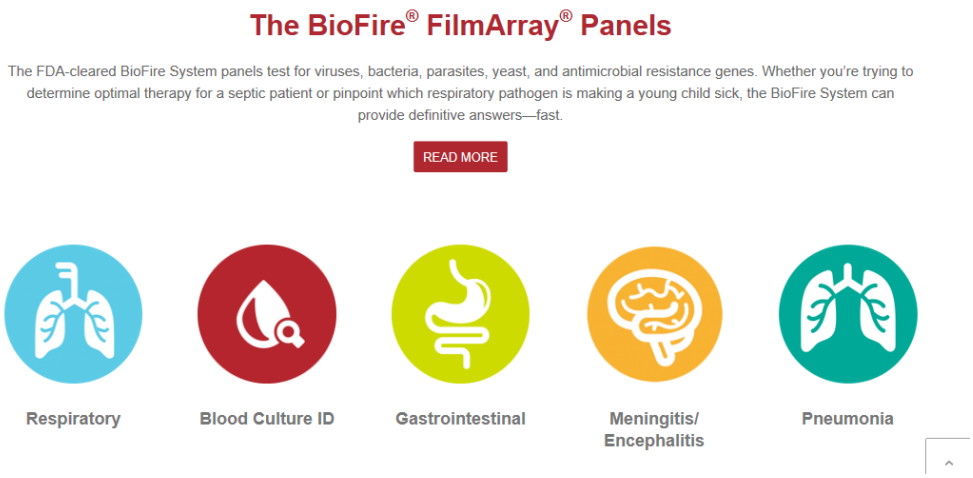
24. The FilmArray Torch System is a two-way communication system. *See, e.g.*, FilmArray Torch Operators' Manual at 1:

FilmArray Torch Intended Use

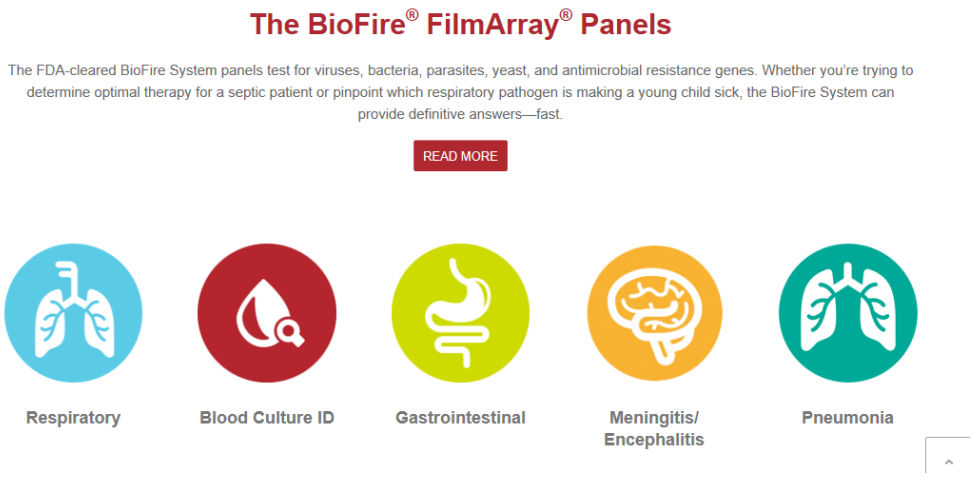
The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

25. The FilmArray 2.0 System is designed to detect an analyte in a bodily fluid from a subject. *See, e.g.*, BioFire Diagnostics Website, https://www.biofiredx.com/:



26. Similarly, the FilmArray Torch System is designed to detect an analyte in a bodily fluid from a subject. *See, e.g.*, BioFire Diagnostics Website, https://www.biofiredx.com/:



See also, e.g., FilmArray Torch Operators' Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

"a) a reader assembly comprising a programmable processor that is operably linked to a communication assembly;"

27. Defendants' FilmArray 2.0 and Torch systems each include a reader assembly comprising a programmable processor that is operably linked to a communication assembly.

28. For example, Defendants' FilmArray 2.0 System includes one or more FilmArray 2.0 Instruments. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

The FilmArray 2.0 system is composed of one to eight FilmArray 2.0 instruments connected to a computer running FilmArray software. The FilmArray software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

29. Defendants' FilmArray Torch System includes one or more FilmArray Torch Modules. *See, e.g.*, FilmArray Torch Operator's Manual at 1:

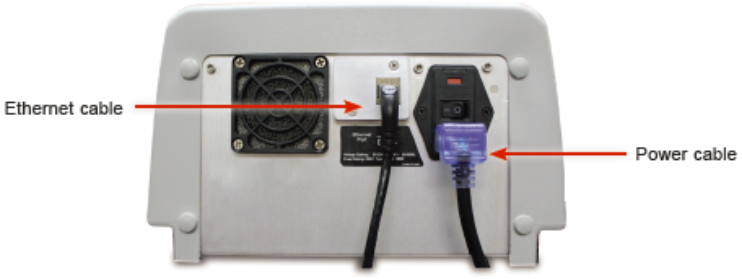
The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

30. Defendant's FilmArray 2.0 Instrument(s) include(s) a programmable processor connected to one or more Ethernet interfaces. *See, e.g.*, FilmArray 2.0 Operator's Manual at 24:

The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

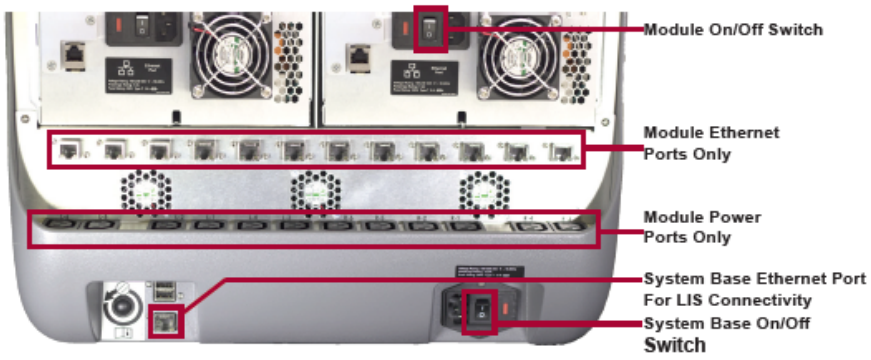
Id. at 9:

3. Connect the instrument Ethernet cable and instrument power cord to the back of the instrument as shown.



31. The Ethernet interface to which a programmable processor of the FilmArray 2.0 Instrument connects is a communication assembly.

32. Defendant's FilmArray Torch Module(s) include(s) a programmable processor connected to one or more Ethernet interfaces. *See, e.g.*, FilmArray Torch Operator's Manual at 10:



33. The Ethernet interface to which a programmable processor of the FilmArray Torch Module connects is a communication assembly.

"b) an external device configured to transmit a protocol to the communication assembly;"

34. Defendants' FilmArray 2.0 and Torch systems each include an external device configured to transmit a protocol to the communication assembly of a reader assembly.

35. For example, the FilmArray 2.0 System includes a computer external to FilmArray 2.0 Instruments. *See, e.g.*, BioFire Diagnostics Website, https://www.biofiredx.com/products/filmarray/:

See also, e.g., FilmArray 2.0 Operator's Manual at 24:

> The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

36. The FilmArray Torch System includes a FilmArray Torch System Base that is external to FilmArray Torch modules. *See, e.g.*, FilmArray Torch Operators' Manual at 1:

> **FilmArray Torch Intended Use**
>
> The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.
>
> The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

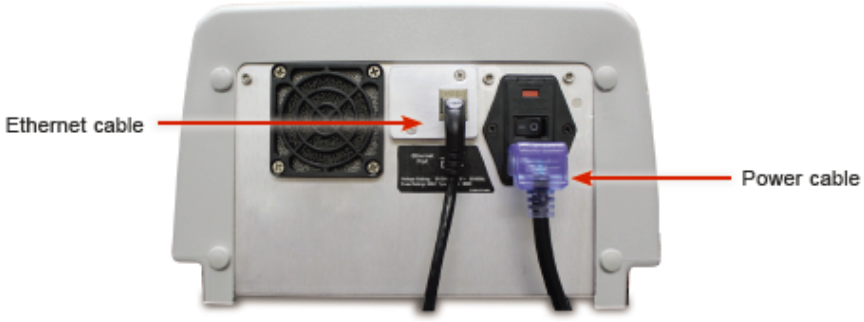
37. The external computer in a FilmArray 2.0 System is configured to transmit a protocol to an Ethernet interface of a FilmArray 2.0 Instrument. *See, e.g.*, FilmArray 2.0 Operator's Manual at 24:

> The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

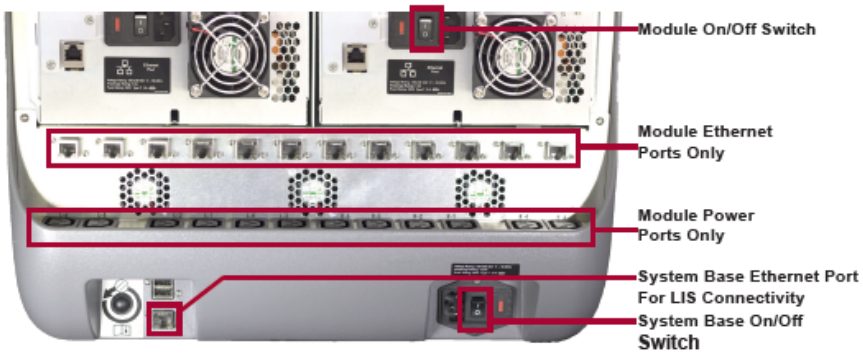
Id. at 3-4:

> **Instrument and Pouch Interaction**
> After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray instrument controls these functions automatically based on the run protocol selected for a specific pouch and sample type in the FilmArray software.

Id. at 9:

> 3. Connect the instrument Ethernet cable and instrument power cord to the back of the instrument as shown.
>
> 
>

38. The FilmArray Torch System Base is configured to transmit a protocol to an Ethernet interface of a FilmArray Torch Module. *See, e.g.*, FilmArray Torch Operator's Manual at 10:



Id. at 27:

Start Run

After the pouch is correctly inserted into the FilmArray Torch Module, the LED will blink green to indicate that the pouch has been seated but the run has not yet started. To continue the run after Manual or Scan Initiation:

1. Select the correct pouch protocol for the pouch and sample type.

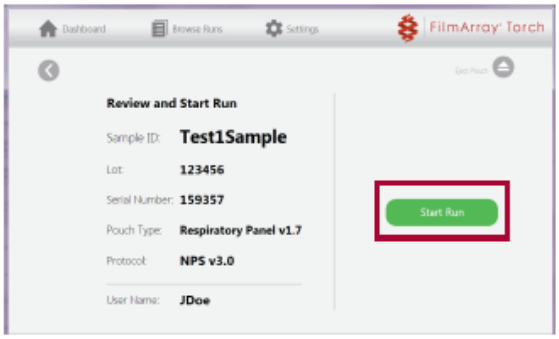
NOTE: If only one protocol is available, it will be automatically selected.

2. Enter operator username and password, then select **Next**.

   The Next key will only become available when a correct username and password is entered. See the *Create New Operator(s)* section in *Chapter 6* for more information on how to create a new operator's username and password.

NOTE: The font color of the username and password is red until the user name is recognized by the FilmArray Torch software.

3. Review run information on the screen and if correct, select **Start Run.**



"c) a test device configured to be inserted into the reader assembly, said test device comprising:"

39. Defendants' FilmArray 2.0 and Torch systems each include a test device configured to be inserted into a reader assembly of the system.

