

Kit Part No: NGDS-ASY-0001

FilmArray®

NGDS BT-E Assay Instructions for Use



**For Use Under the Emergency Use
Authorization (EUA) Only**

Manufactured by
BioFire Defense, LLC for the
U.S. Department of Defense

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Common Information

Intended Use Statement

The FilmArray NGDS BT-E Assay 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, plasma and serum specimens. The FilmArray NGDS BT-E Assay 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 infections or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors.

Testing with the FilmArray NGDS BT-E Assay should not be performed unless the individual is at risk for exposure to Ebola Zaire virus or has signs and symptoms of infection with Ebola Zaire that meet clinical and epidemiologic criteria for testing suspect specimens.

Assay results are for the presumptive identification of Ebola Zaire virus. The definitive identification of Ebola Zaire virus requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required. The diagnosis of Ebola virus infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of the Ebola Zaire virus. The level of Ebola Zaire virus that would be present in blood from individuals with early infection is unknown. Because of the difficulty in obtaining clinical specimens, these assays were evaluated with limited numbers of contrived clinical specimens spiked with inactivated or live Ebola Zaire virus. Negative results do not preclude Ebola Zaire virus infection and should not be used as the sole basis for patient management decisions.

The FilmArray NGDS BT-E Assay is for use only under Emergency Use Authorization (EUA) by United States Department of Defense-specified laboratories and clinical laboratory personnel who have been appropriately trained.

Introduction

The FilmArray NGDS BT-E Assay has been authorized for use under an EUA on the FilmArray instrument platform to provide Ebola Zaire virus testing capability to DoD-specified sites that currently perform testing with the FilmArray System.

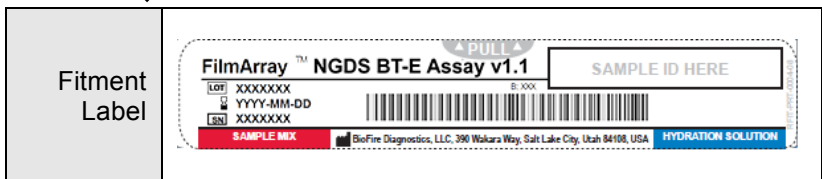
All users, analysts, and persons reporting diagnostic results from the FilmArray NGDS BT-E Assay should be trained in proper use of the instrument and software.

Storage of Contents

- Store the test kit, including reagent pouches and buffers, at room temperature (15-25 °C). **DO NOT REFRIGERATE.**
- Avoid storage of any materials near heating or cooling vents or in direct sunlight.
- Always check the expiration date and do not use reagents beyond the expiration date printed on the pouch or kit.
- Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
- Once a pouch has been loaded, the test run should be started as soon as possible (within 60 minutes).





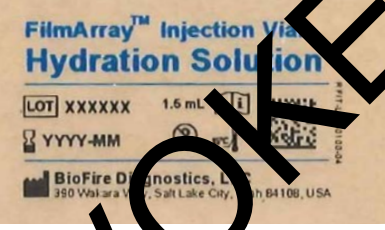
Kit Labels

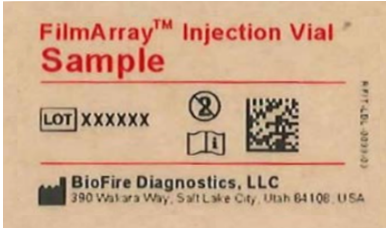
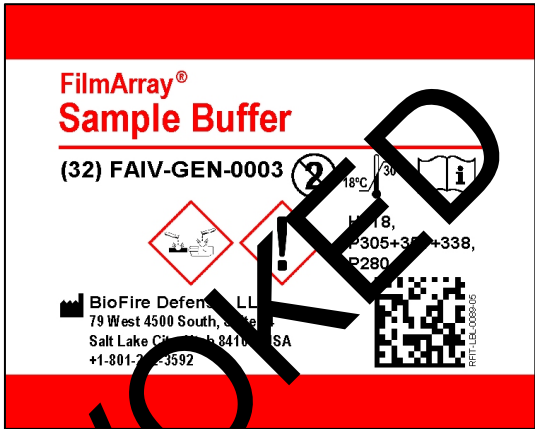

Examples of labels found with the FilmArray NGDS BT-E Assay Kit are:



<p>Mylar Pouch Label</p>	
<p>Protease Vial Label</p>	
<p>Mylar pouch label for the protease vial</p>	

<p>FilmArray Sample Buffer Ampoule Bag Label</p>	
<p>Sample Buffer Ampoule Label</p>	
<p>Hydration Solution Injection Vial Bag Label</p>	

<p>30 Pack Protease Bag Label</p>	<div style="text-align: right;">REF RFIT-SUB-0318</div> <p>The full label information for the contents is provided on this label. Do NOT store contents of this bag separately.</p> <h1 style="text-align: center;">Protease</h1> <hr/> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  30 Vials </div> <div style="text-align: right;"> Store at Room Temperature </div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;"> LOT XXXXXX </div> <div style="text-align: right;">   Danger </div> </div> <p> Wear protective gloves / eye protection / face protection IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. </p> <div style="display: flex; justify-content: space-between;"> <div> <p>Causes skin irritation, May cause an allergic skin reaction Causes serious eye irritation, May cause allergy or asthma symptoms or breathing difficulties if inhaled, May cause respiratory irritation</p> </div> <div style="text-align: right;">  RFIT-Label-002 </div> </div> <div style="background-color: #0056b3; color: white; padding: 5px;"> <p>BioFire Defense, LLC 79 West 4500 South, Suite 14, Salt Lake City, 84107 UT, USA +1-801-262-3592 www.BioFireDefense.com</p> </div>
<p>Hydration Solution Injection Vial Label</p>	 <p style="text-align: center; font-size: 2em; opacity: 0.5; transform: rotate(-45deg); font-weight: bold;">REVOKED</p>

