Ebola PUI: Laboratory Testing & Biosafety Perspective

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DEPARTMENT OF GENERAL SERVICES
DIVISION OF CONSOLIDATED LABORATORY SERVICES
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DCLS

Objectives

- DCLS overview and Ebola Virus response
- Specimen collection – DCLS testing
- Specimen transport
- Specimen packaging & shipping
- Diagnostic laboratory testing

Division of Consolidated Laboratory Services (DCLS)

- Serves as the public health, environmental, agriculture, and consumer protection laboratory for the Commonwealth of Virginia.
- Serves hundreds of local, state, and federal agencies
- Perform >7 million tests annually with over 650 different types of analyses
- Test services include:
  - Microbiology, Mycology, Molecular Biology, Immunology/Virology, Newborn Screening
  - Radiochemistry, comprehensive chemical analyses, food, water, feed, fertilizer analyses
  - Metal/pesticide analyses, motor fuels and commodities analyses, laboratory certification
- Operate a statewide courier that provides routine and emergency transportation for specimens from over 200 locations to DCLS.
- Training and education (hospitals and partner agencies)

DCLS' LRN-Emergency Response Program

- Only Laboratory Response Network (LRN) Reference laboratory for the Commonwealth of Virginia.
- Prepare, identify, and respond 24/7/365 to any public health emergency concerning agents of bioterrorism or highly pathogenic, high consequence, or emerging infectious pathogens.
- Comprised of highly skilled scientists trained and competent to work in BSL-3 containment.
- Test methods include:
  - Nucleic acid extractions and Real-time PCR assays
  - Conventional, microbial assays
  - Immunoassays
  - Mouse bioassay

LRN Bio Testing at DCLS

Agent	Disease
Bacillus anthracis	Anthrax
Brucella spp.	Brucellosis
Francisella tularensis	Tularemia
Burkholderia mallei *Burkholderia pseudomallei*	Glanders Meliodiosis
Yersinia pestis	Plague
Coxiella burnetii	Q fever
Poxviruses	Smallpox, Vaccinia, Chickenpox
Ricin toxin	Ricin poisoning
C. Botulinum & toxins	Botulism

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

LRN –Bio Testing at DCLS
B. Anthracis
Brucella spp.
F. tularensis
B. mallei & pseudomallei
Y. Pestis
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Poxviruses
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2013 - Novel Coronavirus/ MERS

Ebola Virus Disease

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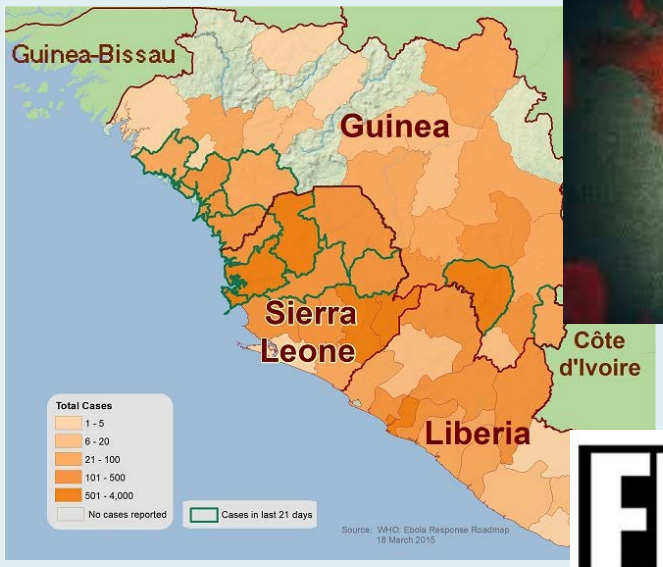
2013 - Novel Coronavirus/ MERS
2014 - Ebola Zaire Virus



Zika Virus

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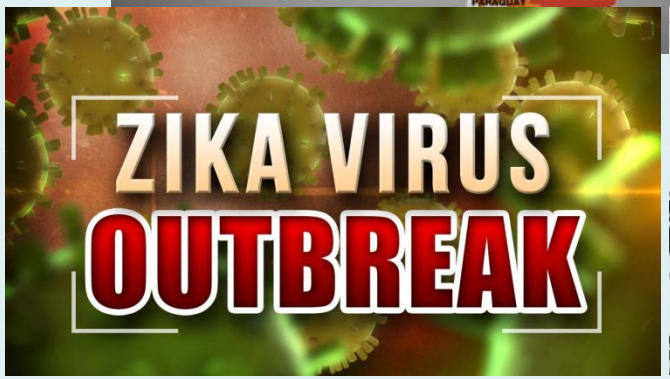
2016 - Zika Virus