40. The FilmArray 2.0 system is used in combination with FilmArray test device pouches. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

41. The FilmArray Torch system is used in combination with FilmArray test device pouches. *See, e.g.*, FilmArray Torch Operator's Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

42. As a further example, each FilmArray pouch is configured to be inserted into a FilmArray 2.0 Instrument. *See, e.g.*, FilmArray 2.0 Operator's Manual at 18:

4. Load the pouch into the FilmArray instrument.

Position the pouch with the black array on the right side and the film portion of the pouch entering the instrument first. The pouch will lock into place when it is properly inserted.

Ensure that the red and blue labels on the pouch align with the red and blue arrows on the FilmArray instrument as shown in the figure above. If inserted correctly, the barcode label is visible on the top of the FilmArray pouch. There is an audible click when the pouch is securely in place.

If the FilmArray pouch is not completely in place, the instrument and software will not continue to the next step.

43. Each FilmArray pouch is configured to be inserted into a FilmArray Torch Module. *See, e.g.*, FilmArray Torch Operator's Manual at 25-26:

Once a pouch has been prepared for testing, follow the on-screen instructions to enter pouch and sample information. Insert the pouch into an available FilmArray Torch Module and start the run.

. . .

2. Insert the pouch into the selected FilmArray Torch Module. The Module's LED will blink blue. Ensure that the pouch fitment label is lying flat on top of the pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.

CAUTION: Do not insert sharp objects to remove a jammed pouch. In the event of a jammed pouch, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for Customer Support.

"i) a sample collection unit configured for collecting a sample of bodily fluid suspected to contain an analyte;"

44. Each of Defendants' FilmArray pouches includes a sample collection unit configured for collecting a sample of bodily fluid suspected to contain an analyte.

45. For example, each FilmArray pouch includes a sample injection port into which the FilmArray operators are instructed to insert a sample mixture for testing such that the sample is collected within the pouch. *See, e.g.*, FilmArray RP2 Reagent Quick Guide:

Step 3: Prepare Sample Mix

a. Hold Sample Buffer Ampoule tip facing up and firmly pinch at textured plastic tab on side of ampoule until seal snaps.

NOTE: *Do not touch ampoule tip.*

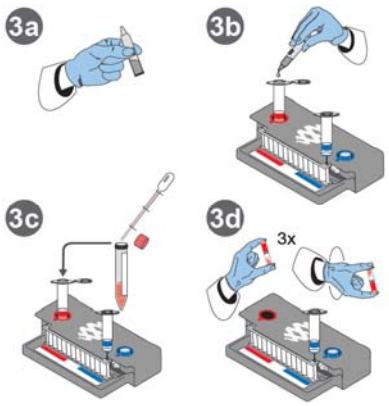
b. Dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze followed by a second squeeze.

NOTE: *Avoid generating excessive foaming.*

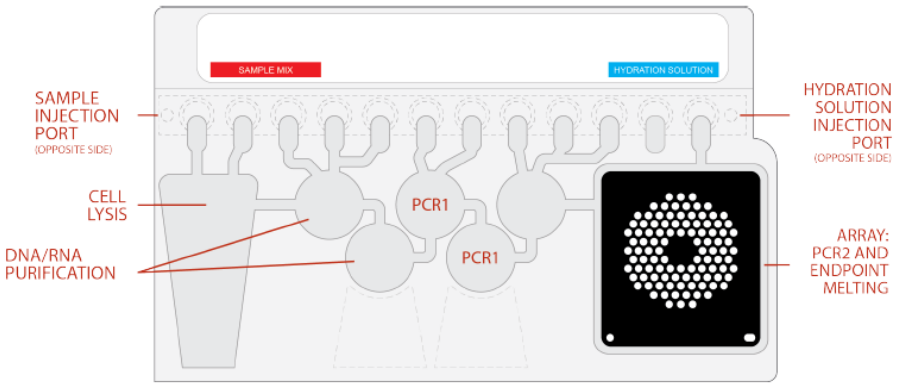
c. Use the transfer pipette to draw specimen to the third line. Add specimen to Sample Injection Vial then tightly close lid.

d. Invert the Sample Injection Vial **3 times** then return to red well of Pouch Loading Station.

WARNING: *The Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.*



See also FilmArray Pneumonia Panel Instructions for Use at 8:



"ii) an assay assembly containing reactants that react with said sample of bodily fluid based on the protocol transmitted from said external device to yield a detectable signal indicative of the presence and/or concentration of said analyte; and"

46. Each of Defendants' FilmArray pouches includes an assay assembly containing reactants that react with a sample of bodily fluid based on the protocol transmitted from an external device to yield a detectable signal indicative of the presence and/or concentration of said analyte.

47. For example, each FilmArray pouch contains polymerase chain reaction (PCR) reactants configured to react with a bodily fluid sample injected into the FilmArray pouches. *See, e.g.*, FilmArray 2.0 Operator's Manual at 3:

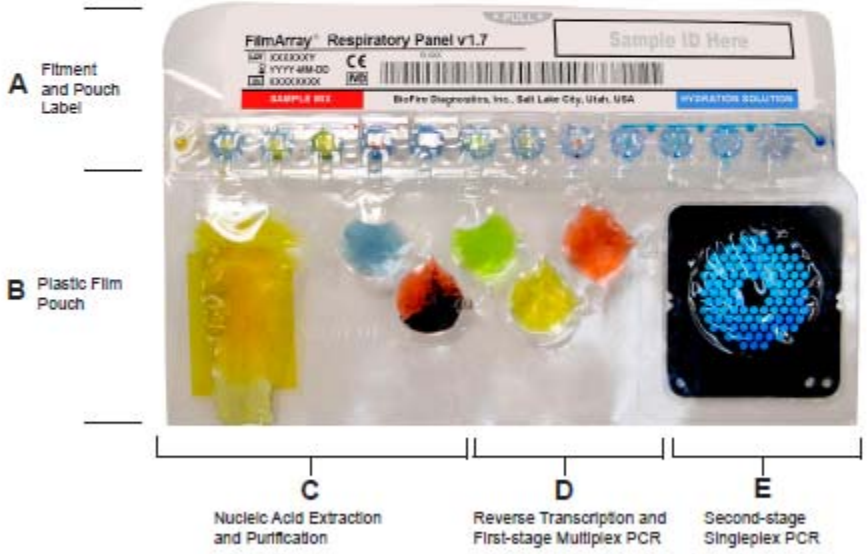
FilmArray Pouch

Each FilmArray pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain colored fluid.

See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

48. The reactants in a FilmArray pouch are configured to react with a sample of bodily fluids based on the protocol transmitted from an external computer in a FilmArray 2.0 System or

the FilmArray Torch System Base in a FilmArray Torch System, respectively, when each FilmArray System is used. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

Id. at 24:

The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

Id. at 3-4:

Instrument and Pouch Interaction

After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray instrument controls these functions automatically based on the run protocol selected for a specific pouch and sample type in the FilmArray software.

See also, e.g., FilmArray Torch Operator's Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

Id. at 27:

Start Run

After the pouch is correctly inserted into the FilmArray Torch Module, the LED will blink green to indicate that the pouch has been seated but the run has not yet started. To continue the run after Manual or Scan Initiation:

1. Select the correct pouch protocol for the pouch and sample type.

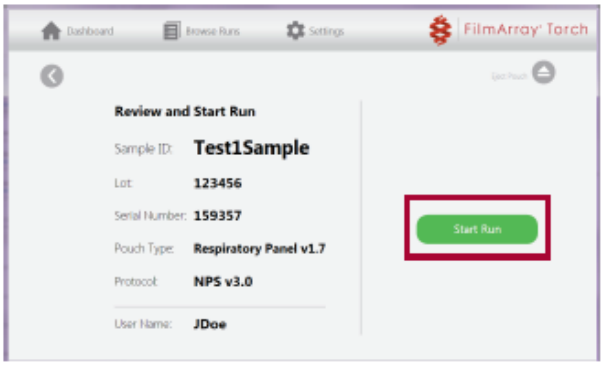
NOTE: If only one protocol is available, it will be automatically selected.

2. Enter operator username and password, then select **Next**.

   The Next key will only become available when a correct username and password is entered. See the *Create New Operator(s)* section in *Chapter 6* for more information on how to create a new operator's username and password.

NOTE: The font color of the username and password is red until the user name is recognized by the FilmArray Torch software.

3. Review run information on the screen and if correct, select **Start Run.**



49. The reactants in FilmArray pouches are configured to react with a sample of bodily fluid to yield a fluorescent signal indicative of the presence and/or concentration of a nucleic acid analyte. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

Id. at 4:

Optics and Imaging
To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

See also, e.g., FilmArray Torch Operator's Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

Id. at 5:

Optics and Imaging
To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

50. The reactants in a BioFire FilmArray Pneumonia Panel, for example, react with a sample of bodily fluids to yield a detectable signal indicative of the presence and/or concentration

of various viruses and bacteria. *See, e.g.*, FilmArray Pneumonia Panel Instructions for Use at 18-19:

Assay Interpretation

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray Operator's Manual). The FilmArray Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The FilmArray Software evaluates the DNA melt curve for each well of the PCR2 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 and compares it against the expected Tm range for the assay. If the software determines that the Tm of the curve is within the assay-specific Tm range, the melt curve is called positive. If the software determines that the Tm of the curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, two associated melt curves must be called positive, and both Tms must be similar. Assays that do not meet these criteria are called negative.

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 10^3.5 copies/mL are called negative. Assays with a value equal to or greater than 10^3.5 copies/mL are called positive.

. . .

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 (10^4 copies/mL, 10^5 copies/mL, 10^6 copies/mL or ≥10^7 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 10^3.5 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 2) such that the bin result reflects the assay value within the nearest ±0.5-log.

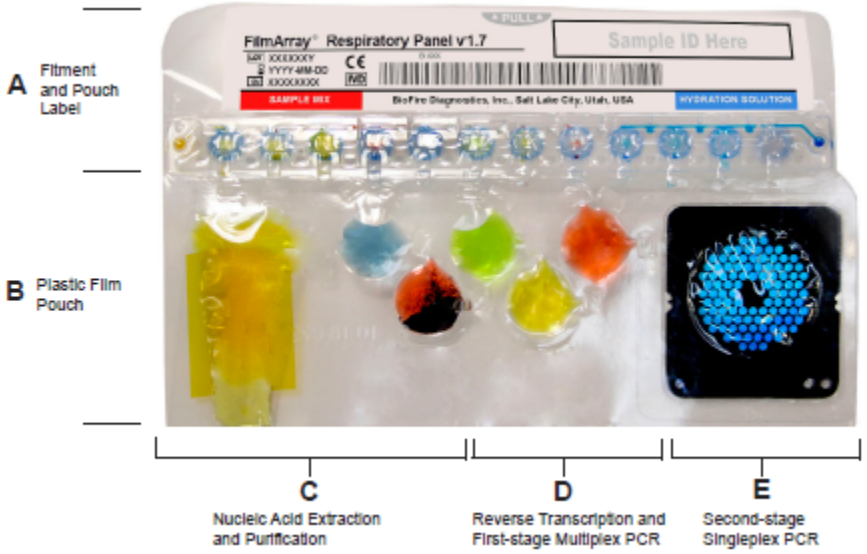
Table 2. FilmArray Pneumonia Panel Bin Results for Bacteria

Assay Result		Reported Result and Bin Result	
Negative OR	<10^3.5 copies/mL	Not Detected	
Positive AND	≥10^3.5 – <10^4.5 copies/mL	Detected	10^4 copies/mL
Positive AND	≥10^4.5 – <10^5.5 copies/mL	Detected	10^5 copies/mL
Positive AND	≥10^5.5 – <10^6.5 copies/mL	Detected	10^6 copies/mL
Positive AND	≥10^6.5 copies/mL	Detected	≥10^7 copies/mL

"iii) an identifier that is configured to provide the identity of said test device and is also configured to trigger the transmission of said protocol that is selected based on said identifier;"

51. Defendants' FilmArray pouches each include an identifier that is configured to provide the identity of said test device and is also configured to trigger the transmission of said protocol that is selected based on said identifier.