<p>Sample Buffer Injection Vial Label</p>	 <p>FilmArray™ Injection Vial Sample</p> <p>LOT XXXXXX</p> <p>BioFire Diagnostics, LLC 390 Watara Way, Salt Lake City, Utah 84108, USA</p>
<p>Sample Buffer Injection Vial Bag Label</p>	 <p>FilmArray® Sample Buffer</p> <p>(32) FAIV-GEN-0003</p> <p>18°C/30</p> <p>18, P305+338, P280</p> <p>BioFire Defense, LLC 79 West 4500 South, Suite 14 Salt Lake City, Utah 84107, USA +1-801-262-3592</p> <p>REF-LEL-0008-08</p>
<p>Transfer Pipette Bag Label</p>	 <p>FilmArray® Transfer Pipettes</p> <p>(32) CNSB-PIP-0009</p> <p>BioFire Defense, LLC 79 West 4500 South, Suite 14 Salt Lake City, Utah 84107, USA +1-801-262-3592</p> <p>REF-LEL-0008-08</p>

Outer Kit
Box Label

FilmArray® NGDS BT-E Assay

BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, Utah 84107, USA | +1-801-262-3592
Patent Information: <http://www.biofiredefense.com/legal/notice/>

REF NGDS-ASY-0001



LOT XXXXXXXX

XXXXXXXXXXXX

NGDS-BL-0009-02

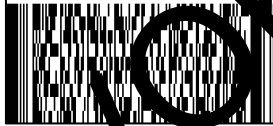
FilmArray® NGDS BT-E Assay

For FilmArray systems
For Use Under an Emergency
Use Authorization (EUA) Only



! DANGER

NGDS-ASY-0001XXXXXXXXXXXX



- (32) RFIT-SUB-0317
- (32) CNSB-PIP-0009
- (32) FAIV-SUB-0001
- (32) FAIV-SUB-0002
- (32) FAIV-GEN-0003

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Materials Provided

Each kit contains sufficient reagents to test 30 samples:

- Individually packaged FilmArray NGDS BT-E Assay pouches
- Single-use (1.0 mL) Sample Buffer ampoules
- Single-use freeze-dried protease vials
- Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)
- Single-use Sample Injection Vials (red)
- Individually packaged Transfer Pipettes

Materials Required But Not Provided

- FilmArray System with laptop computer and FilmArray Pouch Loading Station compatible with the use of the FilmArray Injection Vials (included with FilmArray System)
- Bleach
- De-ionized water

Principle of the Procedure

The following is an overview of the operations and processes that occur during a FilmArray run:

1. **Nucleic Acid Purification** - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by a combination of chemical and mechanical (bead-beating) mechanisms and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes, and the bead-beater apparatus can be heard as a high-pitched whine during the first few minutes of operation.
2. **Reverse Transcription and 1st Stage Multiplex PCR** - Since the Ebola virus has an RNA genome, a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The purpose of 1st stage PCR is to enrich for the target nucleic acids present in the sample.

3. **2nd Stage PCR** - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing a double stranded DNA-binding fluorescent dye (LCGreen® Plus, BioFire Defense, LLC.). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers, for different assays (each present in triplicate), that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are 'nested' or internal to the specific products of the 1st stage reaction, which enhances both the sensitivity and specificity of the reactions.
4. **DNA Melting Analysis** – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or T_m) is consistent and predictable, and the FilmArray Software automatically evaluates the data from replicate wells for each assay to report results.

The FilmArray Software controls the operation of the instrument, collects and analyzes data, and automatically generates a test report at the end of the run. The entire process takes about an hour. Additional detail can be found in the FilmArray Operator's Manual.

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Testing Procedure

NOTE: Testing should be performed under the appropriate biosafety conditions and in accordance with CDC guidelines. This information can be found in *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the U.S. Centers for Disease and Prevention (CDC) in conjunction with the World Health Organization (WHO) and found at

<http://www.cdc.gov/vhf/abroad/healthcare-workers.html> and in: Information for Healthcare Workers in the United States: <http://www.cdc.gov/vhf/ebola/hcp/>.

Refer to the FilmArray NGDS BT-E Assay Quick Guide, or abbreviated pictorial representations of these instructions

Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one FilmArray pouch should be prepared at a time. Once sample is added to the pouch, it should be promptly transferred to the instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

Prepare Pouch

1. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse. Note: Ensure that the Pouch Loading Station is compatible with the use of the FilmArray Injection Vials.
2. Obtain the following required materials and place in the clean hood:
 - FilmArray NGDS BT-E Assay pouch
 - Sample buffer ampoule
 - Protease vial
 - Hydration Injection Vial (blue cap)
 - Sample Injection Vial (red cap)
 - Transfer pipette

3. Place a blue-capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
4. Place a red-capped Sample Injection Vial in the red well of the Pouch Loading Station.
5. Obtain patient sample and place into hood.
6. Remove the FilmArray pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

7. Slide the pouch into the Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the base of the Pouch Loading Station.

Hydrate Pouch

1. Twist the Hydration Injection Vial (blue cap), leaving cap in Pouch Loading Station, and insert the tip of the cannula into the hydration port of the pouch located directly below the blue arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
2. Verify that the pouch has been hydrated. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), verify that the seal of the port was broken by ensuring the vial cannula was fully inserted into the hydration port. If the pouch fails to hydrate, retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.
3. Discard the Hydration Injection Vial in a suitable puncture proof container.

