

Update #5 on Ebola Virus Disease (EVD)

Monday November 3, 2014

Target audience: Clinical laboratories

Emergency Use Authorization for Ebola Zaire testing using Biofire FilmArray and Options for Malaria testing

This is a rapidly evolving situation. This document is based on currently available information. Updates will be provided as additional information becomes available.

Biofire FilmArray BioThreat-E

Recently, the Biofire Defense “FilmArray Biothreat E-Test” received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) to test for the presumptive presence of Ebola Zaire virus in whole blood or undiluted urine specimens. This test is authorized for use only from individuals with signs and symptoms of EVD in conjunction with epidemiological risk factors. Previously, EVD diagnostic testing was only available in MI at MDCH BOL, utilizing a Department of Defense PCR assay or through CDC.

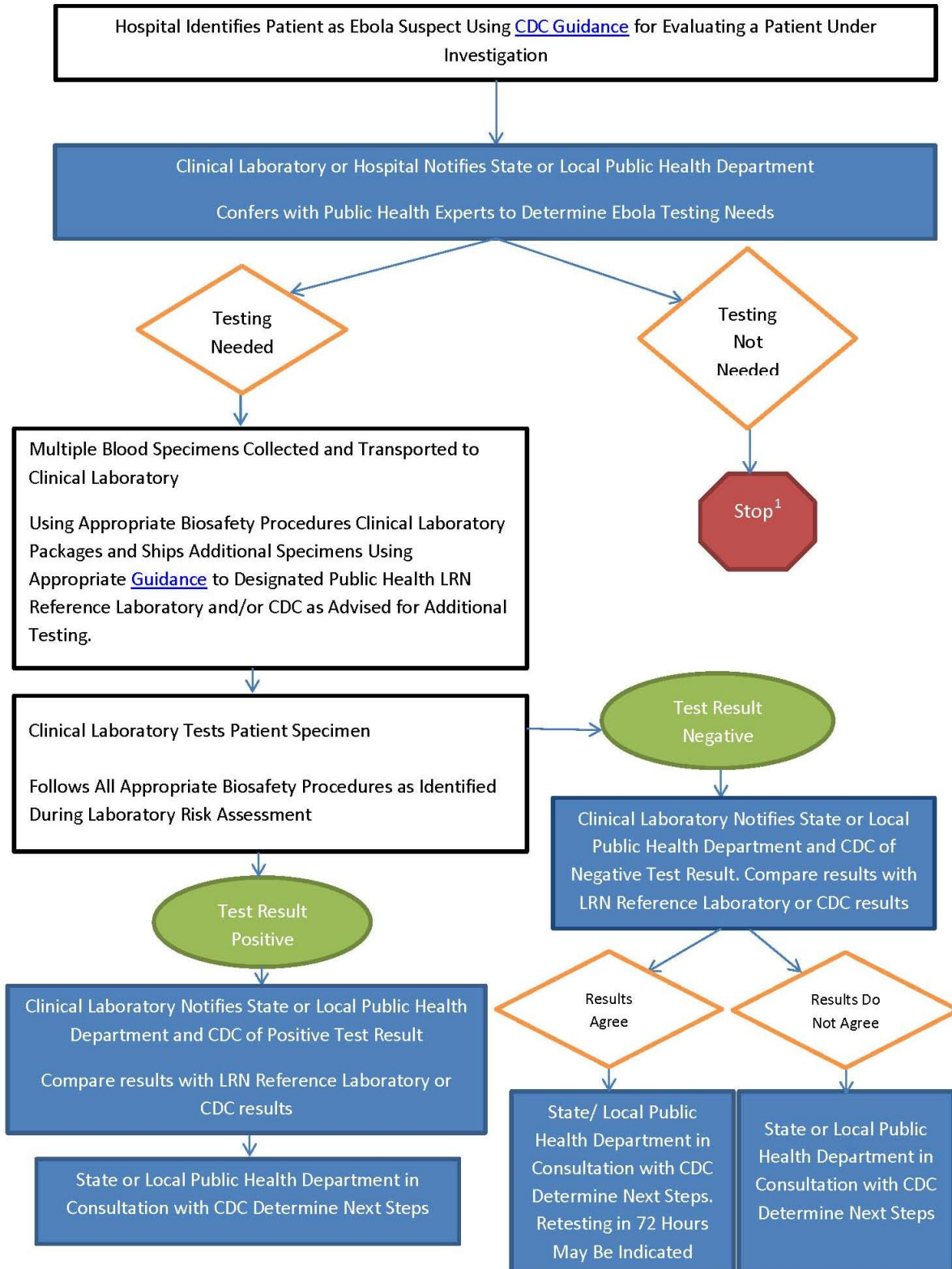
Clinical laboratories that elect to implement the FilmArray Biothreat-E assay in their laboratory should consider the following points:

- Consultation with state and local Public Health partners both before and after testing is required.
- Laboratories must be certified by CLIA to perform moderately complex or highly complex tests.
- Perform a biosafety risk assessment prior to implementing test in the laboratory.
- Verification of performance characteristics of the assay in your laboratory is required by CLIA.
- Test should not be performed on asymptomatic patients.
- Test results of this assay are presumptive.
- Manufacturer states that positive test results MUST be confirmed in collaboration with state public health laboratory and/or CDC.
- A negative test result does not rule out the absence of EVD. CDC and the Association for Public Health Laboratories (APHL) suggest all testing be confirmed by your state public health laboratory and/or CDC.
- Review the attached algorithm for guidance when implementing this test in your laboratory.

A link to the attached document is available on APHL’s website:

<http://www.aphl.org/aphlprograms/preparedness-and-response/Documents/APHL-Guidance-for-Clinical-Laboratories-Using-FDA-Authorized-Assays-for-Ebola.pdf>

Guidance for Clinical Laboratories Using FDA Authorized Diagnostic Assays for Ebola Virus Detection



Malaria testing

MDCH has received multiple questions about malaria testing. On request, the laboratory will perform PCR testing for malaria in conjunction with EVD testing on a blood specimen authorized by CDC for EVD testing. The laboratory will continue to offer malaria PCR for all other patients when the blood specimen is accompanied by stained thick and thin blood films.

Several clinical laboratories have elected to utilize a point of care rapid test for malaria. Binax NOW Malaria is the only FDA approved rapid test available in the United States. Clinical laboratories that plan to implement rapid malaria testing should consider the following points:

- Testing is performed on venous or capillary EDTA whole blood.
- The test differentiates *Plasmodium falciparum* from other malarial infections. The test does not distinguish between *P. vivax*, *P. ovale*, and *P. malariae*.
- Negative test results are considered presumptive and should be confirmed by thin/thick smears. The CDC recommends that all test results be confirmed by microscopy. For additional information refer to: http://www.cdc.gov/malaria/diagnosis_treatment/rdt.html
- Blood specimens positive for rheumatoid factor may cause false-positive results.
- The assay performs well when the level of parasitemia is high, but sensitivity diminishes as the level of parasitemia decreases.
- Because of the potential for false-negative results in samples with low levels of parasitemia, the use of serial blood samples collected over a 24 to 48 hour time period should be considered (see Murray, C.K. *et.al*, 2008. Clin. Micro.Rev. 21:97-107).
- The test requires a laboratory validation and competency assessment prior to implementation.
- A risk assessment for point of care or in-laboratory testing should be performed prior to purchasing the test system.

Steps for laboratories to take now

Please review and share this information with others in your facility.

Further Information

More information is available at the following:

Under "What's New" on the MDCH BOL website: <http://www.michigan.gov/mdchlab>

MDCH EVD website: <http://www.michigan.gov/ebola>

CDC EVD website at: <http://www.cdc.gov/vhf/ebola/index.html>

Questions

For laboratory related questions, please contact:

Dr. Janice Matthews – Greer, MDCH BOL Virology Section Manager

MatthewsGreerJ@michigan.gov (517) 335-8099

Dr. James Rudrik, Director, MDCH BOL Division of Infectious Diseases

RudrikJ@michigan.gov (517) 335-8063