52. For example, the FilmArray pouches include one or more identifiers, including barcode and human readable identifiers, that provide the identity of each pouch to the FilmArray 2.0 external computer and the FilmArray Torch System Base, respectively, based on the FilmArray System being used. *See, e.g.*, FilmArray 2.0 Operator's Manual at 3:



See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

See also, e.g., FilmArray 2.0 Operator's Manual at 16:

FilmArray Reagent Kits

Each kit includes FilmArray pouches and all components required to run tests on the FilmArray instrument. Components will vary based on the type of FilmArray reagent kit. Refer to the instruction booklet or quick guide for specific preparation and testing procedures.

CAUTION: Do not attempt to use components from one reagent kit to prepare a different pouch type. Components are pouch specific.

Each FilmArray pouch is labeled with:

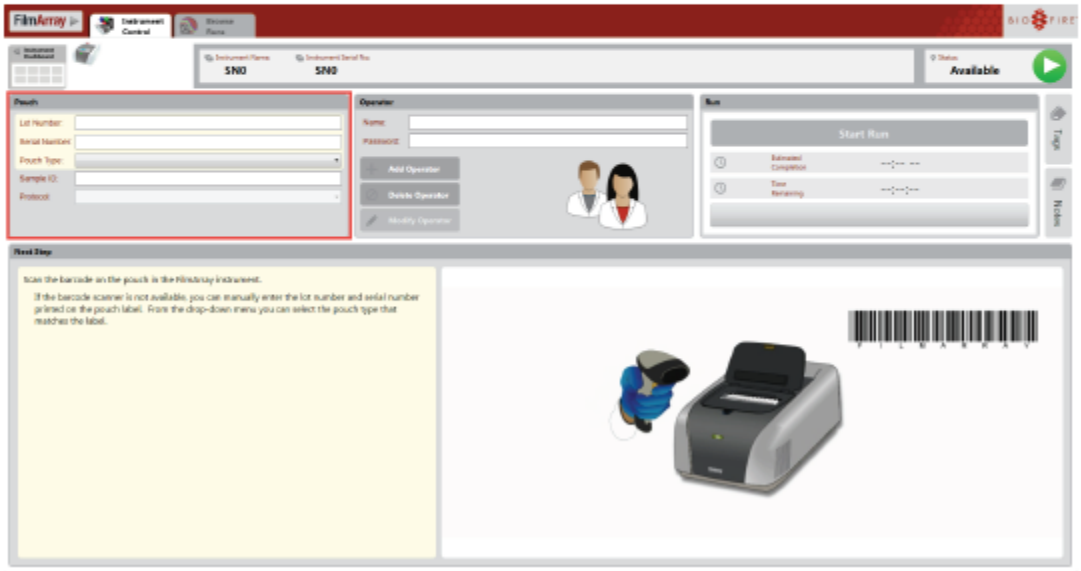
LOT Lot Number Expiry Date SN Serial Number

This information is both human-readable and contained in the barcode. The pouch also includes a space to write the Sample ID or affix a Sample ID barcode.

See also, e.g., FilmArray Torch Operator's Manual at 24 (same); *see also* FilmArray 2.0 Operator's Manual at 19:

5. Scan the barcode on the FilmArray pouch label using the barcode scanner provided. If the barcode scanner is not available, manually enter the lot number and serial number printed on the pouch label. Use the drop-down menu to select the pouch type that matches the label. Be sure that all barcode labels are as smooth and flat as possible. Hold the scanner about 10 centimeters from the barcode. Center the aiming beam on the barcode to scan.

   Pouch information and protocols are preprogrammed in the rectangular barcode located on the FilmArray pouch. The first three fields of the FilmArray pouch section of the screen (Lot Number, Serial Number, and Pouch Type) will be filled in by scanning the barcode.



See also, e.g., FilmArray Torch Operator's Manual at 27:

Scan Initiation

The operator scans the fitment label on the pouch while the Dashboard is displayed on the touch screen. To initiate a run by scanning:

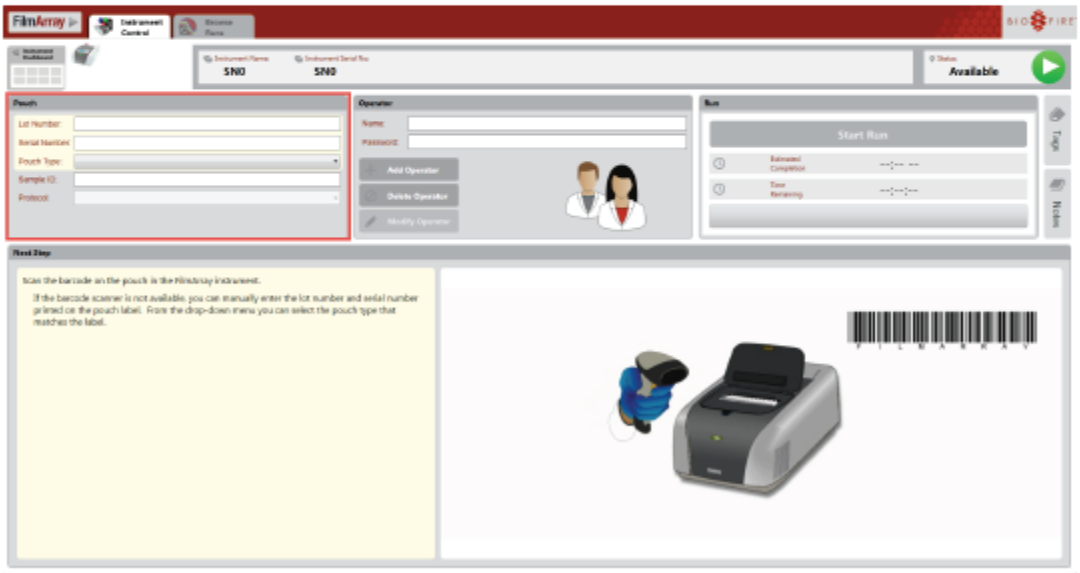
1. Scan the pouch barcode on the fitment label. Then scan or manually enter the Sample ID.

Id. at 56:

The software for the scanned pouch is not installed or is inactive. Please install or activate the required pouch module.	Verify the correct pouch module is installed and the correct barcode has been scanned for the pouch.

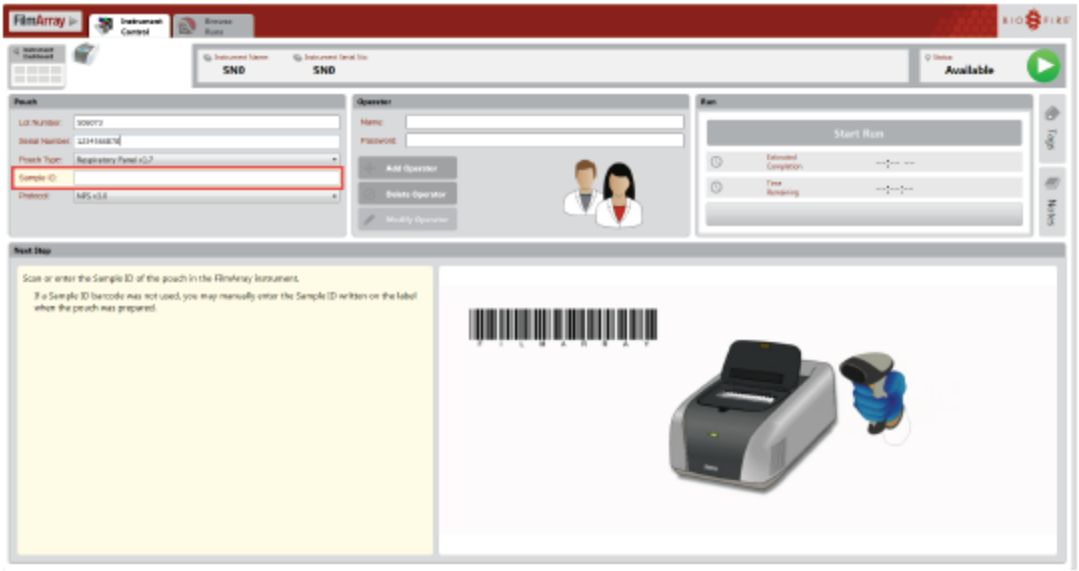
53. Such barcode or other identifier on the FilmArray pouches are also configured to trigger the transmission of a protocol that is selected based on the barcode or other identifier. *See, e.g.*, FilmArray 2.0 Operator's Manual at 19-20:

> 5. Scan the barcode on the FilmArray pouch label using the barcode scanner provided. If the barcode scanner is not available, manually enter the lot number and serial number printed on the pouch label. Use the drop-down menu to select the pouch type that matches the label. Be sure that all barcode labels are as smooth and flat as possible. Hold the scanner about 10 centimeters from the barcode. Center the aiming beam on the barcode to scan.
>
> Pouch information and protocols are preprogrammed in the rectangular barcode located on the FilmArray pouch. The first three fields of the FilmArray pouch section of the screen (Lot Number, Serial Number, and Pouch Type) will be filled in by scanning the barcode.



. . .

6. Scan the Sample ID. If a Sample ID barcode was not used, manually enter the Sample ID written on the label when the pouch was prepared.



7. Confirm or select the correct protocol for the sample type from the protocol drop down list.

NOTE: If only one protocol is available, it will be automatically selected.

See also, e.g., FilmArray Torch Operator's Manual at 39:

Operators

An operator username and password are required to run a pouch on FilmArray Torch.

The FilmArray Torch software prompts the operator to enter these credentials after a pouch has been inserted into an available Module and pouch information has been captured.

The Operators feature displays all current operators on FilmArray Torch. This feature allows for the addition, modification, and/or deletion of operators.

Id. at 53:

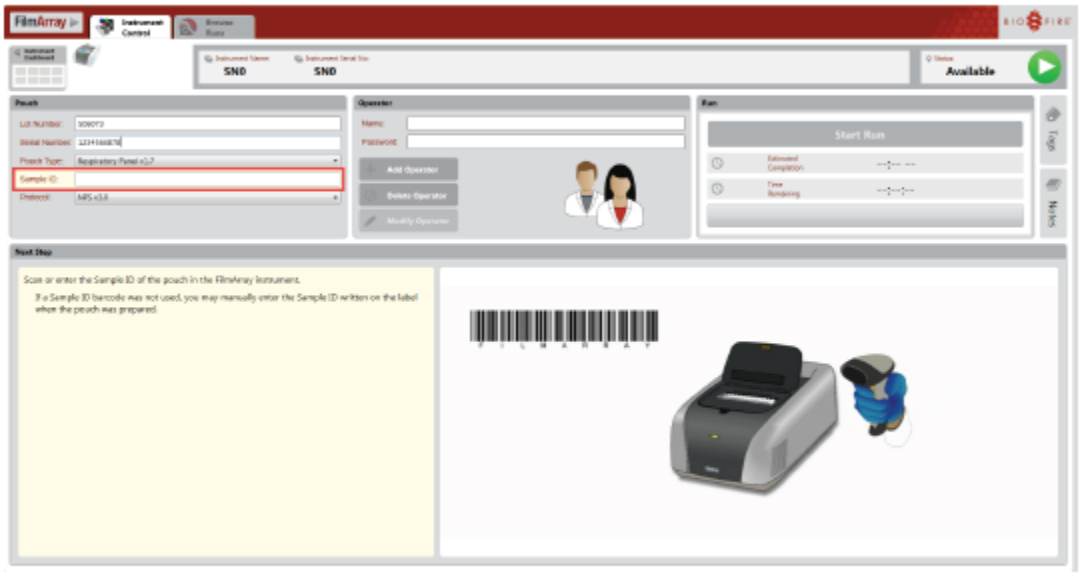
The software for the scanned pouch is not installed or is inactive. Please install or activate the required pouch module.	Verify the correct pouch module is installed and the correct barcode has been scanned for the pouch.