Prepare Sample Mix

1. Hold the Sample Buffer ampoule so that the tip is facing up.

NOTE: Use care to avoid touching the tip during handling, as this may introduce contamination.

2. Gently pinch the textured plastic tab on side of ampoule until the seal snaps.
3. Re-position thumb and forefinger to grip between the textured plastic tab and the bottom of the ampoule, then invert over the un-capped Protease vial and dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.
4. Re-cap Protease Vial and invert 3 times to mix.
5. Un-cap Protease Vial and pour buffer/protease mixture into red Sample Injection Vial.
6. Using the transfer pipette provided in the test kit, draw patient sample to the second line (approximately 0.2 mL). Add sample to the red-capped Sample Injection Vial.

NOTE: Do not use the transfer pipette to mix the sample once it is loaded into the Sample Injection Vial.

7. Tightly close the lid of the Sample Injection Vial and mix by gently inverting at least 3 times.
8. Return the Sample Injection Vial to the Pouch Loading Station.

Load Sample Mix

1. Slowly unscrew Sample Injection Vial from the cap and pause for 3-5 seconds.

NOTE: It is important to pause after unscrewing the Sample Injection Vial to avoid sample leakage and contamination of the work area.

2. Remove Sample Injection Vial leaving cap in Pouch Loading Station and insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in

resistance. The correct volume of liquid will be pulled into the pouch by vacuum.

3. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.
4. Discard the Sample Injection Vial and the Hydration Injection Vial in a suitable biohazard and puncture proof container.
5. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

Run Pouch

The FilmArray Instrument Control Software includes a step-by-step on-screen tutor that shows each step of the test.

1. Ensure that the computer and FilmArray Instrument have been turned on. Launch the FilmArray Instrument Control Software by double clicking on the desktop icon.
2. Open the instrument lid (if not already open).
3. Insert the FilmArray pouch into the instrument.

Position the pouch so that the array is on the right with the film directed downward into FilmArray Instrument. The red and blue labels on the FilmArray pouch should align with the red and blue arrows on the FilmArray Instrument. The pouch will click into place. If inserted correctly, the barcode is visible and the label is readable on the top of the pouch. The instrument and software must detect that the pouch has been inserted correctly before continuing to the next step.

NOTE: If the pouch does not slide into the instrument easily, gently push the lid of the instrument back to be sure that it is completely open.

4. Scan the barcode on the FilmArray pouch using the barcode scanner.

Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the barcode located on the FilmArray pouch and will be automatically

entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: The barcode cannot be scanned prior to placing the pouch in the instrument. A “Cannot scan now” message will be displayed.

5. Enter the Sample ID.

The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcode sample ID is used.

6. If not already selected, select the NGDS Blood Protocol from the Protocol drop down list.
7. Enter a user name and password in the Name and Password fields.
8. Close the FilmArray Instrument lid.
9. Click Start Run.

Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first few minutes of operation.

10. When the run is finished, results are automatically displayed in the report section of the screen. The report is automatically saved into the database.
11. Select **Print** to print the report, or **Save** to save the report as a PDF file.
12. Follow the on-screen instructions to open the instrument and remove the pouch.

Immediately discard the pouch in a biohazard container.

Quality Control

Process Controls

Two process controls are included in each pouch:

1. RNA Process Control

The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR and DNA melting. A positive control result indicates that all steps carried out in the FilmArray NGDS BT-E Assay pouch were successful.

2. PCR2 Control

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.

Both control assays must be positive for the test run to pass. If either control fails, the Controls field of the test report (upper right hand corner) will display “Failed” and all results will be listed as “Invalid”. If the controls fail, the sample should be retested using a new pouch.

External Controls

Information on how to obtain optional external control material is posted on the BioFire Defense website at

<http://biofiredefense.com/support/filmarray-support/>

Assay Interpretation

When 2nd stage PCR is complete, the FilmArray Instrument performs a high resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see FilmArray Operator’s Manual). The FilmArray Software then performs several analyses and assigns a final assay result. The steps in the analysis are described below.

Analysis of melt curves. The FilmArray Software evaluates the DNA melt curve for each well of the 2nd stage PCR 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 (T_m) of the curve. The T_m value is then compared against the expected T_m range for the assay. If the software determines that the melt curve is positive and the T_m falls inside the assay-specific T_m range, the melt curve is called positive. If the software determines that the melt curve is negative or is not in the appropriate T_m range, the melt curve is called negative.

Analysis of replicates. Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the T_m for at least two of the three positive melt curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.



FilmArray Test Report

The FilmArray NGDS BT-E assay test report is automatically displayed upon completion of a run and contains three sections, the Run Summary, the Result Summary, and the Run Details. The test report can be saved as a PDF or printed. Examples of negative (Figure 1) and positive (Figure 2) run reports are shown below.

Figure 1. Example test report of a negative FilmArray run.

