Contamination Prevention and Decontamination

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Introduction

FilmArray® is an automated *in vitro* diagnostic (IVD) system that utilizes nested multiplex PCR (nmPCR) and high-resolution melting analysis to detect and identify multiple nucleic acid targets from clinical specimens.

Polymerase chain reaction (PCR) is the process of making millions of copies of DNA by amplifying a specific DNA region. A common concern with PCR-based methods is false positive results caused by contamination. Contamination is the introduction of organisms or amplicons into specimens during collection or handling, or introduced into reagents during the testing process.

This document provides guidelines for preventing or eliminating sources of contamination while performing FilmArray tests.

Contamination Prevention

Preventing Organism Contamination

Healthcare workers can be infected or colonized with organisms detected by the FilmArray and may inadvertently contaminate the sample during collection or processing. Organisms can be carried asymptomatically, particularly on skin and mucosal surfaces.

- During sample collection, healthcare workers are advised to wear a surgical mask (or equivalent) and avoid touching the mask while collecting specimens. In particular, wearing a mask can help prevent contamination from:

    a. Individuals with active respiratory symptoms (runny nose, cough, etc)
    b. Individuals with active or latent HSV-1 infection (i.e. Cold sore).
    c. Healthy individuals who may actively shed *S. pneumoniae*, *H. influenzae* as well as other organisms.

- Do not collect or process specimens in areas that are exposed to vaccine material targeting pathogens that may be detected by FilmArray panels (e.g. Rotavirus, *Bordetella pertussis,* etc). Some *Bordetella pertussis* acellular vaccines (i.e. Pentacel®, Daptacel®, and Adacel®) contain PCR detectable DNA. Contamination of specimens or testing materials with vaccine can cause false positive *B. pertussis* results. (http://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-pcr-bestpractices.html.

- Process specimens and load pouches in a biosafety cabinet. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a

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splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield should be used when preparing specimens.

- A biosafety cabinet used to perform viral, bacterial, or fungal culture should not be used for specimen preparation or FilmArray reagent setup.
- Prior to processing specimens, thoroughly clean both the work area and the FilmArray Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach solution (1-part bleach to 9-parts water) or a similar disinfectant effective against potential nucleic acid contamination. To avoid residue build-up and potential PCR inhibition, wipe disinfected surfaces with distilled water.

⚠ **WARNING:** Bleach should never be added to Sample Buffer or sample waste.

- Handle specimens and FilmArray pouches one-at-a-time. Completely set up a single FilmArray test and start the run before moving to the next specimen.
- Clean the work area between each specimen.
- Change gloves between each specimen. Change gloves during testing if you have touched your face or other potentially-contaminated surface.

Preventing Amplicon Contamination

The FilmArray pouch is a closed system. Therefore, the risk of amplicon contamination is low, provided that pouches remain intact after the test is completed. Adhere to the following guidelines to prevent amplicon contamination:

- Discard used pouches in an appropriate biohazard container immediately after the run has completed.
- Avoid excessive handling of pouches after test runs.
- Avoid exposing pouches to sharp edges or anything that might cause a puncture.

⚠ **WARNING:** If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. Treat all broken pouches as capable of contaminating your work area. The instrument and workspace must be decontaminated as described in the Decontamination and Cleaning Procedures section below. Do not perform additional testing until the area has been decontaminated.

Suspected False Positive Results Caused by Contamination

When false positive results caused by contamination are suspected an external negative control should be run as follows:

1. Test a negative sample by preparing a pouch using a fresh sample buffer ampoule and Sample Injection Vial without the addition of a patient specimen or control material.
2. If unexpected positive results are obtained, decontamination and cleaning procedures should be completed. After decontamination is completed, test

an additional pouch as described in step 1. If unexpected positive results are obtained, call BioFire Technical Support.

3. Swab testing. (Refer to the Swab test procedure below)

Decontamination and Cleaning Procedures

The following decontamination and cleaning procedures are recommended to be followed as a general practice for preventing contamination and/or when false positive result potentially caused by contamination are suspected. Additionally, the following decontamination and cleaning procedures are recommended if an event that may have resulted in potential or suspected contamination of the work area occurs (i.e. sample spill, reagent pouch leak or breakage). Decontamination is necessary to prevent false-positive results in subsequent runs.

Change gloves often during the decontamination process and before touching any clean surface. All personal protective equipment (PPE) should be discarded after decontamination.

Cleaning Materials

This list provides items that are necessary in a laboratory to keep contamination to a minimum.

- 10% bleach solution in a squeeze or spray bottle (1-part bleach to 9-parts water) – mix a fresh solution frequently (daily is recommended).
- Distilled water in a squeeze or spray bottle
- DNAZap™or equivalent DNA degradation reagent
- Paper towels
- Bleach wipes

⚠ **CAUTION:** Do not use decontamination or cleaning agents that could cause a hazard as a result of a reaction with parts of the equipment or with material contained in it. If you are unsure whether a cleaning agent will react negatively with the parts of the equipment or with the materials contained in it contact BioFire Diagnostic's Technical Support or an authorized distributor.