"wherein the programmable processor of the reader assembly is configured to receive said protocol from said external device, wherein said protocol in turn effects (1) a reaction in said assay assembly for generating said signal, and (2) selection of a detection method for detecting said signal, and wherein said reader further comprises a detection assembly for detecting said signal which is transmitted via said communication assembly to said external device."

54. The programmable processors in the reader assemblies of Defendants' FilmArray 2.0 and Torch systems are configured to receive a protocol from an external device, wherein the protocol in turn effects (1) a reaction in a FilmArray pouch assay assembly for generating a signal, and (2) selection of a detection method for detecting the signal, and wherein the reader further comprises a detection assembly for detecting said signal which is transmitted via said communication assembly to said external device.

55. As an example, the programmable processor of the FilmArray 2.0 Instrument receives a protocol from the FilmArray 2.0 external computer. *See, e.g.*, FilmArray 2.0 Operator's Manual at 20:

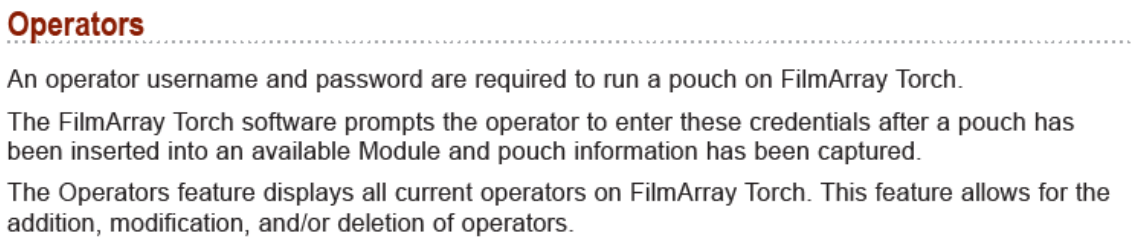
6. Scan the Sample ID. If a Sample ID barcode was not used, manually enter the Sample ID written on the label when the pouch was prepared.



7. Confirm or select the correct protocol for the sample type from the protocol drop down list.

NOTE: If only one protocol is available, it will be automatically selected.

56. As a further example, the programmable processor of the FilmArray Torch Module receives a protocol from the FilmArray Torch System Base. *See, e.g.*, FilmArray Torch Operator's Manual at 39:



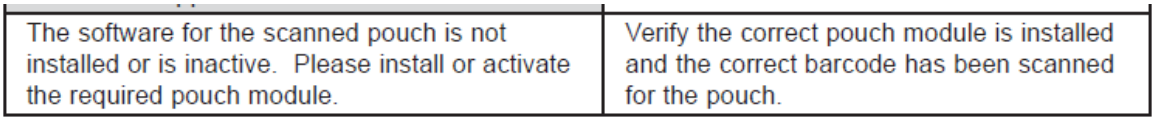
Operators

An operator username and password are required to run a pouch on FilmArray Torch.

The FilmArray Torch software prompts the operator to enter these credentials after a pouch has been inserted into an available Module and pouch information has been captured.

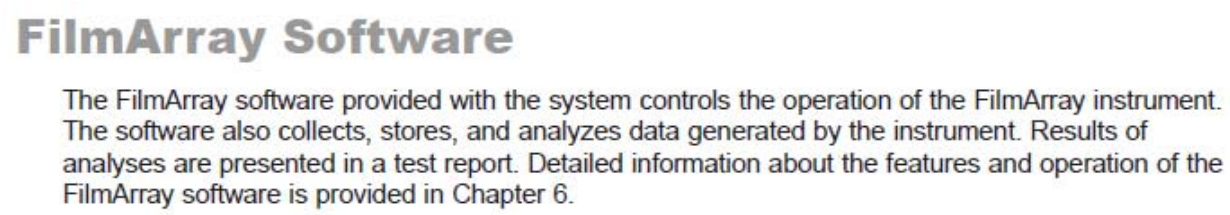
The Operators feature displays all current operators on FilmArray Torch. This feature allows for the addition, modification, and/or deletion of operators.

Id. at 53:



The software for the scanned pouch is not installed or is inactive. Please install or activate the required pouch module.	Verify the correct pouch module is installed and the correct barcode has been scanned for the pouch.

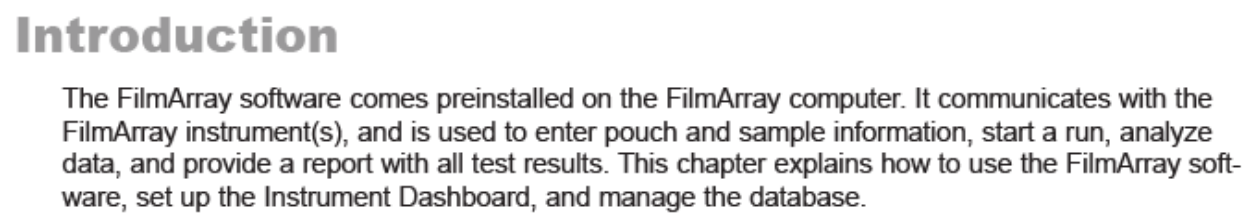
57. Additionally, each protocol effects a reaction in the assay assembly of the FilmArray pouch inserted in the FilmArray 2.0 Instrument or FilmArray Torch Module, for generating a signal and effects the selection of a detection method. *See, e.g.*, FilmArray 2.0 Operator's Manual at 4:



FilmArray Software

The FilmArray software provided with the system controls the operation of the FilmArray instrument. The software also collects, stores, and analyzes data generated by the instrument. Results of analyses are presented in a test report. Detailed information about the features and operation of the FilmArray software is provided in Chapter 6.

Id. at 24:



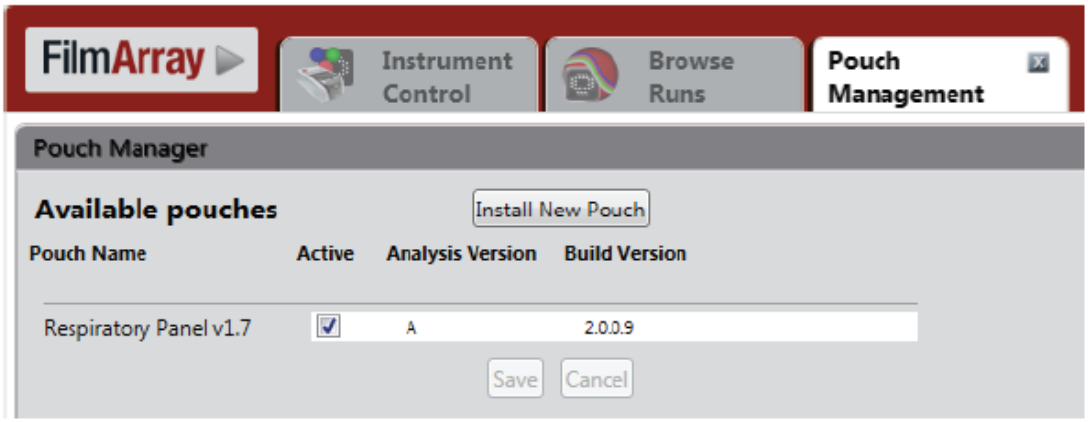
Introduction

The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

Id. at 25:

Pouch Management

The Pouch Management feature enables the operator to see which FilmArray pouch modules are currently installed and available for use. This feature also enables the operator to install new pouch modules. These pouch modules contain definitions, instrument protocols, analysis and reporting for specific FilmArray reagent kits.



Id. at 3-4:

Instrument and Pouch Interaction

After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray instrument controls these functions automatically based on the run protocol selected for a specific pouch and sample type in the FilmArray software.

Id. at 4:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray instrument is aligned, focused, and calibrated at the factory. Proper operation and calibration of instrument optics is monitored by the instrument self tests and pouch control reactions.

Id. at 14:

FilmArray System Specifications

Sample Description	• One sample capacity per instrument
Run Time	• Sample run time about one hour
User Interface	• Computer and (optional) barcode reader
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

See also, e.g., FilmArray Torch Operator's Manual at 4:

FilmArray Pouch Modules

Each FilmArray reagent pouch requires a pouch specific software called a pouch module to be installed on the FilmArray Torch in order to perform a test. These pouch modules contain definitions, protocols, analysis and reporting for specific FilmArray reagent kits. See the *Pouch Modules* section in *Chapter 6* for more information.

Id. at 40:

Pouch Modules

This feature enables the operator to install, and inactivate/uninstall pouch modules. These pouch modules contain definitions, protocols, analysis and reporting for specific FilmArray reagent kits.

Id. at 5:

FilmArray Torch Module and Pouch Interaction

After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray Torch Module controls these functions automatically based on the pouch module run protocol selected for a specific pouch and sample type in the FilmArray Torch software.

. . .

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

Id. at 22:

FilmArray Torch System Specifications

Sample Description	• One sample capacity per FilmArray Torch Module (with up to 12 samples per FilmArray Torch)
Run Time	• Sample run time about one hour
User Interface	• System Base with touch screen and barcode scanner
Data Output	• Automatic analysis with end-of-run result reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

58. A FilmArray 2.0 Instrument includes a detection assembly for detecting a signal, which is transmitted through one or more Ethernet interfaces to the FilmArray 2.0 external computer. *See, e.g.*, FilmArray 2.0 Operator's Manual at 4:

FilmArray Software

The FilmArray software provided with the system controls the operation of the FilmArray instrument. The software also collects, stores, and analyzes data generated by the instrument. Results of analyses are presented in a test report. Detailed information about the features and operation of the FilmArray software is provided in Chapter 6.

Id. at 4:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray instrument is aligned, focused, and calibrated at the factory. Proper operation and calibration of instrument optics is monitored by the instrument self tests and pouch control reactions.

Id. at 14:

FilmArray System Specifications

Sample Description	• One sample capacity per instrument
Run Time	• Sample run time about one hour
User Interface	• Computer and (optional) barcode reader
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

59. A FilmArray Torch Module includes a detection assembly for detecting a signal, which is transmitted through one or more Ethernet interfaces to the FilmArray Torch System Base. *See, e.g.*, FilmArray Torch Operator's Manual at 5:

FilmArray Torch software

The FilmArray Torch software manages and controls the operation of each FilmArray Torch Module. The software also collects, stores, and analyzes data generated by the FilmArray Torch Module. Results of analyses are presented in a test report. A brief overview of major software components are described below. For more detailed information about the features and operation of the FilmArray Torch software, see *Chapter 6, FilmArray Torch software*.