FilmArray™ NGDS BT-E Assay		BIO FIRE www.BioFireDefense.com	
Run Summary			
Sample ID:	011409390-0939	Run Date:	05 Nov 2014 11:36 AM
Detected:	None	Controls:	Passed
Result Summary			
Not Detected		Viruses	
Ebola Zaire			
Run Details			
Pouch:	NGDS BT-E Assay v1.1	Protocol:	NGDS Blood v2.1
Run Status:	Completed	Operator:	Ethan Y
Serial No.:	02036706	Instrument:	ITI FA "FA1307"
Lot No.:	141030F		

Figure 2. Example test report of a positive FilmArray run.

 FilmArray® NGDS BT-E Assay		 BIO FIRE <small>www.BioFireDefense.com</small>	
Run Summary			
Sample ID:	011409390-0939	Run Date:	05 Nov 2014 11:36 AM
Detected:	Ebola Zaire	Controls:	Passed
Result Summary			
Viruses			
✓ Detected	Ebola Zaire		
Run Details			
Pouch:	NGDS BT-E Assay v1.1	Protocol:	NGDS Blood v2.1
Run Status:	Completed	Operator:	Ethan Y
Serial No.:	02036706	Instrument:	ITI FA "FA1307"
Lot No.:	141030F		

The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. An “Ebola Zaire” result will be listed in the “Detected” field of the summary. If the test is negative then “None” will be displayed in the “Detected” field. Controls are listed as “Passed”, “Failed” or “Invalid”. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures.

The **Result Summary** section of the test report lists the result for Ebola Zaire. Possible results are “Detected”, “Not Detected”, or “Invalid”. See the Results Summary - Interpretations section below for detailed information about interpretation of test results and appropriate follow-up for invalid results.

The **Run Details** section provides additional information about the run including pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator who performed the test, and the instrument used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called **Change History** will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator who made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Controls Field

The Controls field on the test report will display “Passed”, “Failed”, or “Invalid”. The Controls field will display “Passed” only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (RNA Process Control and PCR2 Control) were successful. The Controls field will display “Failed” if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed. The Controls field will display “Invalid” if the run did not complete (typically indicates a software or hardware error). If the control result is “Failed” or “Invalid”, then the result for Ebola Zaire is displayed as “Invalid” and the sample will need to be retested with a new pouch.

Table 1 provides a summary and explanation of the possible control results and follow-up actions.

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Table 1. Interpretation of Controls Field on the FilmArray NGDS BT-E Assay Test Report

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch controls were successful.	None	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch.	Accept the results of the repeat testing. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error).	Note any error codes displayed during the run and the value of the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument.	Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction.

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Results Summary—Interpretations

The Results Summary – Interpretations section lists the Ebola Zaire result. Possible results include “Detected”, “Not Detected”, and “Invalid”. Table 2 provides an explanation for each interpretation and any follow-up actions necessary to obtain a final result.

Table 2. Reporting of Results and Required Actions

Result	Explanation	Action
Detected	<p>The run was successfully completed</p> <p>AND</p> <p>The pouch controls were successful (Passed)</p> <p>AND</p> <p>The assay(s) associated with the interpretation were positive based on the following requirements for at least 2 of the 3 assay replicates:</p> <ul style="list-style-type: none"> • a positive melt curve, and • the Tm for the melt data were within the assay specific limits, and • the Tm for the melt data were within 1°C of each other. 	None. Report results.
Not Detected	<p>The run was successfully completed</p> <p>AND</p> <p>The pouch controls were successful (Passed)</p> <p>AND</p> <p>The assay(s) associated with the interpretation were negative (did not meet the requirements for a positive assay described in Detected).</p>	None. Report results.
Invalid	<p>The run did not complete successfully (Aborted, Incomplete, Instrument Communication Error, Instrument Error, or Software Error)</p> <p>OR</p> <p>The pouch controls were not successful (Failed)</p>	See Table 1, <i>Interpretation of Controls Field on FilmArray Report</i> , for instruction.

Assay Limitations

- This product can only be used with the FilmArray Instrument
- This test is a qualitative test and does not provide a quantitative value for the virus in the sample.
- This test has been evaluated for use with human whole blood, plasma and serum only.
- All results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms.
- Interpretation of results from the FilmArray NGDS BT-E Assay must account for the possibility of false-positive and false-negative results.
- Negative results do not preclude infection with Ebola virus and should not be the sole basis of patient treatment/management decisions.
- False positive results may occur from cross-contamination by target organisms, their nucleic acids, or from PCR amplicon.
- Failure to follow assay procedures may lead to false-negative results.
- Inhibitors present in the samples may lead to false-negative results.
- Specimens from patients who have received therapeutics or vaccines based on nucleic acid sequences derived from Ebola Zaire virus may exhibit false positive or other confounding test results.

Warnings and Precautions

- For *in vitro* diagnostic use under an Emergency Use Authorization only.
- Use of this assay should only be for designated personnel.
- Treat all specimens as potentially infectious. Follow necessary precautions when handling samples and reagents.
- Performance of the FilmArray NGDS BT-E Assay has only been evaluated for the specimen type described in the Intended Use.
- Proper sample collection, storage, and transport are essential for valid test results.
- Do not use reagents from other manufacturers with this assay.
- Use appropriate laboratory and personal protective equipment when using this kit.

