

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the BioFire Defense FilmArray BioThreat-E test.

Testing should be conducted on specimens from people with signs and symptoms of Ebola virus disease (EVD) and with epidemiological risk factors. If Ebola is suspected based on current clinical and/or epidemiological screening criteria **AND** testing is recommended by Centers for Disease Control and Prevention (CDC) and state and local public health authorities the FilmArray BioThreat-E test should be ordered only to presumptively diagnose EVD. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of EVD. All information and guidance, including for Ebola virus laboratory testing, may change as more data is gathered on this virus. Please check the CDC's Ebola virus website (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

All patients whose specimens are tested with this assay should receive the Fact Sheet for Patients: FilmArray BioThreat-E

What are the symptoms of EVD?

Most patients with EVD develop fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, abdominal pain, and lack of appetite. Some cases also have a rash, conjunctival hemorrhage, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or other unexplained hemorrhage. Signs and symptoms may appear any time from 2 to 21 days after exposure to Ebola virus, although an incubation period of 8-10 days is typical.

Public health officials have determined that Ebola virus has the potential to spread to the United States and pose risks for the public health. The first imported case in the U.S. was identified on September 30, 2014. All EVD cases confirmed as of September 2014 have been directly or indirectly linked through residence in or travel

This test should be performed only on individuals with signs and symptoms of EVD and/or with epidemiological risk factors AND testing is recommended by CDC and state and local public health authorities.

to African countries that are involved in Ebola virus epidemics.

What do I need to know about Ebola virus testing?

Current information on EVD for healthcare providers, including case definitions and infection control, is available at CDC's website, *Information for Healthcare Workers* (see links provided in "Where can I go for updates and more information" section).

- The FilmArray BioThreat-E can be used to test whole blood and urine. Whole blood specimens are considered a priority for collection and testing. Urine specimens should be tested in conjunction with a patient-matched whole blood specimen.
- The FilmArray BioThreat-E should be ordered for the presumptive detection of Ebola virus (species *Zaire ebolavirus* in individuals with signs and symptoms of EVD in conjunction with epidemiological risk factors (including geographic locations with high prevalence of EVD) AND testing is recommended by the CDC and state and local public health authorities.
- The FilmArray BioThreat-E is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests and by laboratories certified under CLIA to perform high complexity tests and by clinical laboratory personnel that have been appropriately trained.

Specimens should be collected with appropriate infection control precautions for Ebola viruses following CDC guidance for case investigation and specimen collection and according to the manufacturer's instructions for the specimen collection device, handling, and storage.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with Ebola virus. These specimens should be shipped for analysis only to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform moderate complexity and high complexity tests or to similarly qualified non-U.S. laboratories. For additional information, refer to CDC *Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing* (see links provided in “Where can I go for updates and more information” section).

What does it mean if the specimen tests positive for Ebola virus?

A positive test result for Ebola virus indicates that RNA from Ebola virus was detected, and the patient is presumptively infected with Ebola virus (species *Zaire ebolavirus*) and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The FilmArray BioThreat-E test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for quarantine of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially EVD infected patients, the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the recommended standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for Ebola virus?

A negative test result for this test means that Ebola virus RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out

EVD and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of EVD.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient’s recent exposures and the presence of clinical signs and symptoms consistent with EVD. The possibility of a false negative result should especially be considered if the patient’s recent exposures or clinical presentation indicate that EVD is likely, and diagnostic tests for other causes of illness (e.g., other hemorrhagic illness) are negative. If EVD is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of treatment, stopping treatment too soon, lack of monitoring of household or other close contacts for symptoms resulting in increased risk of spread of EVD within the community, or other unintended adverse events.

What is an EUA?

The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the use of in vitro diagnostic devices (IVDs) under EUA for the detection of Ebola virus.

An IVD made available under an EUA has not undergone the full validation of an FDA-approved or cleared IVD. However, based on the totality of scientific evidence, it is reasonable to believe that this IVD may be effective in the detection of Ebola virus, in the absence of an FDA-approved or cleared alternative.

The EUA for this test is in effect for the duration of the Ebola emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

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Where can I go for updates and more information?

CDC websites:

General: <https://www.cdc.gov/vhf/ebola/index.html>

Information for Healthcare Workers:

<https://www.cdc.gov/vhf/abroad/healthcare-workers.html>

For Clinicians:

<https://www.cdc.gov/vhf/ebola/clinicians/index.html> **Lab Guidance:**

<https://www.cdc.gov/vhf/ebola/laboratory-personnel/index.html>

Specimen Collection: <https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html>

FDA websites:

EUAs:(includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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For Technical Assistance: E-Mail: support@biofiredefense.com

Report Adverse Events: <https://www.biofiredefense.com/product-support/filmarray-support/biothreat-e-adverse-reporting-form/>

Any significant new findings that negatively impact the performance of the test will be made available at www.BioFireDefense.com