DCLS' LRN-Emergency Response Program

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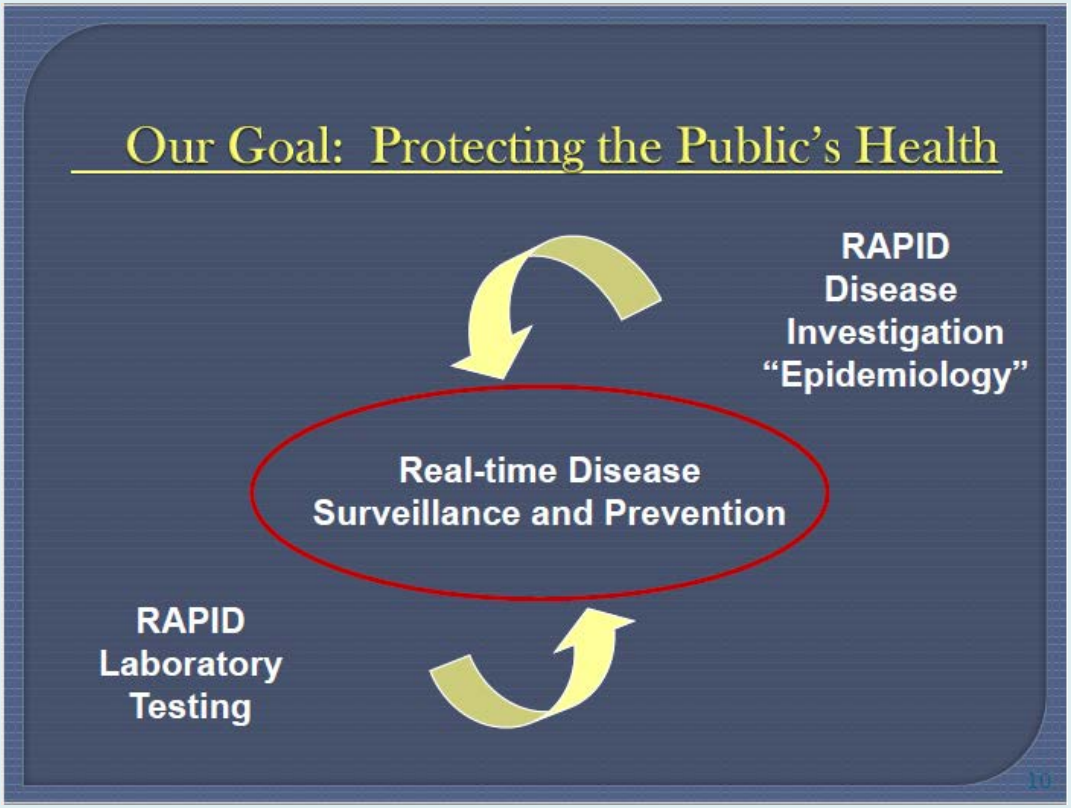


DCLS - Ebola Virus Response

Risk Mitigation - Enhanced PPE

Standard DCLS BSL-3 PPE:

- PAPR
- PAPR head cover
- Fluid-impervious, back closing gown
- shoe covers
- EC gloves (double while working in BSC)

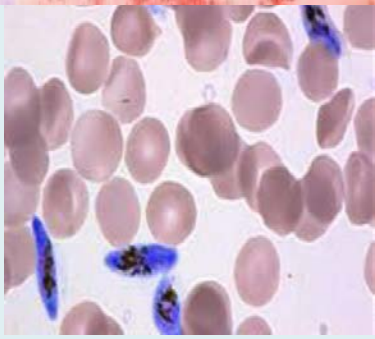
Enhanced DCLS Ebola testing PPE:

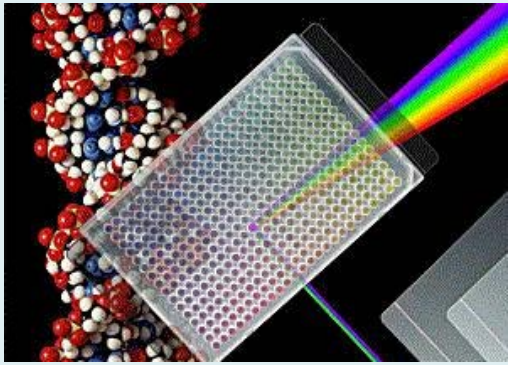
- Tyvek suit
- PAPR (inside Tyvek suit)
- Full PAPR hood (inner bib inside Tyvek suit)
- Tyvek boots (inside Tyvek suit)
- Fluid-impervious, back closing gown
- EC gloves (double while working in BSC)

Ebola Virus Disease (EVD) Test Approval Process

- Physician suspects EVD in a PUI with correlated symptoms, travel, and/or exposure history.
- Physician contacts VDH to discuss suspect case.
- VDH consults with the CDC.
- VDH and CDC Ebola SME determine risk classification and decide if Ebola virus testing is warranted.
- Once approved, VDH contact DCLS to request Ebola virus testing.
- DCLS contacts hospital to provide specimen collection/packaging guidance and arrange a STAT courier pickup at the healthcare facility.
- Courier delivers specimen to DCLS for emergency testing.

DCLS Ebola Virus Testing





DCLS Ebola Response Team

- Specialized BSL-3 trained scientists with molecular biology experience.
- Perform specimen handling, inactivation, and extraction in a restricted BSL-3 containment lab.

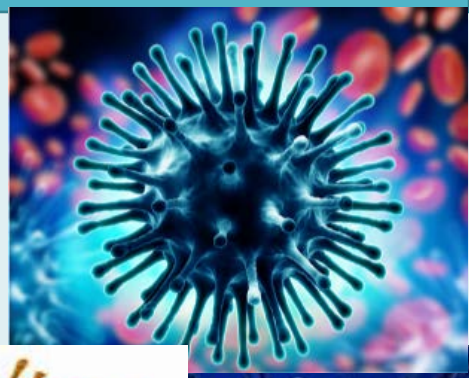
First Tier molecular testing:

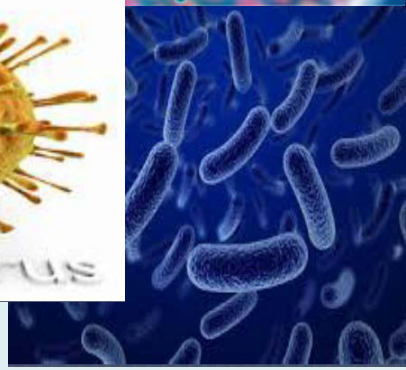
- Ebola virus real-time RT-PCR – detects Ebola Zaire virus
- Malaria real-time PCR – detects 4 *Plasmodium* species

Results within 5 hours of specimen receipt at the laboratory

- False negative EVD results possible when specimen is collected less than 72 hours from symptom onset.
  - If patient remains symptomatic without alternative diagnosis, submit a later specimen to DCLS to rule-out EVD.
- Any positive EVD result will require confirmation at the CDC.

DCLS Enhanced Testing Capabilities





Second Tier molecular testing:

- Influenza real-time RT-PCR – detects 3 common circulating viruses
- Norovirus real-time RT-PCR – detects GI and GII genogroups
- Rapid, molecular GI pathogen panel – 22 GI pathogens (bacterial, viral, parasitic)

Additional Testing Capabilities – to provide a comprehensive testing menu in the absence of an alternative diagnosis

- Arbovirus testing
- Facilitate shipment of specimens to the CDC for additional or confirmatory testing.

DCLS Outreach

DCLS outreach to sentinel hospital laboratories to discuss biosafety, specimen collection and packaging and shipping

- Provided EVD testing and submission instructions and FAQ documents
  - shared via DCLS website, sentinel lab communications, and in DCLS Ebola kits
- DCLS Training Coordinators provided on-site, risk assessment training to Virginia hospitals
- Offer ed free Packaging and Shipping training courses for hospital laboratories
- Provided Ebola Category A/UN2814 specimen collection and shipping kits to:
  - 35 VDH Health Districts, 5 regional epidemiologists, 4 OCME offices, >100 hospitals, 6 Ebola Assessment Centers, and 2 Ebola Treatment Centers
- Served on the VDH Ebola Assessment Team and participated in 2016 Ebola Summit
- Provided 24/7 transport of Ebola virus PUI specimens to DCLS