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Performance Characteristics

Analytical Sensitivity/Limit of Detection (LoD)

Limit of Detection (LoD) studies were performed to estimate and determine the lowest detectable concentration of Ebola Zaire virus at which approximately 95% of all replicates test positive.

Estimated Limit of Detection (LoD) – Inactivated Ebola Zaire in Whole Blood

The LoD of the FilmArray NGDS BT-E Assay was estimated using inactivated Ebola Zaire virus in whole blood matrix. Template material was provided by the Critical Reagents Program: Ebola Zaire-76 Mayinga (T), UCC# Ebola001, Lot# R3828. Ten-fold serial dilutions were prepared in a whole-blood matrix and tested in triplicate (Table 3).

Table 3. Estimated LoD using Inactivated Ebola Zaire in Whole Blood

Strain	Target Concentration (PFU/mL)	Detection Results
Zaire (Mayinga)	1.00E+06	3/3
	1.00E+05	3/3
	1.00E+04	3/3

NOTE: PFU = plaque-forming unit

LoD Confirmation – Inactivated Ebola Zaire in Whole Blood

Based on the initial estimates of LoD for this virus, 24 whole blood specimens were spiked with inactivated virus at 1.00E+04 PFU/mL (the estimated LoD) and analyzed, along with 3 negative whole blood specimens. The results of the analysis can be found in Table 4 below.

Table 4. LoD Confirmation Study – Inactivated Ebola Zaire in Whole Blood

Results

Virus Concentration = 1.00E+04 PFU/mL (4.36E+05 GE/mL)		
Whole Blood Sample	Result (Detected/Not Detected)	Reported Virus
NTC 1	Not Detected	
NTC 2	Not Detected	
NTC 3	Not Detected	
Spiked 1	Detected	Ebola Zaire
Spiked 2	Detected	Ebola Zaire
Spiked 3	Detected	Ebola Zaire
Spiked 4	Detected	Ebola Zaire
Spiked 5	Detected	Ebola Zaire
Spiked 6	Detected	Ebola Zaire
Spiked 7	Detected	Ebola Zaire
Spiked 8	Detected	Ebola Zaire
Spiked 9	Detected	Ebola Zaire
Spiked 10	Detected	Ebola Zaire
Spiked 11	Detected	Ebola Zaire
Spiked 12	Detected	Ebola Zaire
Spiked 13	Detected	Ebola Zaire
Spiked 14	Detected	Ebola Zaire
Spiked 15	Detected	Ebola Zaire
Spiked 16	Detected	Ebola Zaire
Spiked 17	Detected	Ebola Zaire
Spiked 18	Detected	Ebola Zaire
Spiked 19	Detected	Ebola Zaire
Spiked 20	Detected	Ebola Zaire
Spiked 21	Detected	Ebola Zaire
Spiked 22	Detected	Ebola Zaire
Spiked 23	Detected	Ebola Zaire
Spiked 24	Detected	Ebola Zaire
24/24 - Ebola Zaire		

NOTE: PFU, plaque forming unit; GE, genomic equivalent; NTC, no template control

LoD Confirmation – Inactivated Ebola Zaire in Plasma and Serum

Based on the LoD determined using whole blood, 20 plasma and 20 serum specimens were spiked with inactivated virus at 1.00E+04 PFU/mL and tested. These specimens were spiked with the same material used to spike the whole-blood specimens. The LoD of 1.00E+04 PFU/mL was confirmed. The results of the testing can be found in Tables 5, 6 and 7 below.

Table 5. Confirmation of LoD (1.00E+04 PFU/mL)

Strain	Sample Type	Detected/Total
Zaire (Mayinga)	Plasma	19/20
	Serum	20/20

Table 6. LoD Confirmation Study – Inactivated Ebola Zaire Result for Plasma

Virus Concentration = 1.00E+04 PFU/mL (4.36E+05 GE/mL)		
Plasma Sample	Result (Detected/Not Detected)	Reported Virus
Spiked 1	Detected	Ebola virus/Zaire
Spiked 2	Detected	Ebola virus/Zaire
Spiked 3	Detected	Ebola virus/Zaire
Spiked 4	Detected	Ebola virus/Zaire
Spiked 5	Detected	Ebola virus/Zaire
Spiked 6	Detected	Ebola virus/Zaire
Spiked 7	Detected	Ebola virus/Zaire
Spiked 8	Detected	Ebola virus/Zaire
Spiked 9	Detected	Ebola virus/Zaire
Spiked 10	Detected	Ebola virus/Zaire
Spiked 11	Detected	Ebola virus/Zaire
Spiked 12	Detected	Ebola virus/Zaire
Spiked 13	Detected	Ebola virus/Zaire
Spiked 14	Detected	Ebola virus/Zaire
Spiked 15	Detected	Ebola virus/Zaire
Spiked 16	Detected	Ebola virus/Zaire
Spiked 17	Detected	Ebola virus/Zaire
Spiked 18	Not Detected	Ebola virus/Zaire
Spiked 19	Detected	Ebola virus/Zaire
Spiked 20	Detected	Ebola virus/Zaire
Total	19/20 - Ebola virus/Zaire	

