

# “Ebola” Biosafety Initiative

New Jersey Department of Health  
Public Health and Environmental Laboratories  
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# About Our Facility.....

- ◆ 194,000 square feet of laboratory and non-laboratory space combined; 160,000 square feet laboratory space
- ◆ Houses Public Health, Environmental and Agricultural laboratories - soon adding more DEP testing
- ◆ Administered by Depts. Health, Agriculture and soon Environmental Protection.
- ◆ 8,000 sf of BSL3 space
- ◆ BSL3 space shared - TB laboratory, Select Agent Laboratory, federal Biowatch laboratory
- ◆ NJ State Police Campus, Ewing, NJ
- ◆ Occupied in May 2011

# Type of Testing

- ◆ Clinical specimens for Newborn Screening, influenza surveillance, serology, chemical terrorism analysis, biomonitoring, mycobacteriology, molecular virology - for respiratory viruses (non-flu)
- ◆ Cultures for foodborne testing, mycobacteriology and special bacteriology (i.e. *Neisseria meningitidis*)
- ◆ Food for microbiology, chemistry and radiation
- ◆ Water for microbiology and chemistry
- ◆ White powders and air samples for bioterror agents
- ◆ Soil for chemistry
- ◆ Plant material - medicinal marijuana - contaminants and levels of active ingredients

# Clients

- ◆ State agencies - DOH, DEP and State Police
- ◆ Local health departments
- ◆ Regional agencies - i.e. Delaware River Basin Commission
- ◆ Hospitals and healthcare providers
- ◆ Public

# Safety at PHEL

- ◆ Safety Officer - Frank Gordon
- ◆ Safety Committee - 1-2 reps from each unit (20 people)
- ◆ Mandated trainings - OSHA, RTK and Emergency Response
- ◆ (Tier 1 - Select Agent trainings - Safety Security and Incident Response)
- ◆ Packaging and Shipping trainings
- ◆ Monthly Audits - Audit reports to all Program Managers, Monthly summary to Leadership team

# Safety Regulations and Guidelines

- ◆ 42 CFR part 73 - Select Agent Rule - Tier 1
- ◆ OSHA Bloodborne Pathogens 1910.1020
- ◆ Chemical Right to Know
- ◆ Hazardous Chemical Communications
- ◆ CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- ◆ MMWR Guidelines for Safe Work Practices in Biomedical Laboratories
- ◆ USDOT Pipeline and Hazardous Materials Transport Regulations 49 CFR 171-178

# BSL 2, BSL 2+ and BSL 3 Operations

- ◆ BSL 2 Microbiology and Molecular Laboratories
- ◆ BSL 3 Select Agent registered laboratory and Mycobacteriology laboratory and Biowatch Laboratory
- ◆ **Outreach to Clinical Laboratories (BSL 2 and BSL 2 + and BSL 3) - training, exercises and PTs**
- ◆ Regulate hospital labs for quality of testing under state and federal mandates

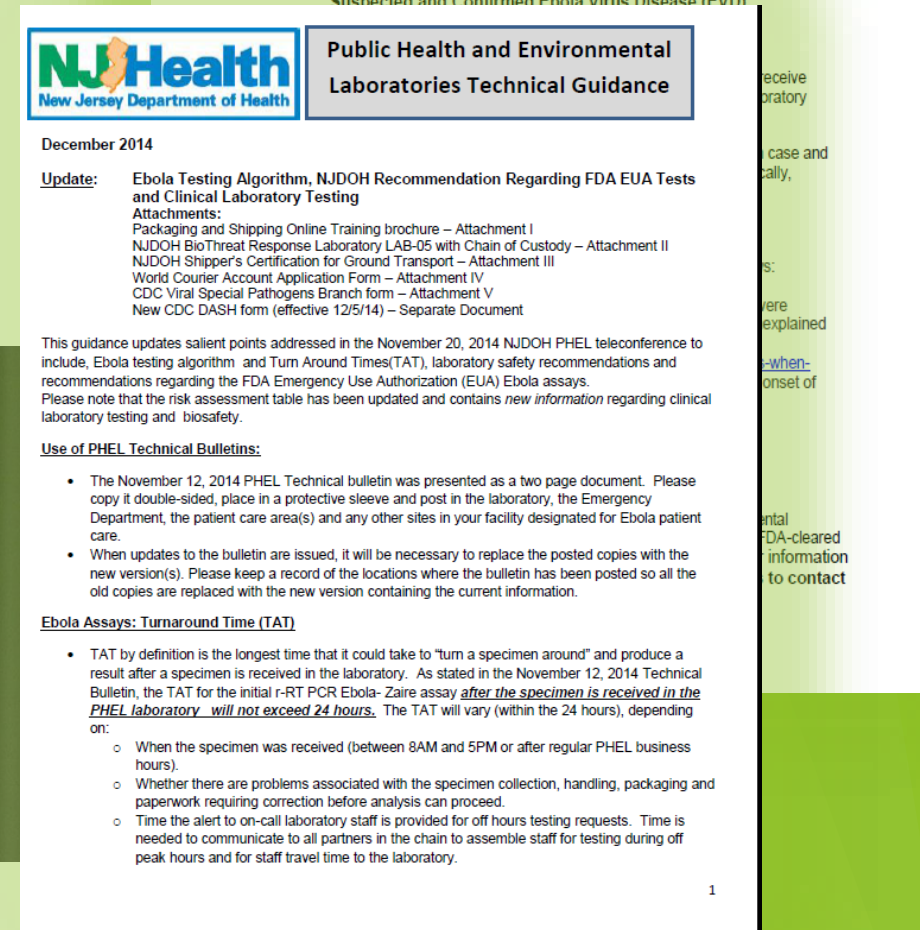
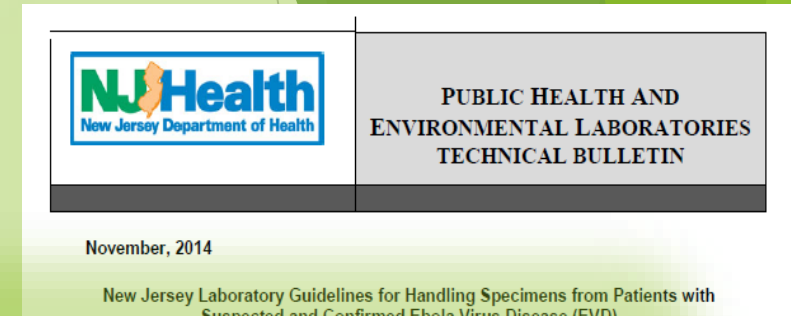


