DESIGNATED TERTIARY HOSPITALS MEETING: 19 NOV 2014

LABORATORY ISSUES

Kirsten St. George

Wadsworth Center, NYSDOH

NYS/NYC Laboratory Guidelines for Handling Specimens from Patients with Suspected or Confirmed Ebola Virus Disease

- First issued August 11, 2014
  - Following numerous requests, discussions and conference calls with multiple SMEs including lab director at Emory
- Revision issued September 16, 2014
  - Following extensive discussions and evidence from literature and laboratory experience
- Revision issued November 12, 2014
  - Additional and more extensive guidance on PPE; malaria testing; specimen storage, decontamination and disposal; and the handling of regulated medical waste.
  - New risk group names/classifications
  - Guidance on the use of commercially available FDA-EUA-approved PCR Ebola assays by clinical laboratories

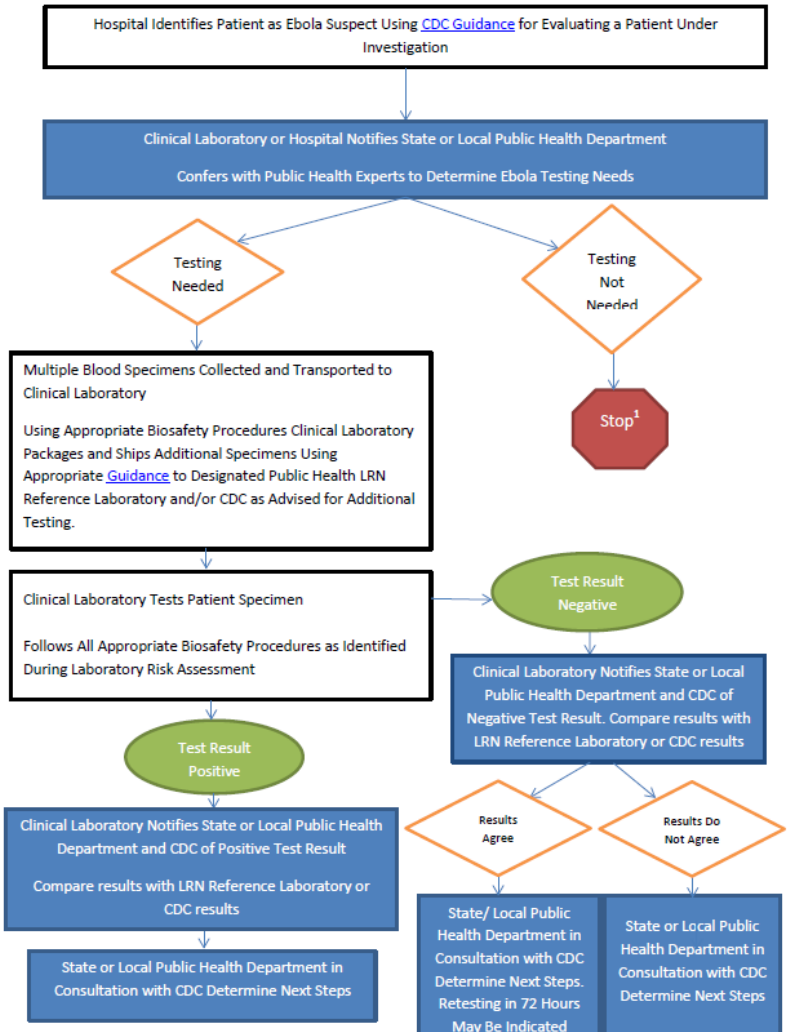
Molecular EVD testing with other FDA-approved devices

- FDA issued EUA approval for some commercially available EVD tests
- All carry provision that patient results obtained with them **not** be used for patient management decisions
- Must ensure concurrent and immediate submission of additional samples through the relevant health department for testing.

FDA 2014 Ebola Virus Emergency Use Authorizations

Diagnostic Test	Date	Sensitivity/LOD
RealStar® Ebolavirus RT-PCR Kit 1.0	11/10/14	1 PFU/ml
BioFire Defense LLC FilmArray Biothreat-E Test	10/25/14	600,000 PFU/ml
BioFire Defense LLC FilmArray NGDS BT-E Assay	10/25/14	
DoD EZ1 Real-time RT-PCR Assay	10/10/14	
CDC Ebola Virus NP Real-time RT-PCR Assay	10/10/14	5,000 PFU/ml
CDC Ebola Virus VP40 Real-time RT-PCR Assay	10/10/14	5,000 PFU/ml

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



Additional guidance on PPE

- Specimen collection
  - gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth. Additional PPE may be required in certain situations (http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html)
- Laboratory testing
  - gloves, fluid-resistant or impermeable gowns, masks to cover all of nose and mouth, eye protection such as full face shield or goggles
  - use of certified class II Biosafety cabinet (BSC2) or Plexiglass splash guard if BSC2 not available
  - if neither a BSC2 nor Plexiglass splash guard are available, laboratorians should wear all of the above and in addition, a full face shield
  - manufacturer-installed safety features for instruments, that reduce the likelihood of exposure