Table 7. LoD Confirmation Study – Inactivated Ebola Zaire Result for Serum

Virus Concentration = 1.00E+04 PFU/mL (4.36E+05 GE/mL)		
Serum Sample	Result (Detected/Not Detected)	Reported Virus
Spiked 1	Detected	Ebola virus/Zaire
Spiked 2	Detected	Ebola virus/Zaire
Spiked 3	Detected	Ebola virus/Zaire
Spiked 4	Detected	Ebola virus/Zaire
Spiked 5	Detected	Ebola virus/Zaire
Spiked 6	Detected	Ebola virus/Zaire
Spiked 7	Detected	Ebola virus/Zaire
Spiked 8	Detected	Ebola virus/Zaire
Spiked 9	Detected	Ebola virus/Zaire
Spiked 10	Detected	Ebola virus/Zaire
Spiked 11	Detected	Ebola virus/Zaire
Spiked 12	Detected	Ebola virus/Zaire
Spiked 13	Detected	Ebola virus/Zaire
Spiked 14	Detected	Ebola virus/Zaire
Spiked 15	Detected	Ebola virus/Zaire
Spiked 16	Detected	Ebola virus/Zaire
Spiked 17	Detected	Ebola virus/Zaire
Spiked 18	Detected	Ebola virus/Zaire
Spiked 19	Detected	Ebola virus/Zaire
Spiked 20	Detected	Ebola virus/Zaire
Total	20/20	- Ebola virus/Zaire

LoD Study- Live Ebola Zaire in Whole Blood

This LoD study was carried out using the following characterized sample.

Strain of viral stock	Ebola Zaire Live (CRP Lot#R3816)
Titer (PFU/mL)	1.70E+07
How were stocks prepared	Viral stocks were cultured and frozen
How were titers determined	Plaque assay prior to freezing of stock
How were samples prepared	Virus dilutions were made in 1X Eagle's Minimum Essential Medium with Earle's salt & L-glutamine (EMEM). Once the virus dilutions were made, they were aliquoted, stored at -80°C in BSL-4, and only thawed immediately before blood-spiking. On the day of testing, appropriate virus dilution aliquots were thawed and spiked into whole blood (< 5 day-old human whole blood

	from Bioreclamation) at a blood to virus dilution ratio of approximately 15:1.
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NOTE: PFU, plaque forming unit

Based on the initial estimates of LoD for this virus, 4 whole blood specimens were spiked with live virus at 1.00E+06 PFU/mL (approximately 100X estimated LoD), 4 whole blood specimens were spiked with live virus at 1.00E+03 PFU/mL (approximately 0.1X estimated LoD), and 4 whole blood specimens were spiked with live virus at 1.00E+02 PFU/mL (approximately 0.01X estimated LoD). All 12 spiked whole blood samples were then tested. The results of the analysis can be found in Table 8 below.

Table 8. LoD Study – Live Ebola Zaire in Whole Blood Results

Whole Blood Sample	Virus Concentration – PFU/mL (GE/mL)	Result (Detected/Not Detected)	Reported Virus
Spiked 1	1.00E+06 (4.36E+07)	Detected	Ebola Zaire
Spiked 2	1.00E+06 (4.36E+07)	Detected	Ebola Zaire
Spiked 3	1.00E+06 (4.36E+07)	Detected	Ebola Zaire
Spiked 4	1.00E+06 (4.36E+07)	Detected	Ebola Zaire
Spiked 5	1.00E+03 (4.36E+04)	Detected	Ebola Zaire
Spiked 6	1.00E+03 (4.36E+04)	Detected	Ebola Zaire
Spiked 7	1.00E+03 (4.36E+04)	Detected	Ebola Zaire
Spiked 8	1.00E+03 (4.36E+04)	Detected	Ebola Zaire
Spiked 9	1.00E+02 (4.36E+03)	Not Detected	
Spiked 10	1.00E+02 (4.36E+03)	Detected	Ebola Zaire
Spiked 11	1.00E+02 (4.36E+03)	Detected	Ebola Zaire
Spiked 12	1.00E+02 (4.36E+03)	Detected	Ebola Zaire
	100X LoD	4/4 - Ebola Zaire	
	0.1X LoD	4/4 - Ebola Zaire	
	0.01X LoD	3/4 - Ebola Zaire	

NOTE: PFU, plaque forming unit; CFU, colony forming unit; GE, genomic equivalent

Analytical Reactivity in Whole Blood

No additional reactivity testing was performed for the FilmArray NGDS BT-E Assay because non-Mayinga strains of Ebola Zaire are currently unavailable. However, *in silico* analysis of the primer sequences and the available corresponding target gene sequences (n=30 for non-outbreak strain gene targets, n=99 for current 2014 outbreak strain target gene sequences) was performed. For all 30 non-outbreak strain target sequences, the primer sequences and annealing regions were found to be identical. For the 99 2014 outbreak strain target sequences, 98 were identical to the primer sequences. A single nucleotide mismatch was detected in 1 of 99 2014 outbreak strain target gene sequences. The significance of this single difference is unknown.

Analytical Specificity (Cross-Reactivity) in Whole Blood

Analytical Specificity (Cross-reactivity) for the FilmArray NGDS BT-E Assay was evaluated by testing additional non-Zaire strains of Ebola virus and other strains in Ebola's taxonomic family (Marburg viruses) at various concentrations in quadruplicate. The results of this analysis are shown in Table 9 below. No cross-reactivity was observed for any of the viruses at the concentrations tested.