Id. at 5:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

Id. at 22:

FilmArray Torch System Specifications

Sample Description	• One sample capacity per FilmArray Torch Module (with up to 12 samples per FilmArray Torch)
Run Time	• Sample run time about one hour
User Interface	• System Base with touch screen and barcode scanner
Data Output	• Automatic analysis with end-of-run result reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

* * *

60. Defendants have had knowledge of the '155 Patent and their infringement of the '155 Patent at least since shortly after June 5, 2018 when bioMerieux, Inc., a US subsidiary of Defendant bioMerieux S.A., entered into an agreement with the former owner of the '155 Patent to allow it and its subsidiaries and affiliates, including Defendants, to inspect patent assets, which

included the '155 Patent. As such, Defendants were at least aware of the portfolio which included the '155 Patent. Yet despite this notice, Defendants proceeded to infringe the '155 Patent.

61. Additionally, to the extent that Defendants have continued or continue to make, have made, use, sell, or offer for sale products or services that infringe the '155 Patent following their awareness of the '155 Patent, Defendants' infringement is willful and entitles Labrador to an award of enhanced damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

62. Labrador is informed and believes, and on that basis alleges, that Defendants actively, knowingly, and intentionally induced infringement of one or more claims of the '155 Patent following their awareness of the '155 Patent by, for example, controlling the design and manufacture of, offering for sale, selling, supplying, and otherwise providing instruction and guidance regarding the Accused Products with the knowledge and specific intent to encourage and facilitate infringing uses of such products by its customers both inside and outside the United States.

63. For example, Defendants publicly provide documentation, including product manuals and instruction booklets available through both BioFire's and bioMerieux's websites, instructing customers on uses of Defendants' products that infringe the '155 Patent. *See, e.g.,* BioFire Diagnostics Website, https://www.biofiredx.com/support/documents, bioMerieux Diagnostics Website, https://www.biomerieux-diagnostics.com/molecular-diagnostics. As a further example, Defendants' manuals and instruction booklets direct customers to contact BioFire sales support and bioMerieux's website directs customers to contact bioMerieux's sales force for each country, including the United States. *See, e.g.,* bioMerieux Contact Us Page, https://www.biomerieux-usa.com/contact-us (listing sales contacts in Boston, MA and Lombard,

IL among others). On information and belief, Defendants' customers directly infringe the '155 Patent by, for example, at least using within the United States, without authority or license, the above-described BioFire products.

64. Labrador is informed and believes, and on that basis alleges, that Defendants have contributed to the infringement by its customers of the '155 Patent by, without authority, selling and offering to sell within the United States materials and products for practicing the claimed invention of the '155 Patent both inside and outside the United States. For example, the above-described products each and in combination constitute a material part of the inventions of the '155 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use.

65. On information and belief, Defendants know that the above-described products each and in combination constitute a material part of the inventions of the '155 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants' customers directly infringe the '155 Patent by, for example, making, using, offering to sell, and selling within the United States, without authority or license, the above-described products.

66. As a result of Defendants' infringement of the '155 Patent, Labrador has been damaged. Labrador is entitled to recover for damages sustained as a result of Defendants' wrongful acts in an amount subject to proof at trial.

67. To the extent 35 U.S.C. § 287 is determined to be applicable, its requirements have been satisfied with respect to the '155 Patent.

68. In addition, Defendants' infringing acts and practices have caused and are causing immediate and irreparable harm to Labrador.

69. Labrador is informed and believes, and on that basis alleges, that Defendants' infringement of the '155 Patent has been and continues to be willful. As noted above, Defendants had knowledge of the '155 Patent and their infringement of the '155 Patent. Defendants' have deliberately continued to infringe in an egregious manner, with reckless disregard for Labrador's patent rights. Thus, Defendants' infringing actions have been and continue to be consciously wrongful.

70. Based on the information alleged in this claim, as well as the information alleged in the Second Claim, *infra*, Labrador is informed and believes, and on that basis alleges, that this is an exceptional case, which warrants an award of attorney's fees to Labrador pursuant to 35 U.S.C. § 285.

SECOND CLAIM

(Infringement of U.S. Patent No. 10,533,994)

71. Labrador re-alleges and incorporates herein by reference Paragraphs 1-70 of its Complaint.

72. The '994 Patent, entitled "Systems and Methods of Sample Processing and Fluid Control in a Fluidic System," was duly and lawfully issued on January 14, 2020. A true and correct copy of the '994 Patent is attached hereto as Exhibit 2.

73. The '994 Patent has been in full force and effect since its issuance. Labrador owns by assignment the entire right, title, and interest in and to the '994 Patent, including the right to seek damages for past, current, and future infringement thereof.

74. The '994 Patent relates generally to "the field of medical devices," including "portable medical devices that allow real-time detection of analytes from a biological fluid." Ex. 2 at Abstract.

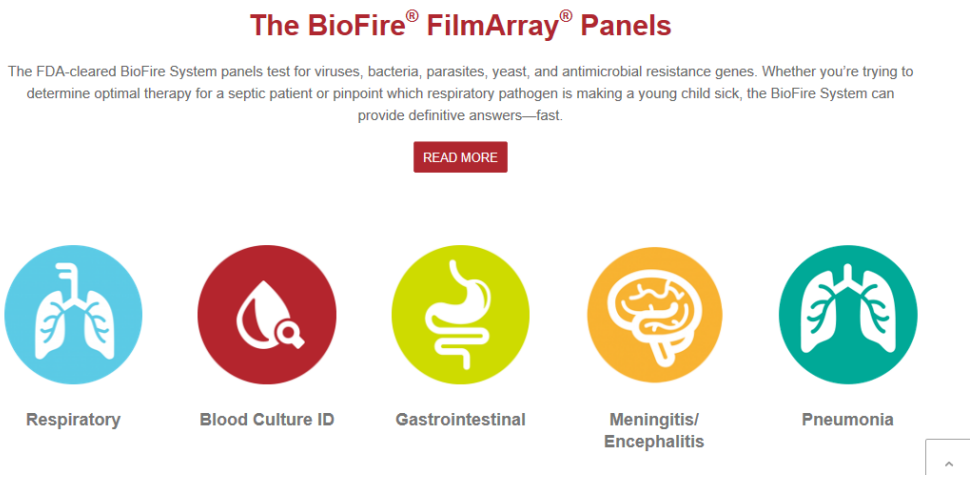
75. Labrador is informed and believes, and on that basis alleges, that Defendants individually and collectively have infringed and unless enjoined will continue to infringe one or more claims of the '994 Patent, in violation of 35 U.S.C. § 271, by, among other things, making, using, offering to sell, and selling within the United States, and/or supplying or causing to be supplied in or from the United States, without authority or license, the Accused Products for use together in an infringing manner.

76. The Accused Products in at least the Accused FilmArray System embody at least claim 1 of the '994 Patent, literally or under the doctrine of equivalents, as set forth below. The further descriptions below, which are based on publicly available information, are preliminary examples and are non-limiting. On information and belief, the FilmArray 2.0 and FilmArray Torch devices operate, together with the FilmArray pouches and software, similarly as pertinent to the non-limiting examples set forth below.

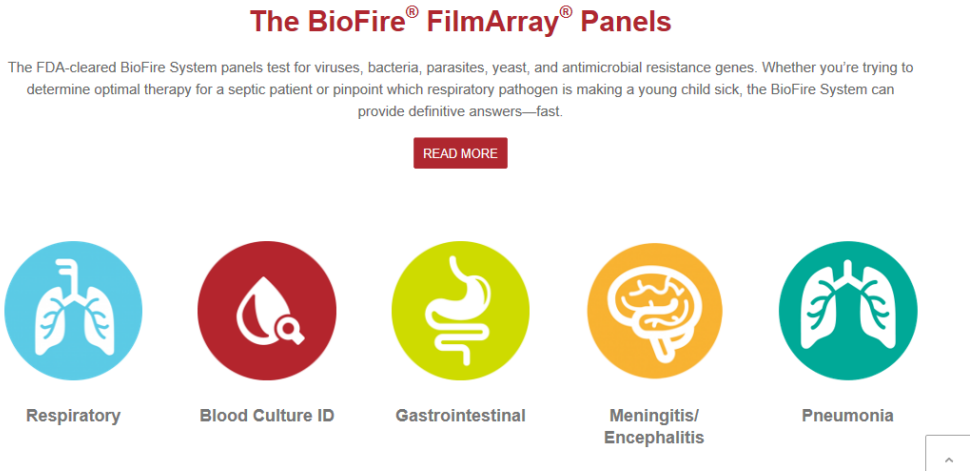
"1. A system for detecting the presence or absence of an analyte in a bodily fluid sample obtained from a subject, comprising:"

77. Defendants' FilmArray 2.0 and Torch systems are each systems for detecting the presence or absence of an analyte in a bodily fluid sample obtained from a subject.

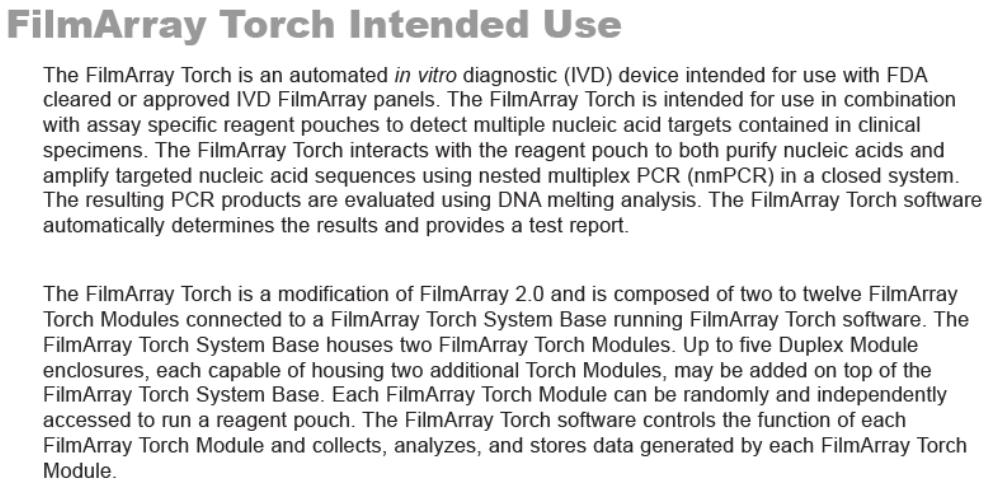
78. For example, the FilmArray 2.0 System is designed to detect the presence or absence of a nucleic acid sequence of interest in a specimen sample obtained from a patient's bodily fluid. *See, e.g.*, BioFire Diagnostics Website, https://www.biofiredx.com/:



79. As a further example, the FilmArray Torch System is designed to detect the presence or absence of a nucleic acid sequence of interest in a specimen sample obtained from a patient's bodily fluid. *See, e.g.*, BioFire Diagnostics Website, https://www.biofiredx.com/:



See also, e.g., FilmArray Torch Operators' Manual at 1:

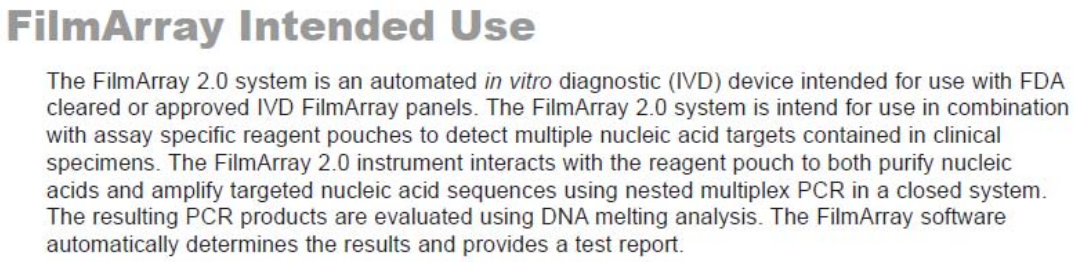


FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

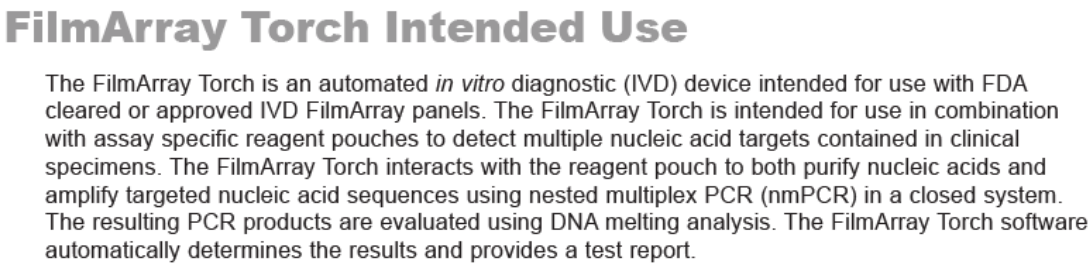
80. Each of Defendants' FilmArray pouches is designed to and does detect the presence or absence of a sequence of interest from such bodily fluid sample. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:



FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

See also, e.g., FilmArray Torch Operator's Manual at 1:



FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

81. The PCR reactants in the FilmArray pouches react with a bodily fluid sample to detect the presence or absence of a sequence of interest in a bodily fluid sample through the use

of, for example, fluorescence and melting curve analysis. *See, e.g.*, FilmArray 2.0 Operator's Manual at 4:

> **Optics and Imaging**
> To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

See also, e.g., FilmArray Torch Operator's Manual at 5:

> **Optics and Imaging**
> To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.
>
> The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

82. In a particular FilmArray pouch, the reactants react with said sample to detect the presence or absence of various viruses and bacteria. *See, e.g.*, FilmArray Pneumonia Panel Instructions for Use at 18-19:

Assay Interpretation

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray Operator's Manual). The FilmArray Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The FilmArray Software evaluates the DNA melt curve for each well of the PCR2 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 and compares it against the expected Tm range for the assay. If the software determines that the Tm of the curve is within the assay-specific Tm range, the melt curve is called positive. If the software determines that the Tm of the curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, two associated melt curves must be called positive, and both Tms must be similar. Assays that do not meet these criteria are called negative.

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 10^3.5 copies/mL are called negative. Assays with a value equal to or greater than 10^3.5 copies/mL are called positive.

. . .

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 (10^4 copies/mL, 10^5 copies/mL, 10^6 copies/mL or ≥10^7 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 10^3.5 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 2) such that the bin result reflects the assay value within the nearest ±0.5-log.

Table 2. FilmArray Pneumonia Panel Bin Results for Bacteria

Assay Result		Reported Result and Bin Result	
Negative OR	<10^3.5 copies/mL	Not Detected	
Positive AND	≥10^3.5 – <10^4.5 copies/mL	Detected	10^4 copies/mL
Positive AND	≥10^4.5 – <10^5.5 copies/mL	Detected	10^5 copies/mL
Positive AND	≥10^5.5 – <10^6.5 copies/mL	Detected	10^6 copies/mL
Positive AND	≥10^6.5 copies/mL	Detected	≥10^7 copies/mL

"a cartridge, comprising:"

83. Defendants' FilmArray 2.0 and Torch systems each include a cartridge.

84. The FilmArray 2.0 system is used in combination with FilmArray test device pouches. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

85. The FilmArray Torch system is used in combination with FilmArray test device pouches. *See, e.g.*, FilmArray Torch Operator's Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

"a sample collection unit, comprising:"

86. Each of Defendants' FilmArray pouches includes a sample collection unit.

87. For example, each FilmArray pouch includes a sample injection port into which the FilmArray operators are instructed to insert a sample mixture such that the sample is collected within the pouch. *See, e.g.*, FilmArray RP2 Reagent Quick Guide:

Step 3: Prepare Sample Mix

a. Hold Sample Buffer Ampoule tip facing up and firmly pinch at textured plastic tab on side of ampoule until seal snaps.

NOTE: *Do not touch ampoule tip.*

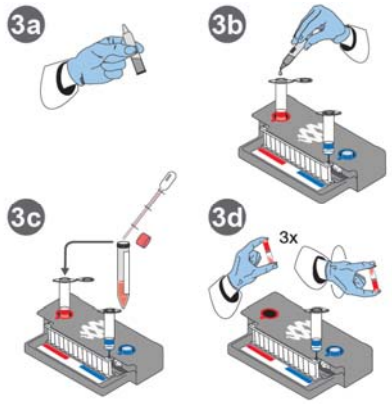
b. Dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze followed by a second squeeze.

NOTE: *Avoid generating excessive foaming.*

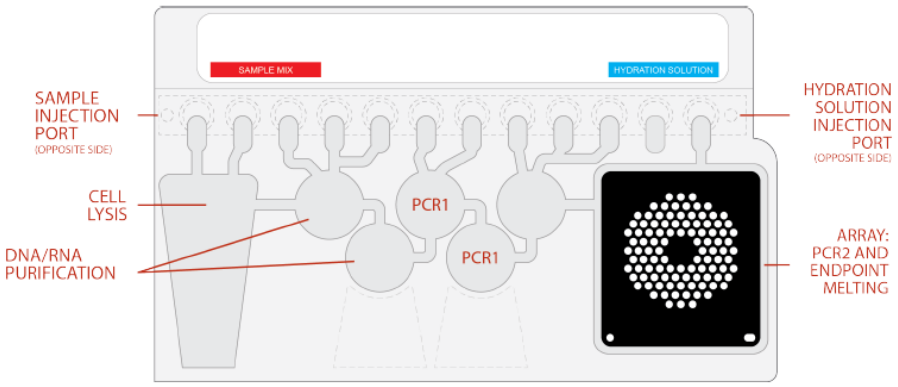
c. Use the transfer pipette to draw specimen to the third line. Add specimen to Sample Injection Vial then tightly close lid.

d. Invert the Sample Injection Vial **3 times** then return to red well of Pouch Loading Station.

WARNING: *The Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.*



See also FilmArray Pneumonia Panel Instructions for Use at 8:



"a sample collection well configured to receive a portion of the sample;"

88. Each of Defendants' FilmArray pouches includes a sample collection unit including a sample collection well configured to receive a portion of the sample.

89. For example, each FilmArray pouch includes a sample injection port into which the FilmArray operators are instructed to insert a sample mixture such that the sample is received within the pouch. *See, e.g.*, FilmArray RP2 Reagent Quick Guide:

Step 3: Prepare Sample Mix

a. Hold Sample Buffer Ampoule tip facing up and firmly pinch at textured plastic tab on side of ampoule until seal snaps.

NOTE: *Do not touch ampoule tip.*

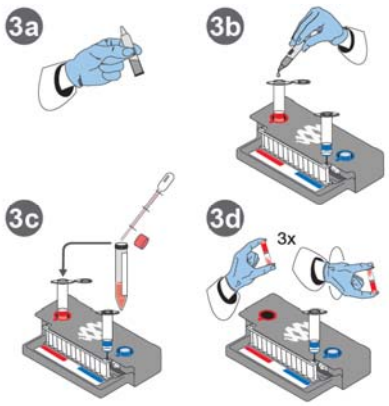
b. Dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze followed by a second squeeze.

NOTE: *Avoid generating excessive foaming.*

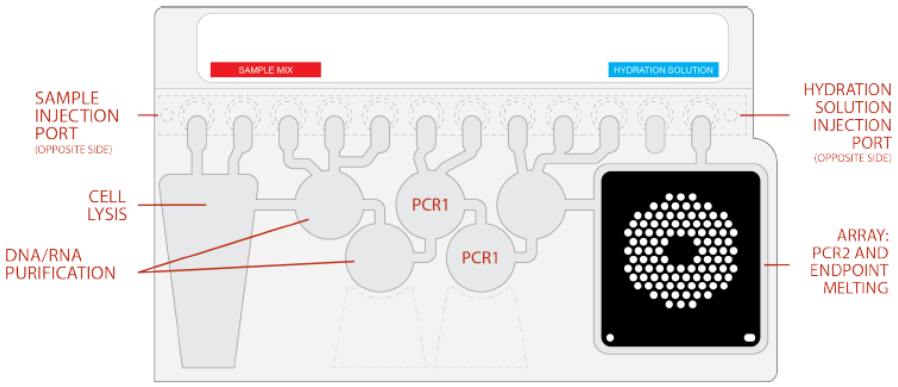
c. Use the transfer pipette to draw specimen to the third line. Add specimen to Sample Injection Vial then tightly close lid.

d. Invert the Sample Injection Vial **3 times** then return to red well of Pouch Loading Station.

WARNING: *The Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.*



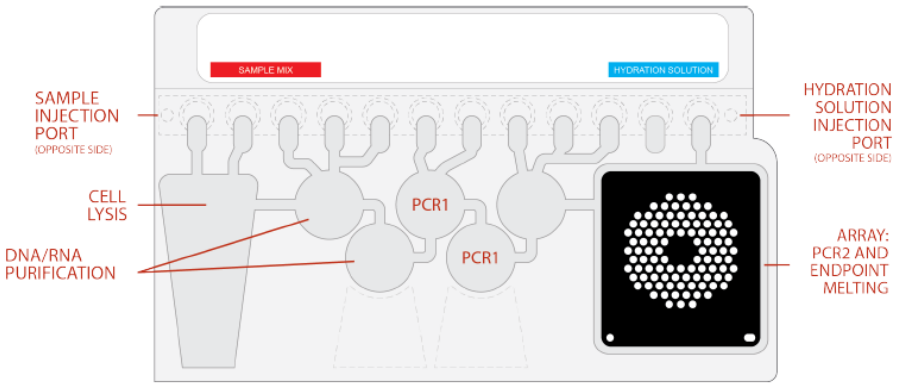
See also FilmArray Pneumonia Panel Instructions for Use at 8:



"a metering channel in fluid communication with the sample collection well and configured such that the sample flows from the sample collection well into the metering channel; and"

90. Each of Defendants' FilmArray pouches includes a sample collection unit including a metering channel in fluid communication with the sample collection well and configured such that the sample flows from the sample collection well into the metering channel.

91. For example, the sample loading and extraction and purification areas of FilmArray pouches meter fluid such that the sample flows from the collection area into a metering channel. *See, e.g.*, FilmArray Pneumonia Panel Instructions for Use at 8:



See also, e.g., FilmArray 2.0 Operator's Manual at 3:

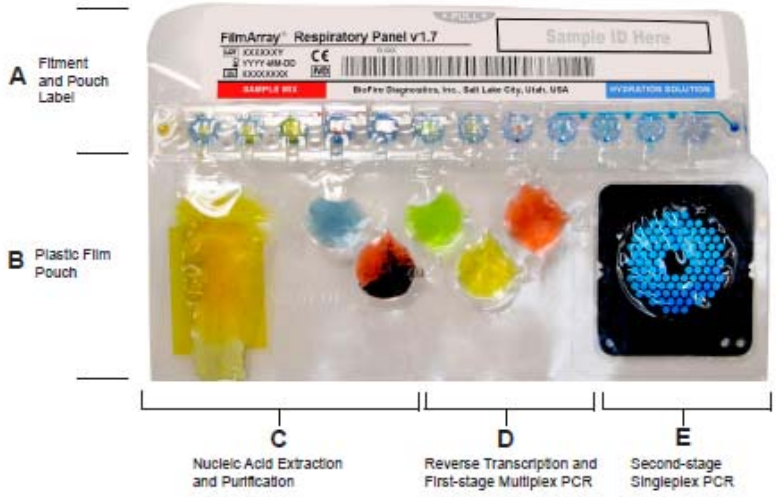
FilmArray Pouch

Each FilmArray pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain colored fluid.