New guidance on malaria antigen testing

- Malaria antigen detection kits
  - assist with initial urgent assessment
  - inherently less sensitive than smear microscopy or PCR (one of which must be performed ASAP)
  - some inactivation/decontamination procedures adversely affect performance of some
- Thin blood smears
  - fix in methanol for 15-30 minutes and dried prior to staining
  - additional heat inactivation not necessary and can disrupt parasite morphology
- Thick blood films
  - should not be hemolysed with water
  - stain with Giemsa that includes Triton X-100 to inactivate Ebola virus.
- Validated malaria PCR assays that have been approved by the CLEP
- CDC recommendations:
- http://www.cdc.gov/malaria/new_info/2014/malaria_ebola.htm

Specimen storage

- Long term storage discouraged
  - exception - where retention is required by regulations
  - Isolate specimens collected from suspected or confirmed EVD cases from other specimens in the lab
  - Dispose of specimens as soon as practical after confirmation that:
    - No further testing needed on that sample
    - Samples are not needed for further evaluation by the PHL or CDC
    - Disposed of in an appropriate manner (below).
- Details of specimen decontamination and disposal should be documented for any samples from a confirmed EVD patient or a PUI of unknown status.
  - While CDC has agreed to not classify them as select agent samples unless they are EVD positive by culture, they reserve the right to request documented confirmation of destruction/disposal.

Specimen decontamination and disposal

- Wipe outside of specimen container with EPA-registered hospital disinfectant labeled for non-enveloped viruses
- The wipe and the disinfected specimen container then placed in a plastic bag and packaged for appropriate disposal or autoclaving
- A list of EPA-registered disinfectants can be found at: http://www.epa.gov/oppad001/list-l-ebola-virus.html
- Bleach or acidic chemicals **must NOT be mixed with TRIzol or any other reagent containing guanidine isothiocyanate, nor should they be disposed of together** in the same container

Handling of regulated medical waste

- RMW from the care of suspected or confirmed EVD patients sent off-site for treatment
  - packaging requirements described in the U.S. Department of Transportation (USDOT) emergency special permit.
  - Information on the USDOT emergency special permit can be found at: http://phmsa.dot.gov/hazmat/transporting-infectious-substances.
  - Facilities should confirm with the DEC that their transporter has approval under the USDOT emergency special permit to transport untreated EVD RMW. Contact DEC by phone at (202) 366-4535 or by email at Specialpermits@dot.gov.
- If EVD RMW will be treated on-site by autoclaving, autoclave facilities require approval from NYSDOH. See:
- http://www.health.ny.gov/diseases/communicable/ebola/docs/autoclave_guidelines.pdf
- Discharge of liquid waste from equipment that drains directly into the sewer is allowed, unless specifically prohibited by local law or ordinance.
- Additional CDC guidance on RMW:
- http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html
- http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

Packaging and Shipping

Jennifer L. Rakeman, PhD

NYC Public Health Laboratory

You need to have:

- Category A packaging – make sure it is current!
- Ice packs
- **Staff trained and certified in Packaging and Shipping**
- Plan to transport specimen from bedside to packaging site
- Procedure and plan for packaging specimens appropriately
- Test request forms: 1 for PHL/Wadsworth, 2 for CDC

Specimens for Initial Diagnosis

- Hospital staff collects and packages 2 specimens
  - One for testing at public health lab
  - One for shipping to CDC to confirm positive – PHL/Wadsworth will ship
- NYS (not NYC)
  - Use Critical Specimen Transport Protocol to transport to Wadsworth Center
- NYC
  - DOHMH will pick up specimens and deliver to NYC PHL

On-going care of patient with EVD

- **Additional testing performed at CDC:**
- Serology
- Viral load testing – reported as Ct value
- Culture

- **Specimens:**
- Blood
- Urine
- Remnant specimens

- Follow-up specimens post-discharge

Shipping specimens from a known EVD patient

- Specimens will need to be shipped to CDC for testing every few days -> every day
- Must use World Courier to ship
  - Category A
  - WHO class 4 pathogen
- NOT a Select Agent until cultured - CDC

Shipping with World Courier

- Create and account – can take several days to a week
- Get a contract to pay them
- They will provide Category A containers if needed (not free)
- Limits on total volume that can be shipped – may need to split shipments
- World Courier will want to see:
  - Documentation of certification of shipper
  - All paperwork
  - Photos of packed box…

BEFORE they come to pick up a package, every time

Shipping hints…

- **PLAN your shipments!**
  - This is not FedEx
  - Pick-up times are limited
  - Lots of up-front work
  - Prepare everything the day before when possible
- **Coordinate specimen collection, shipping time and receipt time at CDC**
  - Especially important as patient gets close to discharge and viral load testing is performed daily