Table 9. Ebola virus family Cross-Reactivity in Whole Blood

Line Virus	Strain	Concentration (PFU/mL or GE/mL)	Ebola Zaire Result (Detected/ Not Detected)	Replicates
Ebola	Ivory Coast	1.00E+08	Not Detected	4/4
		1.00E+05	Not Detected	4/4
		1.00E+04	Not Detected	4/4
	Reston	1.00E+06	Not Detected	4/4
		1.00E+03	Not Detected	4/4
		1.00E+02	Not Detected	4/4
	Sudan	1.00E+05	Not Detected	4/4
		1.00E+03	Not Detected	4/4
		1.00E+02	Not Detected	4/4
	Bundibugyo	3.00E+04	Not Detected	4/4
		1.00E+03	Not Detected	4/4
		1.00E+02	Not Detected	4/4
Marburg	Angola	1.00E+06	Not Detected	4/4

	Ci67	1.00E+04	Not Detected	4/4
		1.00E+03	Not Detected	4/4
		1.00E+06	Not Detected	4/4
		1.00E+03	Not Detected	4/4
	Musoke	1.00E+02	Not Detected	4/4
		1.00E+06	Not Detected	4/4
		1.00E+03	Not Detected	4/4
	Ravn	1.00E+02	Not Detected	4/4
		1.00E+06	Not Detected	4/4
		1.00E+03	Not Detected	4/4
		1.00E+02	Not Detected	4/4

NOTE: PFU, plaque forming unit; CFU, colony forming unit; GE, genomic equivalent

Cross-reactivity of the FilmArray NGDS BT-E Assay was also evaluated for several bacterial, yeast, and viruses outside of the Ebola virus family. Organisms were tested at the given concentration. As shown in Table 10 below, no cross-reactivity was observed for any of the organisms at the concentrations tested.

Table 10. Non-Ebola Virus Family Cross-Reactivity in Whole Blood

Organism	Highest Concentration Tested	Ebola Zaire Result (Detected/Not Detected)
<i>Bacillus anthracis</i>	1.00E+06 CFU/mL	Not Detected
<i>Brucella melitensis</i>	1.70E+06 GE/mL	Not Detected
<i>Brucella abortus</i>	1.70E+06 GE/mL	Not Detected
<i>Brucella suis</i>	1.70E+06GE/mL	Not Detected
<i>Burkholderia thailandensis</i>	1.70E+06GE/mL	Not Detected
<i>Burkholderia pseudomallei</i>	1.70E+06GE/mL	Not Detected
<i>Coxiella burnetii</i>	1.70E+06GE/mL	Not Detected
<i>Francisella novicida</i>	1.70E+06 GE/mL	Not Detected
<i>Francisella tularensis</i>	1.70E+06 GE/mL	Not Detected
<i>Rickettsia spp.</i>	1.70E+06 GE/mL	Not Detected
<i>Yersinia pestis</i>	1.70E+06 GE/mL	Not Detected
<i>Yersinia pseudotuberculosis</i>	1.70E+06 GE/mL	Not Detected
<i>Staphylococcus epidermidis</i>	1.00E+08 CFU/mL	Not Detected
<i>Staphylococcus aureus</i>	1.00E+08 CFU/mL	Not Detected
<i>Enterococcus faecalis</i>	1.00E+08 CFU/mL	Not Detected
<i>Streptococcus pneumoniae</i>	1.00E+08 CFU/mL	Not Detected
<i>Escherichia coli</i>	1.00E+08 CFU/mL	Not Detected
<i>Klebsiella pneumoniae</i>	1.00E+08 CFU/mL	Not Detected
<i>Klebsiella oxytoca</i>	1.00E+08 CFU/mL	Not Detected
<i>Serratia marcescens</i>	1.00E+08 CFU/mL	Not Detected
<i>Acinetobacter baumannii</i>	1.00E+08 CFU/mL	Not Detected
<i>Enterobacter cloacae</i>	1.00E+08 CFU/mL	Not Detected
<i>Pseudomonas aeruginosa</i>	1.00E+08 CFU/mL	Not Detected
<i>Haemophilus influenzae</i>	1.00E+08 CFU/mL	Not Detected

Organism	Highest Concentration Tested	Ebola Zaire Result (Detected/Not Detected)
<i>Proteus mirabilis</i>	1.00E+08 CFU/mL	Not Detected
<i>Mycoplasma pneumoniae</i>	3.00E+01 TCID ₅₀ /mL	Not Detected
<i>Candida albicans</i>	1.00E+05 CFU/mL	Not Detected
<i>Candida parapsilosis</i>	1.00E+05 CFU/mL	Not Detected
VEE	1.10E+09 PFU/mL	Not Detected
Adenovirus	3.00E+02 TCID ₅₀ /mL	Not Detected
Human Rhinovirus	1.00E+00 TCID ₅₀ /mL	Not Detected
Influenza A H1N1 2009	1.00E+02 TCID ₅₀ /mL	Not Detected
Parainfluenza virus 3	1.00E+01 TCID ₅₀ /mL	Not Detected

NOTE: PFU, plaque forming unit; CFU, colony forming unit; GE, genomic equivalent; TCID₅₀, tissue culture infective dose.

In addition, *in silico* analysis of the FilmArray NGDS BT-E Assay primer sequences was performed to evaluate potential cross-reactivity with human DNA. No significant sequence similarities were found between the assay primers and human DNA.