See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

"a metering element comprising a mechanically movable portion configured to be movable from an open position that permits fluid communication between the sample collection well and the metering channel to a closed position that does not provide fluid communication between the sample collection well, thereby isolating a specific volume of the sample in the metering channel;"

92. Each of Defendants' FilmArray pouches includes a sample collection unit including a metering element comprising a mechanically movable portion configured to be movable from an open position that permits fluid communication between the sample collection well and the metering channel to a closed position that does not provide fluid communication between the sample collection well, thereby isolating a specific volume of the sample in the metering channel.

93. For example, upon information and belief, the fluidic connections in the FilmArray pouches' sample loading and extraction and purification areas are mechanically moveable through the use of pistons and/or moveable membrane elements that allow for the flow of the sample when in an open position and which inhibit such flow when in a closed position, such that a particular sample volume may be isolated. *See, e.g.*, FilmArray 2.0 Operator's Manual at 3:

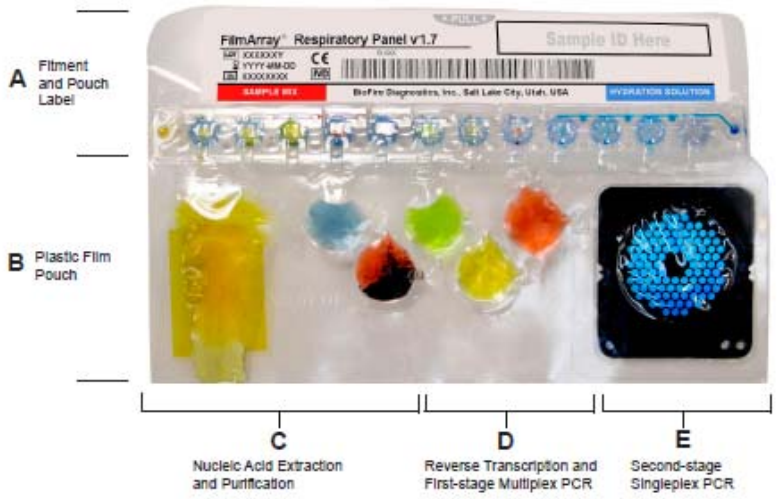
FilmArray Pouch

Each FilmArray pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain colored fluid.

See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

"a lysing assembly configured to lyse cells present in the sample; and"

94. Each of Defendants' FilmArray pouches includes a lysing assembly configured to lyse cells present in the sample.

95. For example, the FilmArray pouches include an extraction and purification of nucleic acids area which, for example, mechanically lyses cells in the sample. *See, e.g.*, FilmArray 2.0 Operator's Manual at 3:

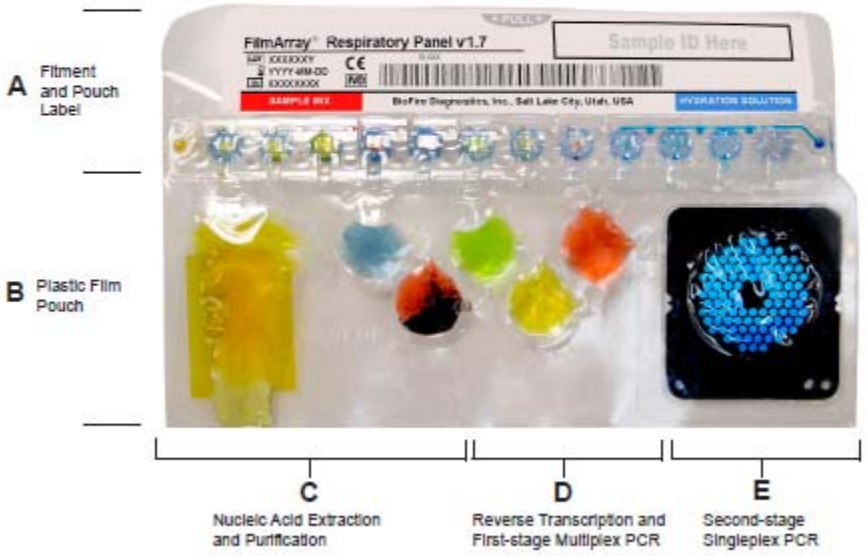
FilmArray Pouch

Each FilmArray pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain colored fluid.

See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

See also, e.g., FilmArray 2.0 Operator's Manual at 4:

Mechanical Lysis

The first step in processing a sample is to break the outer membrane of the target cells or organisms contained in the sample using a device called a bead-beater. A sensor detects the speed and operation of the bead-beater motor and aborts the run if the bead-beater is not working properly.

See also, e.g., FilmArray Torch Operator's Manual at 5 (same).

"an assay assembly comprising a reaction site containing a reactant able to react with the analyte to yield a detectable signal indicative of the presence or absence of the analyte; and"

96. Each of Defendants' FilmArray pouches includes an assay assembly comprising a reaction site containing a reactant able to react with the analyte to yield a detectable signal indicative of the presence or absence of the analyte.

97. For example, each FilmArray pouch includes a series of areas containing polymerase chain reaction (PCR) reactants configured to react with the bodily fluid sample injected into the FilmArray pouches. *See, e.g.*, FilmArray 2.0 Operator's Manual at 3:

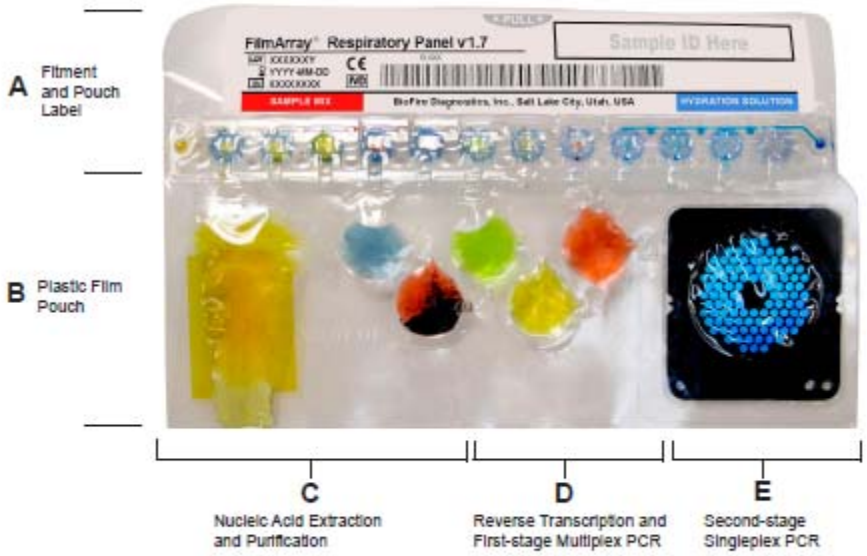
FilmArray Pouch

Each FilmArray pouch is a self-contained, closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray instrument, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a raw sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array



NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain colored fluid.

See also, e.g., FilmArray Torch Operator's Manual at 3 (same).

98. The reactants in the FilmArray pouches are configured to react with a sample of bodily fluids to yield a signal indicative of the presence or absence of nucleic acid analytes. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

FilmArray Intended Use

The FilmArray 2.0 system is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray 2.0 system is intend for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software automatically determines the results and provides a test report.

Id. at 4:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

See also, e.g., FilmArray Torch Operator's Manual at 1:

FilmArray Torch Intended Use

The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

Id. at 5:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

99. The reactants in a BioFire FilmArray Pneumonia Panel, for example, react with a sample of bodily fluids to yield a detectable signal indicative of the presence or absence of various viruses and bacteria. *See, e.g.*, FilmArray Pneumonia Panel Instructions for Use at 18-19:

Assay Interpretation

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray Operator's Manual). The FilmArray Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The FilmArray Software evaluates the DNA melt curve for each well of the PCR2 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 and compares it against the expected Tm range for the assay. If the software determines that the Tm of the curve is within the assay-specific Tm range, the melt curve is called positive. If the software determines that the Tm of the curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, two associated melt curves must be called positive, and both Tms must be similar. Assays that do not meet these criteria are called negative.

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 10^3.5 copies/mL are called negative. Assays with a value equal to or greater than 10^3.5 copies/mL are called positive.

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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 (10^4 copies/mL, 10^5 copies/mL, 10^6 copies/mL or ≥10^7 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 10^3.5 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 2) such that the bin result reflects the assay value within the nearest ±0.5-log.

Table 2. FilmArray Pneumonia Panel Bin Results for Bacteria

Assay Result		Reported Result and Bin Result	
Negative OR	<10^3.5 copies/mL	Not Detected	
Positive AND	≥10^3.5 – <10^4.5 copies/mL	Detected	10^4 copies/mL
Positive AND	≥10^4.5 – <10^5.5 copies/mL	Detected	10^5 copies/mL
Positive AND	≥10^5.5 – <10^6.5 copies/mL	Detected	10^6 copies/mL
Positive AND	≥10^6.5 copies/mL	Detected	≥10^7 copies/mL

"a reader assembly comprising:"

100. Defendants' FilmArray 2.0 and Torch systems each include a reader assembly.

101. For example, Defendants' FilmArray 2.0 System includes one or more FilmArray 2.0 Instruments. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

The FilmArray 2.0 system is composed of one to eight FilmArray 2.0 instruments connected to a computer running FilmArray software. The FilmArray software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

102. For example, Defendants' FilmArray Torch System includes one or more FilmArray 2.0 Modules. *See, e.g.*, FilmArray Torch Operator's Manual at 1:

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

"a detection assembly configured to detect the signal; and"

103. Defendants' FilmArray 2.0 and Torch systems each include a reader assembly including a detection assembly configured to detect the signal.

104. For example, a FilmArray 2.0 Instrument includes a detection assembly for detecting the signal. *See, e.g.*, FilmArray 2.0 Operator's Manual at 4:

FilmArray Software

The FilmArray software provided with the system controls the operation of the FilmArray instrument. The software also collects, stores, and analyzes data generated by the instrument. Results of analyses are presented in a test report. Detailed information about the features and operation of the FilmArray software is provided in Chapter 6.

Id.:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray instrument is aligned, focused, and calibrated at the factory. Proper operation and calibration of instrument optics is monitored by the instrument self tests and pouch control reactions.

Id. at 14:

FilmArray System Specifications

Sample Description	• One sample capacity per instrument
Run Time	• Sample run time about one hour
User Interface	• Computer and (optional) barcode reader
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

105. For example, a FilmArray Torch Module includes a detection assembly for detecting the signal. *See, e.g.*, FilmArray Torch Operator's Manual at 5:

FilmArray Torch software

The FilmArray Torch software manages and controls the operation of each FilmArray Torch Module. The software also collects, stores, and analyzes data generated by the FilmArray Torch Module. Results of analyses are presented in a test report. A brief overview of major software components are described below. For more detailed information about the features and operation of the FilmArray Torch software, see *Chapter 6, FilmArray Torch software*.

