Guidelines for Laboratory Verification of Performance of the FilmArray® BioThreat-E

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Purpose

This document provides examples of verification procedures to assist your laboratory in developing a protocol for the verification of FilmArray BioThreat-E test. A verification scheme, compatible with the FilmArray BioThreat-E, has been designed. The scheme provides positive and negative tests for Ebola Zaire detected by the FilmArray BioThreat-E test and may be easily modified or expanded to meet specific criteria. Day-to-day variation is evaluated by testing each sample on two separate days. To evaluate user-to-user variation, multiple laboratory technicians may test the same sample. The Laboratory Director is ultimately responsible for ensuring that verification procedures meet the appropriate standards for applicable laboratory accrediting agencies.

FilmArray BioThreat-E Intended Use

The FilmArray BioThreat-E test is a qualitative multiplexed nucleic acid based in vitro diagnostic (IVD) test intended for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in whole blood specimens or undiluted urine specimens. The FilmArray BioThreat-E test is performed on the FilmArray Instrument to detect RNA from the Ebola Zaire virus in specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

The complete intended use statement and additional information about the use of the FilmArray system can be found in the *FilmArray BioThreat-E Instructions for Use*.

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Performance Verification: Overview

Each procedure described below will generate positive and negative results for the FilmArray BioThreat-E test. The procedure was developed using BEI Resources NR-31807 and Maine Molecular M251.

A performance verification procedure is described for a single FilmArray Instrument. The procedure should be performed for the sample type(s) (blood, urine, or both) that will be tested by the laboratory. Instructions for preparing samples are described for two different control materials.

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Verification Material	Quantity of Control Material Needed	Replicates per Sample Type	Pouches Required	Expected Positive Results	Expected Negative Results	Approximate Days of Testing
BEI Resources Antigen from Ebolavirus (NR-31807)	1 tube	8	8	4	4	2
Maine Molecular FilmArray Ebola Control Panel (M251)	1 kit (contains 12 tubes)	8	8	4	4	2

Performance Verification: Materials

The following materials may be needed to perform verification procedures:

Material	Part Number
FilmArray BioThreat-E Kit (6 tests)	BioFire Defense,LLC. RFIT-ASY-0122
BEI Resources[a] Zaire Ebolavirus, Mayinga, Gamma-Irradiated	NR-31807
Maine Molecular[a] FilmArray Ebola Control Panel	M251
Human blood	Various sources are appropriate
Human urine	Various sources are appropriate

[a] Any appropriate source of organism/nucleic acid may be used for verification of the FilmArray BioThreat-E test. However, when alternate sources are used the sample volumes suggested in the example below may need to be adjusted.

Performance Verification: preparing samples

Maine Molecular Ebola Control Panel

The Maine Molecular FilmArray positive and negative controls are provided in a simulated blood sample matrix. These samples are ready to be used directly with the FilmArray system by following the *FilmArray BioThreat-E Instructions for Use* and *BioThreat-E Quick Guide*. The control material is aliquoted into single-use tubes; thus, each test will use a different tube of control material. The Maine Molecular Ebola Control Panel is not appropriate for evaluation in urine.

BEI Resources Zaire Ebolavirus, Mayinga, Gamma-Irradiated

1. Transfer 900 µl of blood or urine to a new vial.
2. Add 100 µl of control (BEI Resources Zaire Ebolavirus, Mayinga, Gamma-Irradiated) to the vial containing blood or urine.
3. Ensure the contrived blood or urine sample is effectively mixed by vortexing prior to removing a sample for testing.
4. Refrigerate (2-8˚C) sample while not in use.

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Simple protocol for verification of one instrument

In this example, a total of eight pouches are tested, providing four positive results and four negative results. The estimated total time to completion for this verification example is two days. If multiple sample types (blood and urine) are to be tested by the laboratory, the protocol should be repeated for each sample type.

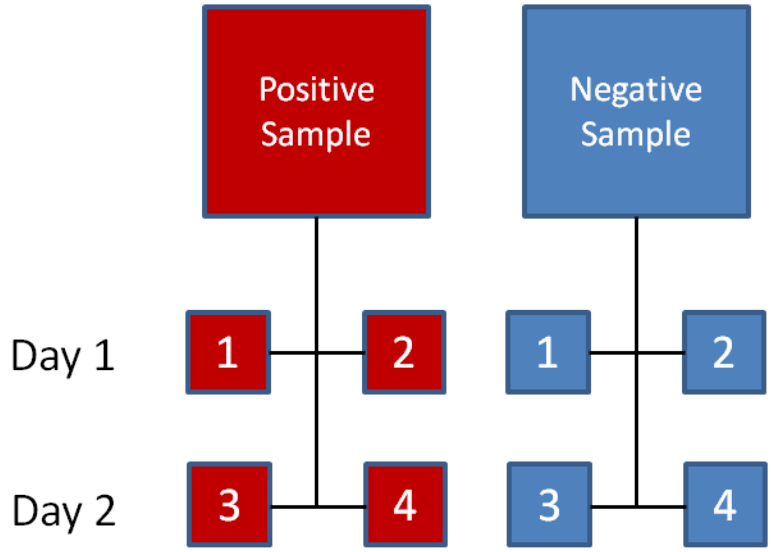

Figure 1. Simple protocol workflow. Each sample should be tested by two different users and on two different days. Additional samples can be prepared to verify additional instruments or additional sample types.

Day 1

1. Prepare a contrived blood or urine sample if necessary (see preparing samples above). Refrigerate (2-8˚C) samples until use, and retain samples in refrigerator until the entire verification procedure is complete.
2. To evaluate user-to-user variation, run two FilmArray tests on a positive control sample with two different users according to the *FilmArray BioThreat-E Instructions for Use* or *FilmArray BioThreat-E Quick Guide*.
3. To evaluate user-to-user variation, run two FilmArray tests on a negative control sample with two different users according to the *FilmArray BioThreat-E Instructions for Use* or *FilmArray BioThreat-E Quick Guide*.

Day 2

1. To evaluate day-to-day variation, run two tests on the positive control sample that was prepared on Day 1. Follow instructions in the *FilmArray BioThreat-E Instructions for Use* and *FilmArray BioThreat-E Quick Guide*.

2. To evaluate day-to-day variation, run two tests on the negative control sample that was used on Day 1. Follow instructions in the *FilmArray BioThreat-E Instructions for Use* and *FilmArray BioThreat-E Quick Guide*.

FilmArray® Instrument Verification Record

Instrument Serial #: _____

FilmArray Biothreat-E Kit Part #: _____ Lot #: _____

Organism/Sample Source and Lot #: _____

_____

Organism	Was the Organism Detected?	No. Positive	No. Negative	No. Days Tested	No. Users	Patient Samples Tested?
Ebola Zaire	☐ Yes ☐ No					

Reviewed by:

_____

Signature Date

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