Specimen Collection & Transport

Specimen Collection - DCLS

Coordinate Ebola PUI testing in collaboration with VDH and DCLS

- Whole blood preserved with EDTA
- Plastic tubes only (NO glass)
- 2 lavender top blood tubes - minimum volume of 4mL each
- Wear CDC recommended PPE during collection and transport
  https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/index.html
- Do NOT centrifuge or manipulate specimens
- Specimens should be stored and shipped at 2-8°C

Specimen Transport In-House

Pre-plan the route of the specimen from site of care to the testing area

- Familiarize staff
- Avoid high traffic areas
- Consider providing an escort
- Wear CDC recommended PPE
- Hand carry - DO NOT use pneumatic tube systems
- Use a durable, leak-proof transport container (29 CFR §1910.1030)
- Decontaminate specimen and outside of transport container with EPA approved disinfectant for Ebola virus before removing from site of care

Staff training is critical for all aspects of handling patient specimens

Specimen Transfer to DCLS

Ebola Virus is classified by the Department of Transportation (DOT) as a Category A infectious substance

- Packaged and shipped in accordance with DOT Hazardous Materials Regulations and International Air Transport Association (IATA) Dangerous Goods Regulations

Individuals packaging and shipping infectious substances must be trained and certified

- Packages require UN-certified materials. labels, marking, and documentation
- DOT requires recertification every 3 years
- IATA requires recertification every 2 years

