Testing Algorithm for Florida Laboratories Using BioFire Diagnostics Ebola Assay

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Introduction

The 2014 Ebola Zaire epidemic is the largest the world has ever seen and has crossed US borders causing widespread concern and declaration of a Public Health Emergency. The laboratory community has been actively engaged in responding to testing and biosafety concerns. Until last week, the assays that have received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) were available only at select state or local public health Laboratory Response Network (LRN) Reference Laboratories and the Centers for Disease Control and Prevention (CDC). On October 25 2014 the BioFire Diagnostics FilmArray Biothreat-E Panel with an Ebola virus test was given an FDA Emergency Use Authorization (EUA).

Clinical laboratories that are considering implementation of this assay must remember the importance of connecting with Public Health authorities whenever Ebola Virus Disease is suspected and consider the risk/benefit of implementing this assay in their laboratory. Clinical laboratories must consult with state or local Public Health partners both prior to testing and after testing to report results (both negative and positive) and determine next steps.

Please refer to the APHL Guidance for Clinical Laboratories Using FDA Authorized Diagnostic Assays for Ebola Virus Detection for important considerations regarding implementation of Ebola testing in your laboratory

Additional Resources

APHL

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

BioFire Testing

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

Patient Evaluation

- Decision Algorithm to Assist with Identifying Testing and Monitoring of Patients with Suspected Ebola Virus Disease (EVD)
  http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html

Packaging and Shipping

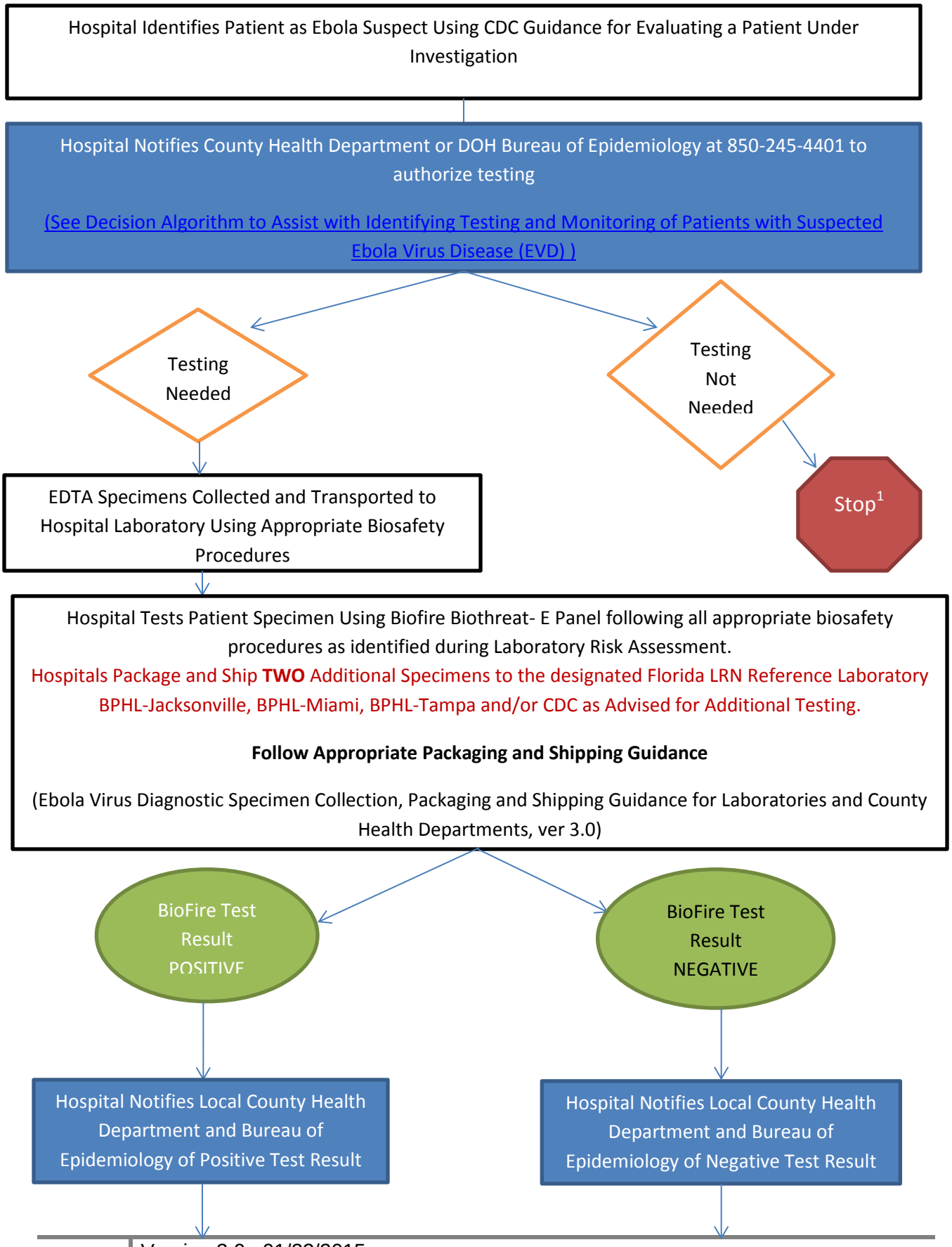
- Interim Guidance for Specimen Collection, Transport, Testing and Submission
- http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html
  http://www.cdc.gov/vhf/ebola/pdf/ebola-lab-guidance.pdf
- Packaging and Shipping eLearning Course
  http://www.cdc.gov/labtraining/course_listing/packing_shipping.html

