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)
Packaging and Shipping
- Interim Guidance for Specimen Collection, Transport, Testing and Submission
- Packaging and Shipping eLearning Course
  http://www.cdc.gov/labtraining/course_listing/packing_shipping.html
Personal Protective Equipment (PPE)
Guidance on PPE
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**

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**

Hospital Notifies Local County Health Department and Bureau of Epidemiology of Positive Test Result

**BioFire Test Result NEGATIVE**

Hospital Notifies Local County Health Department and Bureau of Epidemiology of Negative Test Result

Stop
Result from Florida LRN Reference Laboratory confirm BioFire test result

Florida LRN Reference Laboratory confirms BioFire test result as POSITIVE

CDC MUST confirm Positive result

CDC Confirms Positive test result

Patient Is POSITIVE for EVD

Florida LRN Reference Laboratory test result is NEGATIVE

Sample Taken 3 days or more from Disease Onset?

YES

Patient Is Released from Isolation

NO

Retest Patient 3 days or more after Disease Onset

Florida LRN Reference Laboratory Confirm BioFire test result as NEGATIVE

Florida LRN Reference Laboratory test result is POSITIVE

CDC MUST confirm Positive result

CDC Confirms Positive test result

Patient Is POSITIVE for EVD
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.