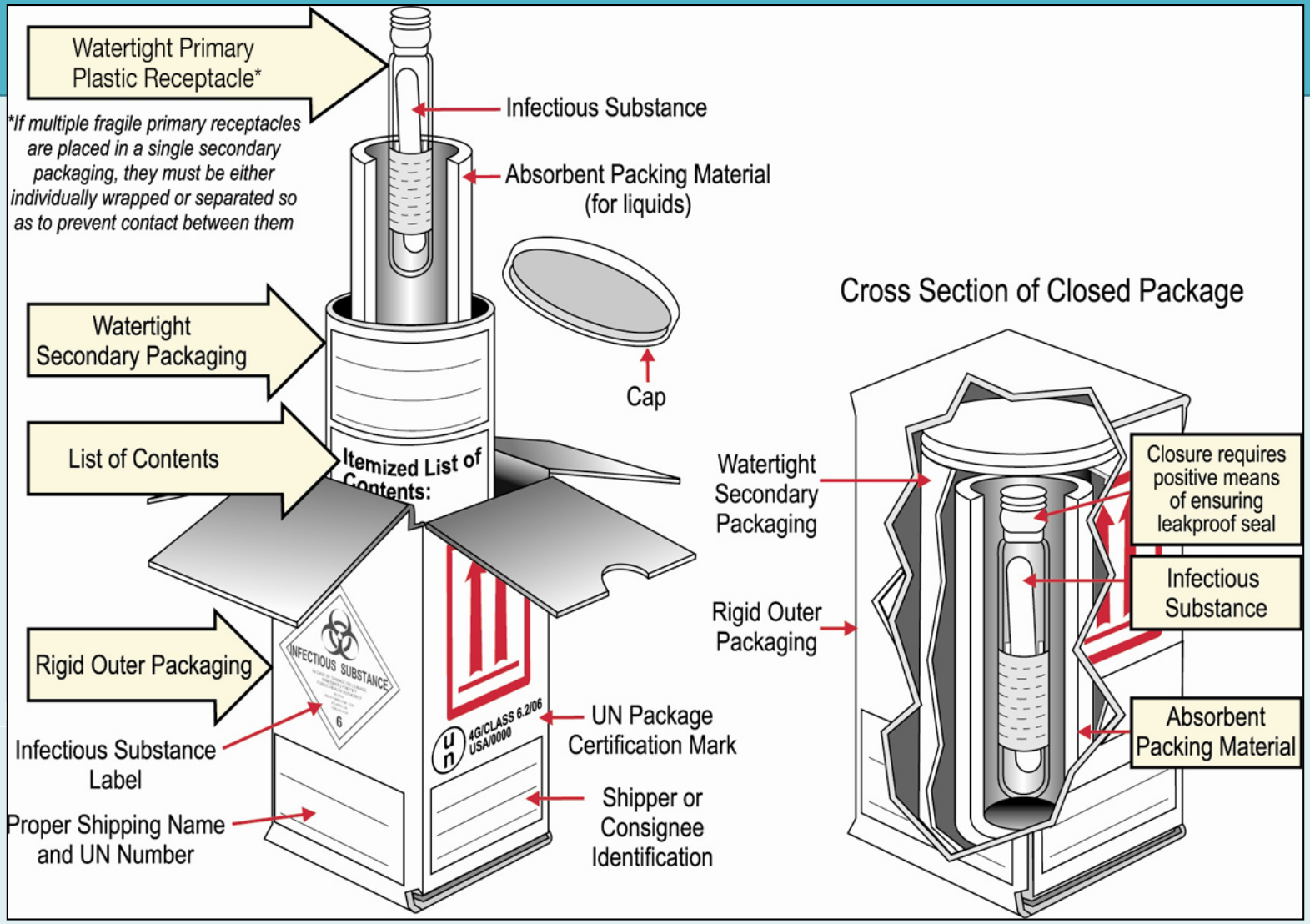
DCLS Courier –Specimen pickup

- Where to park at the facility?
- Consider convenience to the pickup location
- Where and whom to meet?

DCLS Resources

- Ebola Virus Disease Testing and Shipping Instructions (# 23539) - DCLS website Hot Topics
- Micro/Viro Submission Form (# 16857) – DCLS website Resources/Submission Forms
- Ebola FAQs - DCLS website Hot Topics

Specimen Packaging & Shipping



http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/shipping-specimens.html

Clinical Diagnostic Testing

Laboratory Testing: Clinical Care & Differential Diagnosis

Laboratory testing should NOT be delayed. Timely diagnostic testing is essential to ensure patient care is not compromised.

- Use a certified Class II biosafety cabinet (BSC)
- Proper donning and doffing of CDC recommended PPE is critical for safety
- Use manufacturer-installed safety features that reduce likelihood of exposure
- Plan the path of the specimen throughout the testing area and the order of tests
- Staff training and strict adherence to protocols is essential

Assessment hospitals must be capable of safely and timely performing the following:

- CBC, differential, platelet count
- Sodium, potassium, bicarbonate, BUN, creatinine, glucose
- Liver function tests (AST, ALT, total bilirubin)
- Coagulation testing, especially prothrombin time (PT)
- Blood culture for bacterial pathogens (manual or automated)
- Urinalysis (screening test, not requiring centrifugation)
- Malaria smear or rapid test
- Rapid Influenza virus testing

Instruments or methods used in dedicated laboratories to conduct Ebola virus testing

Clinical Chemistry	
Manufacturer	Device
Beckman-Coulter	DxC880i
Abbott Laboratories	ISTAT
Abaxis	Piccolo Xpress

Microbiology	
Test	Method
Blood Culture	Plastic bottle/manual monitoring method
Malaria	Smear fixed in methanol for 15 mins Alere BinaxNOW

Hematology	
Manufacturer	Device
Sysmex	XN 9000
Sysmex	pocH 100i

Coagulation	
Manufacturer	Device
ITC	Hemochron Signature Elite
F. Hoffman-La Roche	CoaguChek

These lists are generated from institutions other than DCLS, are for information only and are not intended as a DCLS or CDC endorsement of these instruments or practices, nor should this be considered a complete list of all test instruments that may be acceptable.

Site-specific Risk Considerations

Administrative controls

- Institutional policies and SOPs, safe work practices, spill response, medical surveillance
- Training, demonstrating proficiency, spill response
- PPE selection and use

Engineering controls

- BSCs, safety equipment, sealed centrifuge rotors, sharps containers
- Test area layout, ventilation, anteroom
- Limit staff, restrict testing area

Infectious Waste Management

- EPA requirements for inactivating Ebola Virus

Instrumentation

- Certification
- Ease of operation/use while wearing PPE
- Aim for closed tube/chamber systems
- Minimize generation of aerosols
- Assess potential routes of exposure
- Consider proximity to other operations
- Can it be segregated after use
- Decontamination
- Will EPA recommended disinfectants affect/interfere with performance or potentially void manufacturer's warranty

After Ebola Virus

What will be next???

Public health and health care organizations are better prepared to handle the next emerging infectious pathogen

Questions?

https://dgs.virginia.gov/division-of-consolidated-laboratory-services

Email us at:

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latoya.griffin-thomas@dgs.virginia.gov

CDC Ebola Virus Disease Guidance for Laboratory Personnel:

http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/index.html
http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/shipping-specimens.html
https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/index.html