

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the DPP® Ebola Antigen System.

Testing should be conducted on specimens from people with signs and symptoms of Ebola virus disease (EVD) and with epidemiological risk factors. 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 "How can I learn more" section) regularly for the most current information.

This test is intended for circumstances when use of a rapid Ebola antigen test is determined to be more appropriate than use of an Ebola nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola virus.

All patients whose specimens are tested with this assay should receive the Fact Sheet for Patients: DPP Ebola Antigen System.

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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- **This test should be performed only on individuals with signs and symptoms of Ebola virus disease (EVD) and with epidemiological risk factors.**
 - **This test is not intended for use for general Ebola virus infection screening, such as airport screening or contact tracing of individuals without signs and symptoms.**
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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 in the guideline, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the CDC in conjunction with the World Health Organization (WHO) (see links provided in "How can I learn more" section).

- The DPP Ebola Antigen System can be used to test capillary "fingerstick" whole blood, EDTA venous whole blood, and EDTA plasma.
- The DPP Ebola Antigen System should be ordered for the presumptive detection of Ebola virus (species *Zaire ebolavirus* and hereafter referred to as Ebola virus) in individuals with signs and symptoms of EVD in conjunction with epidemiological risk factors (including geographic locations with high prevalence of EVD).
- The DPP Ebola Antigen System is authorized for use in laboratories or facilities adequately equipped, trained and capable of such testing (including treatment centers and public health clinics).

Specimens should be collected with appropriate infection control precautions and according to the manufacturer's instructions for the specimen collection device, handling, and storage.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with Ebola virus. The test is

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**

only authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics). For additional information, refer to CDC *Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing* (see links provided in “How can I learn more” section).

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

A positive test result for Ebola virus indicates that the patient is presumptively infected with Ebola virus. The test does not indicate the stage of infection, nor does it distinguish between different Ebola virus species. Laboratory test results should always be considered in the context of clinical observations, epidemiological data, and travel history in making a final diagnosis and patient management decisions.

The DPP Ebola Antigen System has been designed to minimize the likelihood of false positive test results. Cross-reactivity of any of the components of this test resulting in false positive results is not expected. However, in the event of a false positive result, risks to patients could include the following: isolation or contact with other potentially infected patients and delayed diagnosis and treatment of alternative sources of infections.

All laboratories using this test must follow the recommended standard confirmatory testing and reporting guidelines. Patient management should follow current CDC guidelines.

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

A negative test result for this test means that Ebola virus 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 are negative.

How can I learn more?

CDC websites:

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

Healthcare Providers:

<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/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>

Manufacturer: Chembio Diagnostic Systems, Inc.

3661 Horseblock Road, Medford, NY 11763

Phone: 1.844-CHEMBIO (243-6246)

For Technical Assistance: E-Mail: info@chembio.com

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

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