Id.:

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

Id. at 22:

FilmArray Torch System Specifications

Sample Description	• One sample capacity per FilmArray Torch Module (with up to 12 samples per FilmArray Torch)
Run Time	• Sample run time about one hour
User Interface	• System Base with touch screen and barcode scanner
Data Output	• Automatic analysis with end-of-run result reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

"a communication assembly configured to receive an assay protocol in response to receiving an identity of the cartridge from an external device, the external device being separate from the reader assembly, the communication assembly further configured to transmit the signal to the external device."

106. Defendants' FilmArray 2.0 and Torch systems each include a reader assembly including a communication assembly configured to receive an assay protocol in response to receiving an identity of the cartridge from an external device, the external device being separate

from the reader assembly, the communication assembly further configured to transmit the signal to the external device.

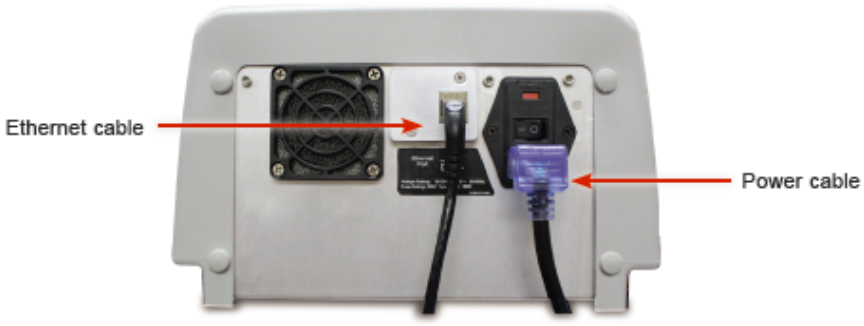
107. For example, Defendants' FilmArray 2.0 Instrument(s) include one or more Ethernet interfaces configured to receive an assay protocol in response to the receipt of one or more barcode identifiers from the FilmArray 2.0 external computer. *See, e.g.*, FilmArray 2.0 Operator's Manual at 24:

> The FilmArray software comes preinstalled on the FilmArray computer. It communicates with the FilmArray instrument(s), and is used to enter pouch and sample information, start a run, analyze data, and provide a report with all test results. This chapter explains how to use the FilmArray software, set up the Instrument Dashboard, and manage the database.

Id. at 3-4:

> **Instrument and Pouch Interaction**
> After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray instrument controls these functions automatically based on the run protocol selected for a specific pouch and sample type in the FilmArray software.

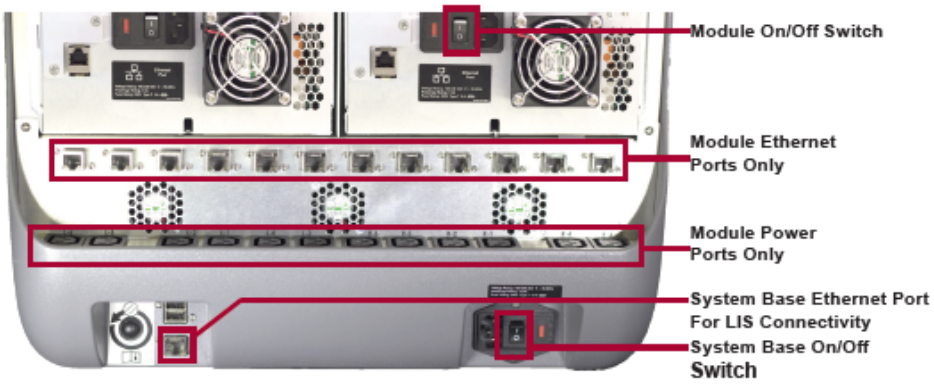
Id. at 9:

> 3. Connect the instrument Ethernet cable and instrument power cord to the back of the instrument as shown.
>
> 
>

108. The Ethernet interface is a communication assembly.

109. As a further example, Defendants' FilmArray Torch Module(s) include(s) one or more Ethernet interfaces configured to receive an assay protocol in response to the receipt of one

or more barcode identifiers from the FilmArray Torch System Base. *See, e.g.*, FilmArray Torch Operator's Manual at 10:



Id. at 27:

Start Run

After the pouch is correctly inserted into the FilmArray Torch Module, the LED will blink green to indicate that the pouch has been seated but the run has not yet started. To continue the run after Manual or Scan Initiation:

1. Select the correct pouch protocol for the pouch and sample type.

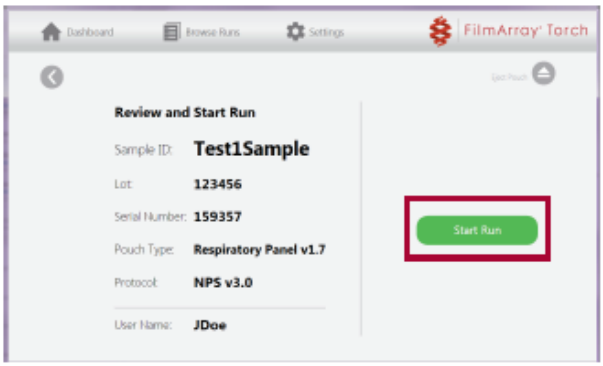
NOTE: If only one protocol is available, it will be automatically selected.

2. Enter operator username and password, then select **Next**.

   The Next key will only become available when a correct username and password is entered. See the *Create New Operator(s)* section in *Chapter 6* for more information on how to create a new operator's username and password.

NOTE: The font color of the username and password is red until the user name is recognized by the FilmArray Torch software.

3. Review run information on the screen and if correct, select **Start Run.**



110. The Ethernet interface is a communication assembly.

111. Defendants' FilmArray 2.0 System includes a communication assembly configured to receive an assay protocol in response to receiving an identity of the cartridge from the FilmArray 2.0 external computer, which is separate from the FilmArray 2.0 Instrument(s). *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

The FilmArray 2.0 system is composed of one to eight FilmArray 2.0 instruments connected to a computer running FilmArray software. The FilmArray software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

112. Defendants' FilmArray Torch System includes a communication assembly configured to receive an assay protocol in response to receiving an identity of the cartridge from

the FilmArray Torch System Base, which is separate from the FilmArray Torch Module(s). *See, e.g.*, FilmArray Torch Operator's Manual at 1:

> The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

113. An Ethernet interface on each of Defendants' FilmArray 2.0 Instruments transmits the signal to the FilmArray 2.0 external computer. *See, e.g.*, FilmArray 2.0 Operator's Manual at 1:

> The FilmArray 2.0 system is composed of one to eight FilmArray 2.0 instruments connected to a computer running FilmArray software. The FilmArray software controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

Id. at 4:

Optics and Imaging
To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the computer, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

114. An Ethernet interface on each of Defendants' FilmArray Torch Modules transmits the signal to the FilmArray Torch System Base. *See, e.g.*, FilmArray Torch Operator's Manual at 1:

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

Id. at 5:

Optics and Imaging
To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

* * *

115. Defendants have had knowledge of the '994 Patent and their infringement of the '994 Patent once issued at least since shortly after June 5, 2018 when bioMerieux, Inc., a US subsidiary of Defendant bioMerieux S.A., entered into an agreement with the former owner of the application which matured into the '994 to allow it and its subsidiaries and affiliates, including Defendants, to inspect patent assets, which included the application that matured into the '994 Patent. As such, Defendants were at least aware of the portfolio which included the application which matured into the '994 Patent. Yet despite this notice, Defendants proceeded to infringe the '994 Patent since it was issued in January 2020.

116. Additionally, to the extent that Defendants have continued or continue to make, have made, use, sell, or offer for sale products or services that infringe the '994 Patent following their awareness of the '994 Patent, Defendants' infringement is willful and entitles Labrador to an award of enhanced damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

117. Labrador is informed and believes, and on that basis alleges, that Defendants actively, knowingly, and intentionally induced infringement of one or more claims of the '994 Patent following their awareness of the '994 Patent by, for example, controlling the design and manufacture of, offering for sale, selling, supplying, and otherwise providing instruction and guidance regarding the Accused Products with the knowledge and specific intent to encourage and facilitate infringing uses of such products by its customers both inside and outside the United States.

118. For example, Defendants publicly provide documentation, including product manuals and instruction booklets available through both BioFire's and bioMerieux's websites, instructing customers on uses of Defendants' products that infringe the '994 Patent. *See, e.g.*,

BioFire Diagnostics Website, https://www.biofiredx.com/support/documents, bioMerieux Diagnostics Website, https://www.biomerieux-diagnostics.com/molecular-diagnostics. As a further example, Defendants' manuals and instruction booklets direct customers to contact BioFire sales support and bioMerieux's website directs customers to contact bioMerieux's sales force for each country, including the United States. *See, e.g.*, bioMerieux Contact Us Page, https://www.biomerieux-usa.com/contact-us (listing sales contacts in Boston, MA and Lombard, IL among others). On information and belief, Defendants' customers directly infringe the '994 Patent by, for example, at least using within the United States, without authority or license, the above-described BioFire products.

119. Labrador is informed and believes, and on that basis alleges, that Defendants have contributed to the infringement by its customers of the '994 Patent by, without authority, selling and offering to sell within the United States materials and products for practicing the claimed invention of the '994 Patent both inside and outside the United States. For example, the above-described products each and in combination constitute a material part of the inventions of the '994 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use.

120. On information and belief, Defendants know that the above-described products each and in combination constitute a material part of the inventions of the '994 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants' customers directly infringe the '994 Patent by, for example, making, using, offering to sell, and selling within the United States, without authority or license, the above-described products.

121. As a result of Defendants' infringement of the '994 Patent, Labrador has been damaged. Labrador is entitled to recover for damages sustained as a result of Defendants' wrongful acts in an amount subject to proof at trial.

122. To the extent 35 U.S.C. § 287 is determined to be applicable, its requirements have been satisfied with respect to the '994 Patent.

123. In addition, Defendants' infringing acts and practices have caused and are causing immediate and irreparable harm to Labrador.

124. Labrador is informed and believes, and on that basis alleges, that Defendants' infringement of the '994 Patent has been and continues to be willful. As noted above, Defendants have had knowledge of the '994 Patent and their infringement of the '994 Patent. Defendants' have deliberately continued to infringe in an egregious manner, with reckless disregard for Labrador's patent rights. Thus, Defendants' infringing actions have been and continue to be consciously wrongful.

125. Based on the information alleged in this claim, as well as the information alleged in the First Claim, *supra*, Labrador is informed and believes, and on that basis alleges, that this is an exceptional case, which warrants an award of attorney's fees to Labrador pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Labrador prays for judgment against Defendants as follows:

A. That Defendants have infringed, and unless enjoined will continue to infringe, each of the Asserted Patents;

B. That Defendants have willfully infringed each of the Asserted Patents;

C. That Defendants pay Labrador damages adequate to compensate Labrador for Defendants' infringement of each of the Asserted Patents, together with interest and costs under 35 U.S.C. § 284;

D. That Defendants be ordered to pay prejudgment and post-judgment interest on the damages assessed;

E. That Defendants pay Labrador enhanced damages pursuant to 35 U.S.C. § 284;

F. That Defendants be ordered to pay supplemental damages to Labrador, including interest, with an accounting, as needed;

G. That Defendants be enjoined from infringing the Asserted Patents, or if their infringement is not enjoined, that Defendants be ordered to pay ongoing royalties to Labrador for any post-judgment infringement of the Asserted Patents;

H. That this is an exceptional case under 35 U.S.C. § 285, and that Defendants pay Labrador's attorneys' fees and costs in this action; and

I. That Labrador be awarded such other and further relief, including equitable relief, as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Labrador hereby demands a trial by jury on all issues triable to a jury.

Dated: March 9, 2020

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

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