



Ebola Testing @ DSHS BioThreat Team

TX LRN Conference

February 25, 2015

Overview

- Procedure: FDA EUA Assay
- Timeline
 - Setup and preparations
 - Coordination with EPIs, submission process
 - Testing EQA Panel
 - Surge capacity
 - Results to date
- Packaging and Shipping
- Post Outbreak planning/recovery

Emerging diseases: Ebola Testing



- August 5 – FDA granted Emergency Use Authorization status for assay
- August 6 – LRN sent notification of DoD assay
- August 7 – DSHS given Request to Accept Ebola Virus Testing Assay
- August 12- received testing kit
- August 13- received EQA panel

Procedure

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

- Presumptive positive or negative result
 - Patient Fact Sheet
 - Physician Fact Sheet
 - Positives must be confirmed at CDC



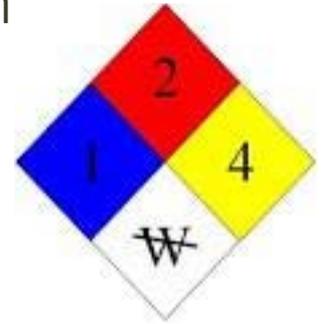
Preparation

- Multiple DoD/LRN Technical Conference Calls
- APHL template for Risk Assessment
 - Reviewed by Safety Officer, management, team
 - Testing to occur in BSL3 in PAPR
- Multiple Planning Meetings
 - Lab leadership, BioThreat and EPIs
 - CDC notification and consultation required
- Devoted RNA items
 - Calibrated second set of pipettes



Preparation

- Administrative items:
 - DSHS SOP from DoD
 - Bench aids: flowchart, sample tracking sheet
 - Updated lab signage: doors and decon
 - Safety concerns
 - Chemical incompatibilities
- Enhanced Medical Surveillance Program
 - Disease symptoms added to visitor training
 - Medical Alert wallet cards
- Safety officer evaluation and walk-through
- Created test in LIMS for reporting to submitter



Emerging diseases: Ebola Testing



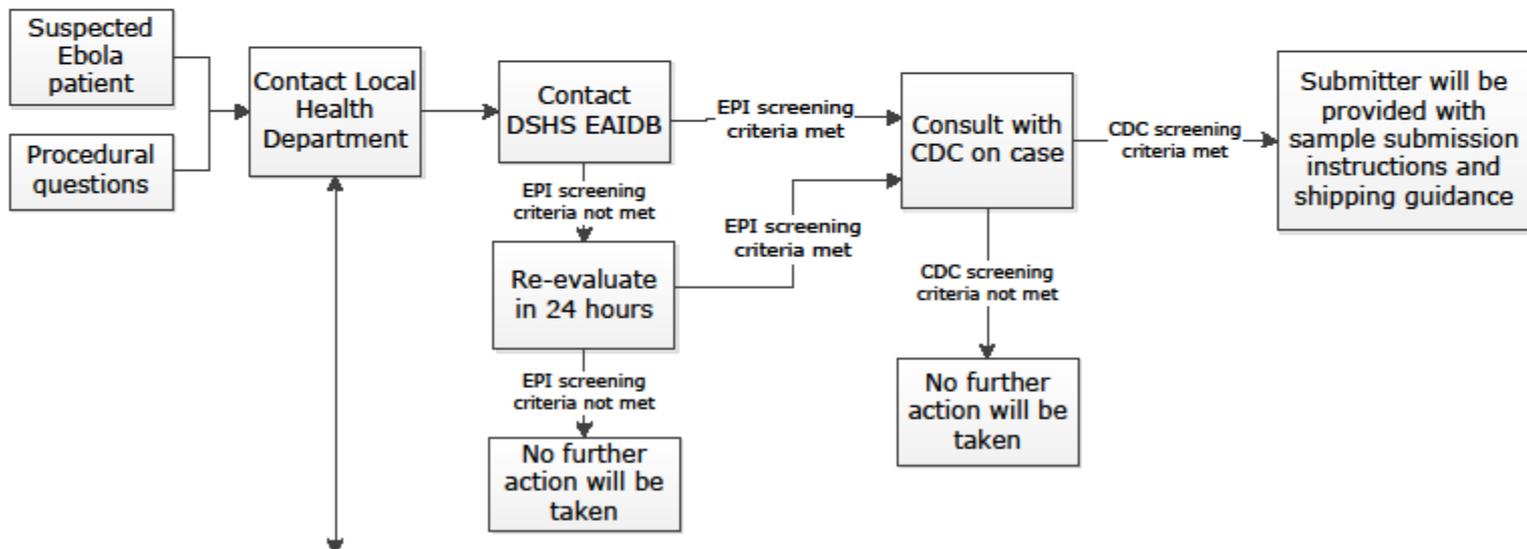
- August 7 – DSHS given Request to Accept Ebola Virus Testing Assay
- August 12/13 - received testing kit and EQA panel
- August 19 – tested EQA panel (5 samples)
- August 22 – received EQA pass
 - Served as Validation Study
- August 26 – final leadership/EPI meeting
- August 26 – go live date
- September 2 – Trained BioThreat team