Contrived Clinical Specimen Studies Using Inactivated Ebola Zaire Virus

Contrived Clinical Testing in Whole Blood

The estimated LoD of the FilmArray NGDS BT-E Assay testing inactivated Ebola Zaire Mayinga virus was 1.00E+04 PFU/ml. To predict clinical performance, 45 independent whole-blood specimens were spiked with inactivated Ebola Zaire Mayinga virus at the concentrations listed in Table 11 below. In addition, 50 negative whole blood specimens were also tested.

Table 11. Contrived Whole-Blood Specimen Spiking Scheme

Spike Level	Number
No virus	50
1 × LoD	15
3 × LoD	15
High Concentration (100 × LoD)	15

Contrived specimens were randomized and analyzed with the FilmArray NGDS BT-E Assay. The blinded spiking key was unmasked after valid runs were obtained for all 95 specimens. The results of this study are summarized in Table 13.

Contrived Clinical Testing in Plasma and Serum

The same inactivated Ebola Zaire Mayinga virus at 1.0×10^4 PFU/ml was used to prepare the contrived plasma and serum samples. To predict clinical performance, 25 plasma specimens and 25 serum specimens were spiked with inactivated Ebola Zaire Mayinga virus at the concentrations listed in Table 12 below. Twenty-five (25) negative specimens were also tested for each sample type.

Table 12. Contrived Plasma and Serum Specimen Spiking Scheme

Sample type	Spike Level	Number
Plasma	Not Spiked	25
	2 × LoD	20
	100 × LoD	5
Serum	Not Spiked	25
	2 × LoD	20
	100 × LoD	5

Contrived specimens were randomized and analyzed with the FilmArray NGDS BT-E Assay. The results of this study are summarized in Table 13.

Table 13. Contrived Clinical Studies Summary

Sample Type	Spike Level	Detected	Not Detected	PPA	NPA	95% CI
Whole Blood	Not Spiked	0	50	-	100%	92.9-100%
	1 × LoD	11	4	86.7%	-	73.8-93.7%
	3 × LoD	13	2			
	100 × LoD	15	0			
Plasma	Not Spiked	0	25	-	100%	86.7-100%
	2 × LoD	18	2	92%	-	75.0-97.8%
	100 × LoD	5	0			
Serum	Not Spiked	0	25	-	100%	86.7-100%
	2 × LoD	18	2	92%	-	75.0-97.8%
	100 × LoD	5	0			

The FilmArray NGDS BT-E Assay correctly identified 39/45 whole-blood specimens spiked with inactivated Ebola Zaire at the concentrations shown above, including concentrations at or near the limit of detection. No false positive results were detected. The assay correctly identified 23/25 (92% positive percent agreement (PPA)) plasma specimens and 23/25 (92% PPA) serum specimens spiked with inactivated Ebola. Two false negative results were observed for each sample type, which may occur when spiking near the LoD. No false positive results were observed for unspiked specimens in either sample type, giving negative percent agreement (NPA) of 100% for both sample types.

Contrived Clinical Testing on the FilmArray 2.0 Instrument

To demonstrate equivalent performance of the FilmArray NGDS BT-E Assay on the FilmArray and FilmArray 2.0 instruments, inactivated Ebola Zaire (Mayinga) virus was used to prepare contrived whole blood, serum and plasma samples. Twenty (20) whole blood, 20 serum and 20 plasma paired samples collected from healthy donors were spiked with the inactivated virus at the previously confirmed

LoD (1.0×10^4 PFU/mL). The FilmArray NGDS BT-E Assay correctly identified 100% (20/20) for both instruments for all three specimen types tested. The Cp values in all sample sets were consistent with the expected values for the spiking concentrations used, which confirmed the inactivated virus LoD (Table 14).

Table 14. FilmArray 2.0 Contrived Clinical Testing Summary

Strain	Sample Type	Detected/Total		Average Cp	
		FilmArray	FilmArray 2.0	FilmArray	FilmArray 2.0
Ebola Zaire	Blood	20/20	20/20	20.1	19.9
	Serum	20/20	20/20	19.8	18.4
	Plasma	20/20	20/20	20.1	19.1

A total of 133 FilmArray runs were initiated for the testing of 132 contrived clinical samples in this evaluation. Of those tested, 125 runs were successful with no failures (94.7%). Five of the failed runs occurred on the FilmArray instrument, and three occurred on the FilmArray 2.0 instrument. On the FilmArray instrument, four failures were due to instrument errors and one was the result of an internal control failure. Testing on the FilmArray 2.0 system produced two instrument errors and one internal control failure (Table 15).

Table 15. Breakdown of Run Failures by Instrument

	FilmArray	FilmArray 2.0
Total Runs Initiated	67	66
Total Runs Completed	63 (94.0%)	64 (97.0%)
Instrument Errors	4 (6.0%)	2 (3.0%)
Control Failures (Run Completed)	1 (1.5%)	1 (1.5%)

In conclusion, the previously established LoD for the NGDS BT-E assay was confirmed for whole blood, serum and plasma on both the FilmArray and FilmArray 2.0 instruments, indicating that the performance of the NGDS BT-E Assay is equivalent on the FilmArray and the FilmArray 2.0.

Points of Contact

Contact information for technical assistance for the FilmArray NGDS BT-E Assay:

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Health care providers will be contacted by the DOD's Joint Project Management Office, Medical Countermeasures System (MCS) in the event of any significant new findings observed during the course of the emergency use of the FilmArray NGDS BT-E Assay.

Any adverse events should be sent to the following website:

http://biofiredefense.com/support/filmarray-support/ngds_bt-e_assay_report/

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