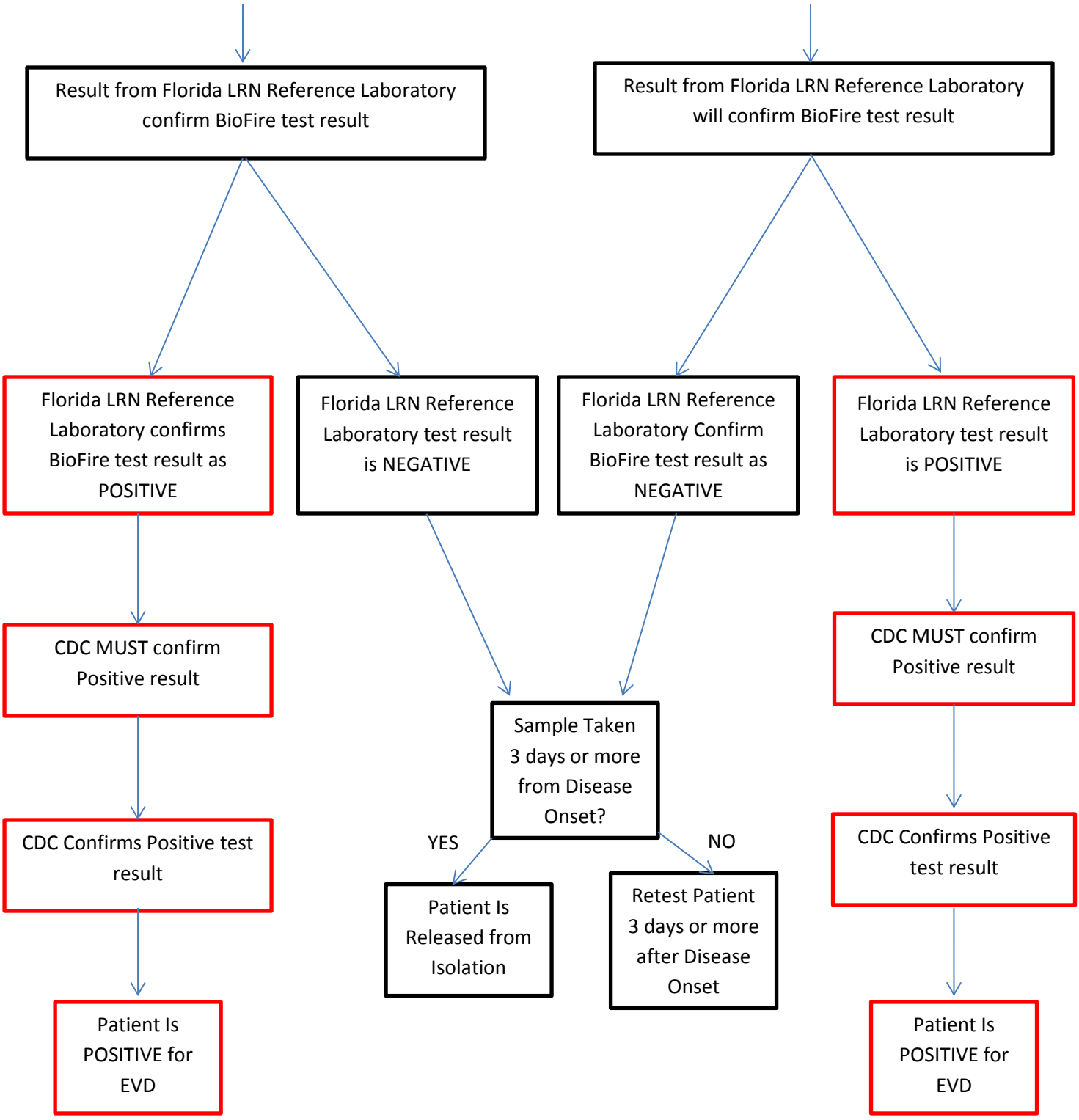
Personal Protective Equipment (PPE)