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)

CDC Website <http://www.cdc.gov/vhf/ebola/>



Find your Local Health Department:
<http://www.dshs.state.tx.us/idcu/investigation/conditions/contacts/>



Team Training Sept 2, 2015





Ebola Testing

- September 29 – received notice of first sample
- September 30
 - First specimen received via FedEx
 - Duplicate samples sent to TDSHS and CDC
 - **Presumptive positive by rRT-PCR for Ebola Zaire**
 - Results confirmed by CDC within an hour

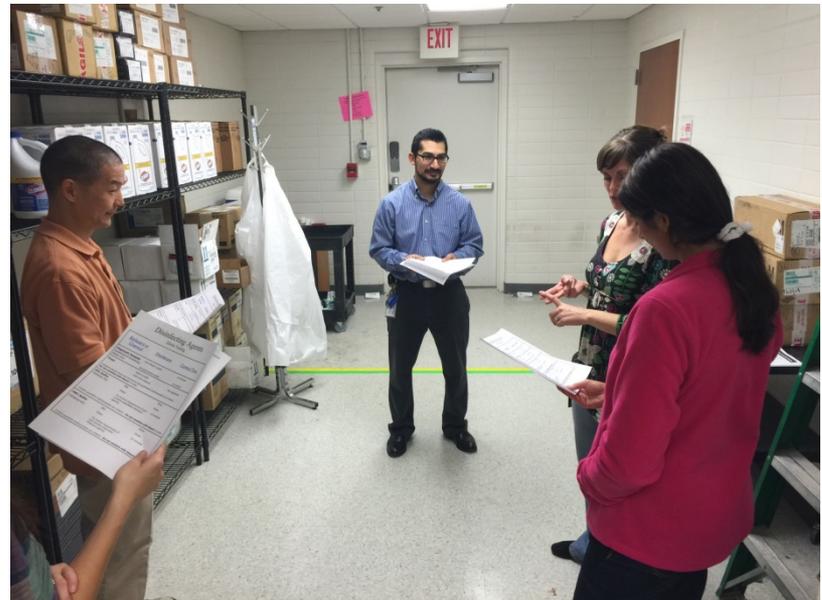
Ebola Testing Timeline



Sunday	Monday	Tuesday	Tuesday	Thursday	Friday	Saturday
		(Sept 30) +	1	2 —	3	4
5	6 —	7	8	9 —	10 —	11 +
12 — —	13 — —	14 + —	15 —	16 — —	17	18 —
19 —	20	21	22	23	24 —	25
26	27	28	29	30	31	(Nov 18) —

Surge Capacity

- 5 Staff 10.16.14
- Refresher BSL3
- Ebola Safety



Sample Delivery

- Packaging and Shipping classification
 - Infectious substance affecting humans
 - Category A
 - Shipped cold (4 C)
 - Will not accept if marked "Ebola"
- All clinical laboratories should have staff certified to package and ship biological materials
- Courier deliveries utilized
- Available methods:
 - FedEx
 - World Courier



Barriers Encountered

- <12 hour rest between samples
- Approval process changing constantly
 - Testing patients who didn't fit initial symptom criteria
 - Fever temperature 101.5 lowered to 100.5 in October
 - Caused communication issues
- Shortage of PPE
- Keeping up with testing, ensuring adequate testing supplies and reagents, shipping recommendations, meetings, conference calls, responding to public and submitter questions



Sample Statistics

- Patients Under Investigation
 - Over 54 individuals evaluated by TDSHS
 - 19 total tests performed on 16 individuals
 - Some evaluated at local HD level and CDC
- Average testing turn around time: 4:16
- Lab testing hours accumulated:
 - 380 regular hours
 - 114 overtime hours
 - >10 hours/day fourteen times
- Travelers from West Africa Monitored by TDSHS: 312

Outcomes

- Medical Surveillance enhanced further
 - Temperature monitoring 21 days post + sample, 2x daily
- Can ship Category A packages 24/7/365
 - Keep cold Cat A shippers in lab
 - Added FedEx Software to lab computer
 - Setup World Courier Account
- >60 labs in the US can now test for Ebola
- TDSHS Ebola website: <http://www.texasebola.org/>
- Future plans will include provisions for:
 - Body disposal
 - Waste removal
 - Animal considerations
 - Monitoring incoming travelers



Outcomes



- Kudos
 - APHL website and blog
 - Lakey meet and greet, received medal
 - Recognized at DSHS meeting
 - Ebola Appreciation Award from DSHS
 - APHL PSA on Jumbotron in NYC