Bridging the Gap:
Connecting Local, State, Federal Laboratory Resources

Clay Hughes
Laboratory Medical Specialist
NC Regional Response Lab – Mecklenburg County
Why Regional Laboratories?

New Reality in Protecting the Public’s Health

- “Environmental Events”
  - October 7 – December 31, 2001: SLPH received 667 pieces of evidence to analyze
  - Previous 2 years 4 suspected BT samples
  - Competition with other core activities
  - Enhance routine core activities
  - Natural Occurrences
    - Water Testing (Hurricanes)

- “Natural Occurrences”
  - Confirmation testing on suspect isolates
  - Coordinates with CDC on new & emerging disease testing such as Avian Influenza and other re-emerging diseases

- **Definitive need for increased Lab Capacity**
The Regional Lab Mission

The primary mission of the NC Public Health Regional Response Laboratories is to provide accurate testing using Laboratory Response Network protocols in rapid response to biological terrorism and emerging infectious diseases.

The secondary mission is to provide surge capacity in the event of other public health emergencies.

These laboratories, in service to their regions, will also establish and maintain a communication network of sentinel and local health department labs and work with regional emergency response agencies to share essential public health laboratory information.
The mission of the NCSLPH is to provide certain medical and environmental laboratory services (testing, consultation, and training) to public and private provider organizations responsible for the promotion, protection, and assurance of health of North Carolina citizens.

The mission of the BTEP Unit is to maintain laboratory capacity for the detection of biological weapons and emerging infectious diseases and to act in a manner that strengthens crisis response within the Division of Public Health.
Laboratory for rapid identification and confirmation of agents. Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Implementation of Real-time Polymerase Chain Reaction (PCR) assays and Time-Resolved Fluorescence (TRF) testing for potential BT agents.
Critical Biological Agents

- Bacillus anthracis
- Yersinia pestis
- Francisella tularensis
- Hemorrhagic Fever Viruses
  - Smallpox
    - Pan Orthopox
  - Clostridium botulinum toxin
- Brucella sp.
- Coxiella burnetti
- Burkholderia mallei
- Ricin toxin
- Staphylococcus enterotoxin B
- Alpha viruses
  - EEE
  - WEE
- Food or waterborne pathogens:
  - Salmonella sp.
  - Shigella dysenteriae
  - E. coli O157:H7
  - Vibrio cholerae
  - Cryptosporidium parvum
Background

Laboratory Response Network

[Diagram of a pyramid with layers labeled National Labs, Reference Labs, and Sentinel Labs, indicating roles such as characterization, testing, and recognition.]
Provided to Each LRN Lab

- Standardized Reagents & Controls
- Agent-Specific Protocols
- Lab Referral Directory
- Secure Communications
- Electronic Laboratory Reporting
- Training & Technology Transfer
- Proficiency Testing
- Appropriate Vaccinations for Lab Workers
Information Technology Support

- Provides secure access for more than 1,700 LRN Lab workers
- Secure communications on emerging and emergency issues
- Order reagents
- View protocols for PCR and TRF assays
- Report and review proficiency tests
- Receive periodic updates regarding reagent availability, etc.
LRN Formula for Success

- Unified operational plan
- Standardized protocols and tests
- Secure communications
- Molecular diagnostics
- Rapid response and reporting
- Safe, secure laboratories
- Trained laboratorians
- Coverage for human, animal, food, environmental specimens
- CDC coordinated support and oversight
- Quality laboratory results
Locations

NORTH CAROLINA Regional Lab Divisions
What We Have Accomplished
So Far...
Certifications

- CDC: Select Agent
- USDA
- Department of Justice
- World BioHazTec
- CLIA
Training

- CDC & Virginia SLPH
- Eagleson Institute & Georgia SLPH
- NC State Lab of Public Health (central lab)
- ASM Workshops
- Onsite and On-line Proficiency
- Weapons of Mass Destruction
- Counter Terrorism
- Emergency Response to Biological Incidents
- PH response for Meth Labs
- Response Planning for Public Water Facilities
- PH Incident Command System
Guidelines for Sentinel (Hospital) Labs

- Develop and maintain capability of Sentinel Laboratories
  - Perform rule-out testing on critical Bioterrorism (BT) agents
  - Safely package and handle specimens
  - Refer to LRN (Reference) Lab for further testing
  - Contact information
Communication Network

- Database of key personnel in Region 7 hospitals and HD for the Lab Response Network
  - Receive and send information rapidly during infectious disease outbreaks and BT drills / events
Federal ⇒ State ⇒ Local

- Continuing education
- Public health updates
- Communicable disease reporting
- Reagent/equipment recalls
- Laboratory operations
  - CAP-CLIA-JCAHO inspection
    - Certificate required for Packaging-Ship training
Surge Capacity H₂O Testing (hurricanes, floods)

- 43 private well water samples from two WNC counties during fall 2004 floods
- using Colilert® and Colisure™ test kits
Surge Capacity
Food-borne outbreaks

- >1000 samples during Meck County *Shigella* outbreak

- ~195 samples during Wilkes County *Shigella* outbreak
Testing Capabilities

- Molecular (presumptive) and Classical Microbiology (confirmatory) for reporting of BT agents and other emerging infectious agents
  - Environmental
  - Clinical
  - Postal Service (BDS)
  - Food
Testing Capabilities

- **DPDx System for diagnosis of food-borne and parasitic diseases**
  - Website developed and maintained by CDC’s Division of Parasitic Diseases
  - **DPDx system:** digital camera, microscope and imaging software using “telediagnosis” to exchange images from diagnostic specimens via the internet
  - Through DPDx, images transmitted to CDC receive answers to inquiries in minutes to hours
Response Planning

- Local county and regional response
- Smallpox vaccination clinics
  - Hepatitis-A
  - MRSA
  - Legionella
  - Group A Strep
  - E. coli 0157 Outbreaks
  - SARS Surveillance
  - Influenza Vaccine shortage
  - Regional Flood Response
Laboratory Improvement

- BT workshops for Hospital and HD labs
- BT Preparedness updates
- Inspections
- Biosafety and Quality Assurance
- Capabilities of all Mecklenburg County Governmental Lab Agencies
Assist PHRSTeams

- Clinical Sample Submission and Environmental Sampling during BT Events
- Information Sessions with Police, Fire and HazMat on BT agents and sample package and delivery
Assist First Responders

- Communication with law enforcement and emergency services to ensure chain of custody concerning specimen transfer

- Forensic Epidemiology presentations
Packaging/Shipping

- Low suspicion – Hospital/HD courier system/FedEx
Packaging/Shipping

- High suspicion – hand delivered by law enforcement
Agents of Concern
- Bacillus anthracis
- Yersinia pestis
- Smallpox
- Brucella spp
- Francis. tularensis
- Ricin

Submission Criteria
- Submission Form
  - Environmental Form
  - Clinical Form
- Shipping Guidelines

FAQ

Contact Numbers

Relevant Links
- NC Epidemiology
- NC EPI PHPR
- CDC Bioterrorism
- FDA Bioterrorism
- CDC

http://slph.state.nc.us
Contact Information

- **NC Regional Response Lab-Mecklenburg:**
  - Clay Hughes: (704) 432-1735
  - Justin Edwards: (704) 432-1514

- **BTEP:**
  - Duty Phone 24/7: (919) 807-8600
  - Duty Pager 24/7: (919) 310-4243
Questions?