Decontamination of the Pouch Loading Station

The Pouch Loading Station can be submerged for decontamination:

1. Put on a lab coat and gloves.
2. Rinse the Pouch Loading Station with water.
3. Fill a sink or bin with water and add bleach to create a 10% bleach solution (1-part bleach to 9-parts water).
4. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
5. Remove Pouch Loading Station from sink or bin. Replace bleach solution with water.
6. Rinse the Pouch Loading Station by completely submerging in water two additional times.

Decontamination Related to Pouch Leakage

1. Put on clean PPE such as gloves and safety shield.

2. Ensure potentially-contaminated areas or instruments are not used
3. Decontaminate and dispose of the pouch using the following steps:
    a. Dispose of potentially contaminated gloves and put on clean gloves.
    b. Dispose of the potentially contaminated lab coat and put on a clean lab coat.
    c. Discard pouch in biohazard waste container.
    d. Change gloves.
    e. Follow decontamination procedures for cleaning affected areas (See below)

Instrument Pouch Loading Chamber Decontamination

1. Put on a lab coat and gloves.
2. Remove pouch from instrument and discard in biohazard waste container.
3. Wipe the area to be decontaminated with water.
4. Wet a paper towel with 10% bleach (1-part bleach to 9-parts water) and wipe the surface of the inner sample chamber and under the lid.
5. Change gloves.
6. Repeat steps 3 to 5 twice with fresh paper towels for a total of three bleach wipes.
7. Wet a paper towel with distilled water and wipe sample chamber.
8. Change gloves.
9. Repeat step 7 with fresh paper towel.

Decontamination of Bench Tops and Other Areas

1. Put on a clean lab coat and gloves.
2. Wipe the area to be decontaminated with water.
3. Wipe the suspected area with a paper towel soaked in 10% bleach solution (1-part bleach to 9-parts water). Let it stand for 5 minutes.
4. Change gloves.
5. Repeat step 3 and 4 twice, for a total of three wipes.
6. Spray the area with distilled water.
7. Wipe the area dry with a new paper towel.
8. Change gloves.
9. Spray the area with DNAZap or an equivalent product. Follow the product's instructions for correct use.
10. Change gloves.
11. Rinse the area by spraying it with distilled water and wiping it dry.

Swab Test

Environmental Swab Testing can be used to monitor for potential contamination that may compromise the FilmArray test results Swab testing may be conducted at regular intervals and/or when contamination is suspected. The frequency of swab testing should be determined by the Laboratory Director.

- Decontaminate all work surfaces used for FilmArray testing including: bio-safety cabinet surfaces, Pouch Loading Stations, and FilmArray instrument using the procedure above.

⚠**WARNING:** Bleach is a known PCR inhibitor. Residue must be adequately removed with distilled water wipes or swab tests may fail.

- Change gloves before beginning swab testing.
- Obtain sterile 1.5 mL microcentrifuge tubes or equivalent.
- Fill the microcentrifuge tube with approximately 500 µL of molecular grade water.
- Unwrap two individually-packaged sterile flocked swabs or equivalent and place them into the tube; allow the swabs to sit for approximately 1 minute.
- Use the wet swabs to swab work surfaces used for FilmArray specimen setup and testing.
- Place the swabs in the Sample Injection Vial. Remove or break-off excess swab stick so that the Sample Injection Vial may be closed.
- Invert Sample Buffer Ampoule so that tip is facing up.
    - Do not touch the tip of the ampoule.
- Firmly pinch textured plastic tab on side of ampoule until seal snaps.
- With the tip facing down, dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.
- Tightly close lid of Sample Injection Vial. Unscrew Hydration Injection Vial, leaving cap in Pouch Loading Station,
    - Insert Hydration Injection Vial into pouch hydration port.
    - Forcefully push down to puncture seal.
    - Wait as Hydration Solution is drawn into pouch.
- Mix sample by gently inverting Sample Injection Vial 3 times.
- Unscrew Sample Injection Vial from cap.
    - Pause for 3-5 seconds, then remove Sample Injection Vial, leaving cap in Pouch Loading Station.
    - Insert Sample Injection Vial into pouch sample port.
    - Forcefully push down to puncture seal.
    - Wait as Sample Mix is drawn into pouch.
- Follow instructions on the FilmArray computer for initiating a test.
- Swab samples should be tested immediately after swab collection.
- Results of the swab test should be negative for all organisms (and the pouch controls should pass).

Technical Support Contact Information

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

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

For FilmArray technical assistance and support outside of the US, please contact your local bioMérieux representative or authorized distributor.

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