Contamination Prevention and Decontamination

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Purpose

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. Copies are made by melting the DNA into separate strands and using each strand as a template for generation of a new strand. To identify specific pathogens using PCR, primers (short pieces of a specific DNA sequence) are included in the PCR reaction to target unique segments of the pathogen genome. If the organism of interest has an RNA genome, a process called reverse transcription (rt) is performed prior to PCR in order to convert the RNA template into a DNA template (rt-PCR).

One of the most important rules when performing polymerase chain reaction (PCR) is to avoid contamination. This document outlines necessary precautions to prevent contamination as well as procedures for cleaning suspected contamination.

Contamination Prevention

Preventing organism contamination

Due to the sensitive nature of the FilmArray system, it is important to guard against contamination of the work area by following these guidelines:

- Laboratory workers can be infected with common respiratory pathogens and can inadvertently contaminate the sample while it is being processed. To avoid this, specimens should be processed and pouches should be loaded in a biosafety cabinet. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield should be used when preparing specimens.
- A biosafety cabinet that is used for performing viral or bacterial culture should not be used for specimen preparation or pouch loading.
- 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 or a similar disinfectant. To avoid residue build-up and potential PCR inhibition, wipe disinfected surfaces with water.
- 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. Specimens should not be collected or processed in areas that are exposed to *B. pertussis* vaccine material and particular care should be taken during specimen collection and handling to avoid contamination

(http://www.cdc.gov/pertussis/clinical/diagnostictesting/diagnosis-pcr-bestpractices.html).

- Specimens and pouches should be handled one-at-a-time.
- Change gloves and clean the work area between preparation of each patient specimen.
- Laboratory workers with active respiratory symptoms (runny nose, cough) should wear a standard surgical mask (or equivalent) and should avoid touching the mask while preparing specimens.

Preventing Amplicon Contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the FilmArray RP pouch is a closed system, 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. The instrument and workspace must be decontaminated as described in the FilmArray Instrument Operator's Manual. 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 vial of unused viral transport medium (VTM) in place of the patient sample.
2. If unexpected positive results are obtained, then contamination of the work area is likely and the following decontamination and cleaning procedures should be completed. After decontamination is completed, test as additional pouch as described in step 1. If unexpected positive results are obtained, call BioFire Diagnostics technical support.

Decontamination and Cleaning Procedures

The following decontamination, cleaning and testing procedures are to be followed when false positive results caused by contaminations are suspected or following any event that may have resulted in contamination of the work area (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, especially during the first steps of decontamination and before touching any clean surface. All PPE should be disposed of after decontamination.

⚠ **CAUTION:** It is extremely important that contamination from leaking and/or punctured pouches be contained and cleaned immediately. Pouches that break after PCR can contain large quantities of contaminants. This material, although noninfectious, is easily spread by normal human activity. Consequently, very small (molecular) quantities can be amplified by PCR in future runs, which can then be identified as positive by the FilmArray instrument. Treat all broken pouches as capable of contaminating your area. See the FilmArray Instrument Operator's Manual for details regarding decontamination related to pouch leakage.

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)
- Distilled water in a squeeze or spray bottle
- DNAZap™, or equivalent DNA degrading system
- 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 Diagnostics'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. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove Pouch Loading Station from sink or bin. Replace bleach solution with water.
5. Rinse the Pouch Loading Station by completely submerging in water two additional times.

Decontamination Related to Pouch Leakage

If a pouch leaks, take the following precautions to avoid contamination: BIOLOGICAL RISKS: If the pouch contained potentially infectious material, the risk of biohazard contamination exists in addition to sample contamination.

1. Put on clean PPE such as gloves and safety shield.
2. Ensure no one else uses any potentially contaminated areas or instruments.
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. Clean up leaked pouch, discard 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. Wet a paper towel with 10% bleach (1 part bleach to 9 parts water) and wipe the inner sample chamber and under the lid. Change gloves.
4. Repeat step 3 twice with fresh paper towels for a total of three bleach wipes.
5. Wet a paper towel with distilled water and wipe sample chamber.
6. Repeat step 5 with fresh gloves and paper towel.

Instrument Exterior Decontamination

1. Put on lab coat and gloves.
2. Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the instrument, including the bottom and the bench top where the instrument had contact. Change gloves.
3. Repeat step 2 twice with fresh paper towels and clean gloves, for a total of three bleach wipes.
4. Change gloves, then wet a new paper towel with distilled water and wipe the surfaces of the inner chamber, including under the lid, and the entire exterior of the instrument, including the bottom and the bench top where the instrument had contact.
5. Repeat step 4, with fresh gloves and paper towel.

Decontamination of Bench Tops and Other Areas

1. Put on a clean lab coat and gloves.
2. Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for 5 minutes.
3. Wipe the area with a clean paper towel. Change gloves.
4. Repeat steps 2 and 3 twice, for a total of three wipes.
5. Change gloves. Spray the area with distilled water.
6. Wipe the area dry with a new paper towel. Change gloves.
7. Spray the area with DNAZap, or an equivalent product. Follow the product's instructions for correct use. Change gloves.
8. Rinse the area by spraying it with distilled water and wiping it dry.

Support

BIOFIRE DIAGNOSTICS, INC.

BioFire Diagnostics is dedicated to providing you with the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team at 801-736-6354, option 5 or by email at support@idahotech.com

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