

You are being given this Fact Sheet because your sample(s) were tested for Ebola virus disease (EVD) using the Biofire Defense FilmArray BioThreat-E. Testing was done because your healthcare provider believes you may have been exposed to Ebola virus.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of EVD. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

- **Ebola virus can spread from person-to-person by contact with blood and body fluids (e.g., saliva, sweat, urine, semen, feces or vomit) from an infected person(s).**
- **Ebola virus can spread by handling objects (like needles and syringes) that have been contaminated with Ebola virus.**
- **Ebola virus may be spread as a result of handling bushmeat (wild animals hunted for food) and/or contact with infected bats collected from or within areas of known local Ebola virus transmission (e.g., Uganda, Democratic Republic of the Congo, Gabon).**
- **Ebola virus *only* spreads to others when a person shows signs or symptoms of being sick (e.g., fever, diarrhea, vomiting, etc.).**

What is Ebola virus disease (EVD)?

EVD is caused by the Ebola virus. Ebola virus infection is a severe, often-fatal disease in humans that has appeared sporadically since it was first recognized in 1976.

What is the FilmArray BioThreat-E test?

The test is designed to detect Ebola virus in blood and urine samples.

Why was my sample tested?

Your sample(s) were tested because your healthcare provider believes you may have been exposed to Ebola virus based on your signs and symptoms, and because:

- You live in or have recently traveled to a place where EVD is known to occur, and/or
- Because you have another possible exposure to Ebola virus.

Typical signs and symptoms of EVD include fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and lack of appetite. Some patients may also develop a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or unexplained bleeding inside and outside of the body.

The sample(s) collected from you were tested to help find out whether you may be infected with Ebola virus.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Where can I go for updates and more information? The most up-to-date information on Ebola virus and EVD is available at the CDC General website: <https://www.cdc.gov/vhf/ebola/index.html>. In addition, please also contact your healthcare provider [with any questions/concerns.](#)

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

The results of this test may help limit the spread of Ebola virus to your family and others in your community.

What does it mean if I have a positive Ebola test result?

If you have a positive test result, it is very likely that you are infected with Ebola virus. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

What does it mean if I have a negative test result?

A negative test result means that Ebola virus was not found in your sample. For Ebola virus, a negative test result for a sample collected while a person has symptoms usually means that Ebola virus did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with EVD, meaning you could possibly still have an infection with Ebola virus even though the test is negative. Therefore, while a negative test most likely means you do not have EVD, your healthcare provider must consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to treat you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States (U.S.) FDA. An FDA approved or cleared test should be used, when applicable and available. Instead, FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). This EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of diagnostic tests under EUA for the detection of Ebola virus. This EUA will remain in effect (meaning this test can be used) for the duration of the Ebola emergency, unless it is terminated or revoked by HHS or FDA (after which the test may no longer be used).

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