Guidance on PPE

http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html

http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html


Hospital Identifies Patient as Ebola Suspect Using CDC Guidance for Evaluating a Patient Under Investigation
Hospital Notifies County Health Department or DOH Bureau of Epidemiology at 850-245-4401 to authorize testing
(See Decision Algorithm to Assist with Identifying Testing and Monitoring of Patients with Suspected Ebola Virus Disease (EVD))
Testing Needed
Testing Not Needed
Stop[1]
EDTA Specimens Collected and Transported to Hospital Laboratory Using Appropriate Biosafety Procedures
Hospital Tests Patient Specimen Using Biofire Biothreat- E Panel following all appropriate biosafety procedures as identified during Laboratory Risk Assessment.
Hospitals Package and Ship TWO Additional Specimens to the designated Florida LRN Reference Laboratory BPHL-Jacksonville, BPHL-Miami, BPHL-Tampa and/or CDC as Advised for Additional Testing.
Follow Appropriate Packaging and Shipping Guidance
(Ebola Virus Diagnostic Specimen Collection, Packaging and Shipping Guidance for Laboratories and County Health Departments, ver 3.0)
BioFire Test Result POSITIVE
BioFire Test Result NEGATIVE
Hospital Notifies Local County Health Department and Bureau of Epidemiology of Positive Test Result
Hospital Notifies Local County Health Department and Bureau of Epidemiology of Negative Test Result


Result from Florida LRN Reference Laboratory confirm BioFire test result
Result from Florida LRN Reference Laboratory will confirm BioFire test result
Florida LRN Reference Laboratory confirms BioFire test result as POSITIVE
Florida LRN Reference Laboratory test result is NEGATIVE
Florida LRN Reference Laboratory Confirm BioFire test result as NEGATIVE
Florida LRN Reference Laboratory test result is POSITIVE
CDC MUST confirm Positive result
CDC MUST confirm Positive result
Sample Taken 3 days or more from Disease Onset?
YES
NO
CDC Confirms Positive test result
CDC Confirms Positive test result
Patient Is Released from Isolation
Retest Patient 3 days or more after Disease Onset
Patient Is POSITIVE for EVD
Patient Is POSITIVE for EVD

[1]Information on Testing When Public Health Officials Determine It Is Not Indicated

Testing performed on individuals who do not meet the intended use criteria as defined in FDA labeling or without consultation with public health is not advisable and carries inherent risk.

- Testing outside the approved parameters of the EUA is considered to be a test modification and the laboratory performing the testing is responsible for establishing and assuring the safety and efficacy of the test in the patient population being tested (e.g. asymptomatic individuals).
- A positive result in a patient who is at low risk for EVD may be a false positive and can cause undue public health concern.
- Patients without symptoms but with risk factors for EVD who are tested outside the recommended parameters of the assay may be overly assured by a negative result and not comply with federal or state Movement and Monitoring requirements or seek medical care if symptoms develop.
- Individuals with a travel history to West Africa may be at risk for other infectious diseases including malaria and other viral hemorrhagic diseases (Lassa Fever, Marburg). All risk factors must be assessed and testing for other conditions should be considered.