# 2014 Ebola Outbreak

- ◆ Bring Ebola testing onboard - using DoD rtRT Ebola Zaire method
- ◆ Advise clinical laboratories on handling Ebola specimens in routine testing
- ◆ Advise clinical laboratories on utilization of FDA EUA Ebola test
- ◆ Advise clinical laboratories on packaging and shipping Ebola specimens

# 2014 Ebola Outbreak - Challenges

- ◆ Documented transmission among HCW
- ◆ Unknown laboratory transmission??
- ◆ Persistence in fluids
- ◆ Sexual transmission



December 2014

**Update:** Ebola Testing Algorithm, NJDOH Recommendation Regarding FDA EUA Tests and Clinical Laboratory Testing

**Attachments:**  
Packaging and Shipping Online Training brochure – Attachment I  
NJDOH BioThreat Response Laboratory LAB-05 with Chain of Custody – Attachment II  
NJDOH Shipper's Certification for Ground Transport – Attachment III  
World Courier Account Application Form – Attachment IV  
CDC Viral Special Pathogens Branch form – Attachment V  
New CDC DASH form (effective 12/5/14) – Separate Document

This guidance updates salient points addressed in the November 20, 2014 NJDOH PHEL teleconference to include, Ebola testing algorithm and Turn Around Times (TAT), laboratory safety recommendations and recommendations regarding the FDA Emergency Use Authorization (EUA) Ebola assays. Please note that the risk assessment table has been updated and contains *new information* regarding clinical laboratory testing and biosafety.

**Use of PHEL Technical Bulletins:**

- The November 12, 2014 PHEL Technical bulletin was presented as a two page document. Please copy it double-sided, place in a protective sleeve and post in the laboratory, the Emergency Department, the patient care area(s) and any other sites in your facility designated for Ebola patient care.
- When updates to the bulletin are issued, it will be necessary to replace the posted copies with the new version(s). Please keep a record of the locations where the bulletin has been posted so all the old copies are replaced with the new version containing the current information.

**Ebola Assays: Turnaround Time (TAT)**

- TAT by definition is the longest time that it could take to "turn a specimen around" and produce a result after a specimen is received in the laboratory. As stated in the November 12, 2014 Technical Bulletin, the TAT for the initial r-RT PCR Ebola- Zaire assay after the specimen is received in the PHEL laboratory will not exceed 24 hours. The TAT will vary (within the 24 hours), depending on:
  - When the specimen was received (between 8AM and 5PM or after regular PHEL business hours).
  - Whether there are problems associated with the specimen collection, handling, packaging and paperwork requiring correction before analysis can proceed.
  - Time the alert to on-call laboratory staff is provided for off hours testing requests. Time is needed to communicate to all partners in the chain to assemble staff for testing during off peak hours and for staff travel time to the laboratory.

