Ebola Testing @ DSHS BioThreat Team

Lab Director’s

October 21, 2014
Overview

- Procedure: FDA EUA Assay

- Timeline
  - Setup and EQA Panel
  - Coordination with EPIs, submission process
  - Results to date
  - Surge capacity

- Packaging and Shipping
Procedure

- FDA EUA Assay
  - Blood or plasma acceptable
  - Blood preferred, EDTA tube, 4°C
  - QIAagen QIamp Viral RNA Extraction Kit
  - rRT-PCR on ABI 7500 Fast Dx

- Presumptive positive or negative result
  - Patient Fact Sheet
  - Physician Fact Sheet
  - Confirmed at CDC
BioThreat Lab @ DSHS

- Biosafety Level 3 (BSL3) Laboratory

- Special considerations
  - Isolated zone with limited access
  - Double door entry with multiple barriers
  - Filtered unidirectional single pass air
  - Work performed within biosafety cabinet
  - Personal Protective Equipment worn
    - PAPR, double gloves, Tyvek suit, booties
  - All materials autoclaved before removal
  - Security clearance required
BSL3 Lab Pics
Emerging diseases: Ebola Testing

- August 5 – FDA granted Emergency Use Authorization status for assay
- August 7 – DSHS given Request to Accept Ebola Virus Testing Assay
- August 12 – received testing kit
- August 19 – tested EQA panel (5 samples)
- August 22 – received EQA pass
- August 26 – go live date
Texas DSHS Ebola Testing Algorithm

- General Ebola Information
- Patient Evaluation
- Case Definition
- Infection Prevention Guidance
- Laboratory Information
- Sample collection and transport
- Shipping
- Symptoms
  - Fever (greater than 38.6°C or 101.5°F)
  - Severe headache
  - Muscle pain
  - Weakness
  - Diarrhea
  - Vomiting
  - Abdominal (stomach) pain
  - Unexplained hemorrhage (bleeding or bruising)

Suspected Ebola patient

Procedural questions

Contact Local Health Department

Contact DSHS EAI DB

- EPI screening criteria met
  - Consult with CDC on case
  - CDC screening criteria met
  - Submitter will be provided with sample submission instructions and shipping guidance
  - No further action will be taken

- EPI screening criteria not met
  - Re-evaluate in 24 hours
    - EPI screening criteria met
      - Consult with CDC on case
      - CDC screening criteria met
      - Submitter will be provided with sample submission instructions and shipping guidance
      - No further action will be taken
    - EPI screening criteria not met
      - No further action will be taken

Find your Local Health Department:
http://www.dshs.state.tx.us/idcu/investigation/conditions/contacts/
**Ebola Testing**

- **September 30** – first specimen received
- **Presumptive positive by rRT-PCR for Ebola Zaire**

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Surge Capacity

- 5 Staff 10.16.14
- Refresher BSL3
- Ebola Safety
Packaging and Shipping

- Category A, shipped cold (4°C)

- Available methods:
  - FedEx
    - “Suspected Category A” Shippers Declaration
    - Will not accept if marked “Ebola”
  - World Courier
    - “Suspected Category A” Shippers Declaration

- Alternative methods:
  - Coast Guard helicopter
  - DOT plane
  - DSHS employees
Thank you!

Questions?

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