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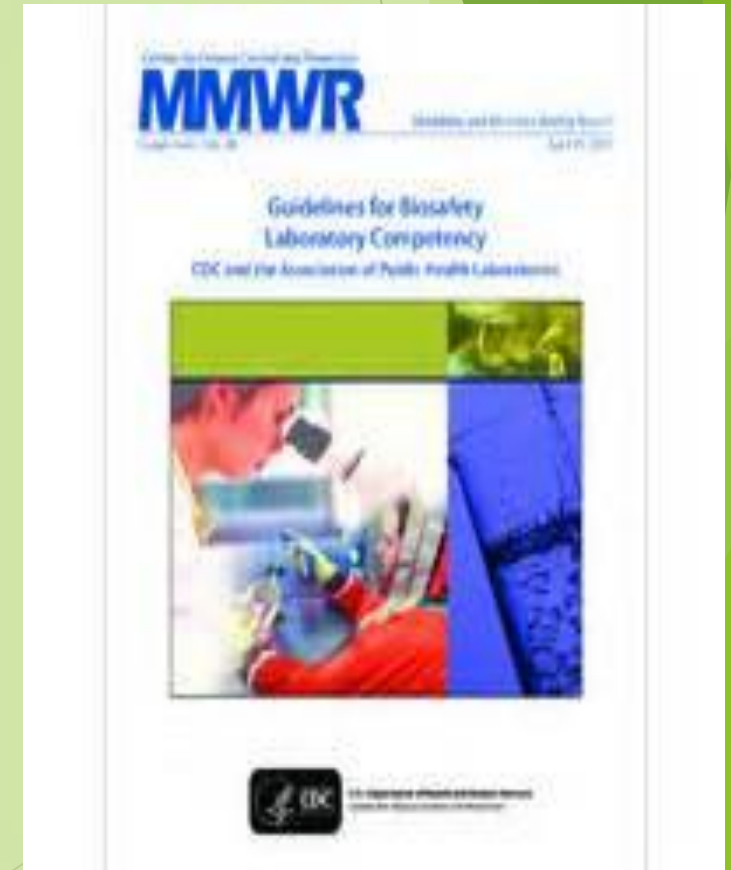


# CDC Grants to States

- ◆ CDC Epidemiology Laboratory Capacity (ELC) Ebola Supplemental Grant
  - ◆ Administered by NJ Communicable Disease Service (CDS) **with Public Health Lab Outreach**
  - ◆ **For Hospitals and Clinical Laboratories and PHL**
- ◆ CDC Public Health Emergency Preparedness (PHEP) Ebola Supplemental Grant
  - ◆ Administered by NJ Public Health Infrastructure, Laboratories and Emergency Preparedness (PHILEP)
  - ◆ For EMS. Local Health, Hospitals and the **NJ PHEL**



- ◆ Association for Public Health Laboratories (contractor for CDC)
- ◆ Develops Biosafety Guidance



# New Jersey Plan

- ◆ Hire a Biosafety Officer
- ◆ Internal Risk Assessments and Training
  - ◆ Partners: PHEAL Safety Committee
- ◆ External Risk Assessments and Training
  - ◆ Partners: LBAC (Laboratory Biosafety Advisory Committee)

# LBAC

- ◆ PHEL Biosafety Officer
- ◆ PHEL BioThreat Response Lab Coordinator
- ◆ Clinical Lab Administrators
- ◆ Clinical Lab Safety Officers
- ◆ Infection Preventionist
- ◆ Clinical Microbiologists
- ◆ Epidemiologist
- ◆ ABSA Member
- ◆ Year one focus will be ETC and EAH

# DRAFT Plan - Year 1 Internal

- ◆ **Biosafety Officer/BTRL Program Manager**
- ◆ Review all Risk Assessments done in the Select Agent Program for Ebola and other Testing - revise as needed
- ◆ **Biosafety Officer /PHEAL Safety Committee/Outreach**
- ◆ Identify all procedures within PHLS which involve testing of clinical specimens and or cultures
- ◆ Draft and pilot Biosafety Competency Assessment Plan to include training, assessment and evaluation

# DRAFT Plan - Year 1 External

- ◆ **LBAC (Laboratory Biosafety Advisory Committee) Goals**
- ◆ Review Risk Assessment Materials Provided by SMEs
- ◆ ETC and EAH laboratories - Identify Procedures in Own labs  
Collection, Handling, Testing, Transporting (internal),  
Reporting and Shipping for Ebola (and other highly infectious)  
Patients
- ◆ ETC and EAH laboratories - Perform Risk Assessments  
procedures in own labs
- ◆ ETC and EAH laboratories - Compare assessments and finetune
- ◆ ETC and EAH Laboratories - Develop scenarios to exercise plans



# January 2016 - Visit Ebola Treatment Center and Ebola Assessment Hospitals

- ◆ Robert Wood Johnson University Hospital - New Brunswick
- ◆ University Hospital - Newark
- ◆ Hackensack University Medical Center - Hackensack
- ◆ CDC Hospital Infection Control Checklist - 11 units from receipt of patient (one component was laboratory)
- ◆ No Laboratory safety deficiencies

3/21/16

◆ Biosafety Officer, Marcia Pindling-Watkins