



APHL's First Responder Outreach Activities

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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Outline

- APHL
- Resources for Members
- Field Screening Policy
- Collaborations with Stakeholders
- Next Steps

APHL

- Non-Profit, Non-Governmental Organization (NGO)
- Over 800 members representing:
  - State & local PHLs
  - State environmental & agricultural labs
  - Federal agencies
  - Academic institutions
- Advocate at the national level to shape public health policy & to secure increased support/resources for members
- Provide training, model practices, and technical assistance domestically and internationally

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APHL

- Public Health Preparedness & Response
- Environmental Health
- Infectious Diseases
- Public Policy
- Food Safety
- Newborn Screening
- Global Health
- Informatics
- Institutional Research
- Laboratory Systems & Standards
- Training & Workforce

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PHPR Staff

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Kara MacKeil, BA, Associate Specialist, PHPR

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Resources for APHL Members

- *Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample*
  - Developed by APHL with input from CDC and FBI
  - Guidance on laboratory testing and field assessments
- First Responder Standards and Technology (FiRST) Subcommittee
  - Overseen by the PHPR Committee
  - Identify the first responder partnership needs of APHL's members
- BT/CT Collaborative Workgroups
  - Forum for sharing challenges & success with trainings, drills, & exercises

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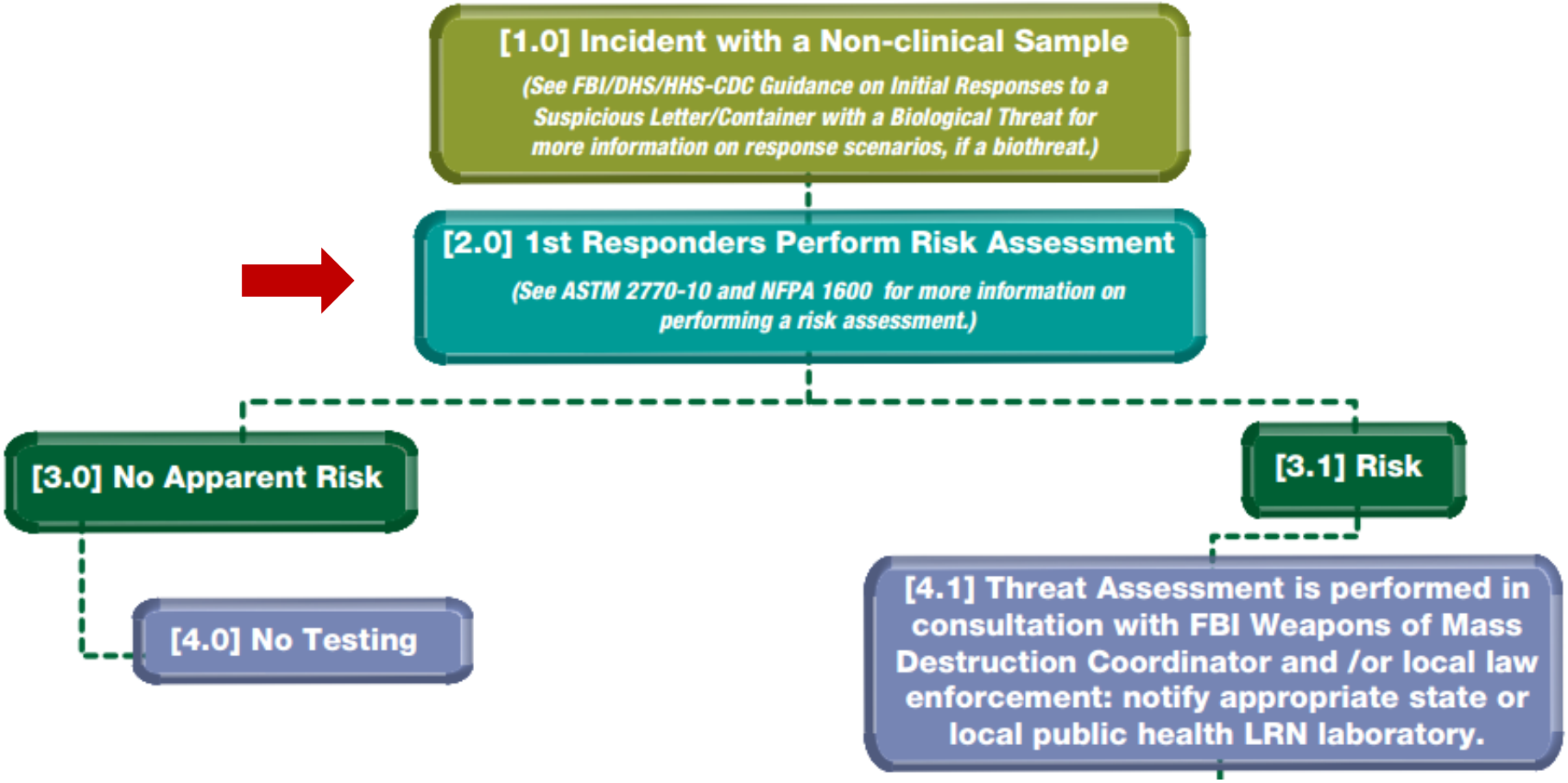
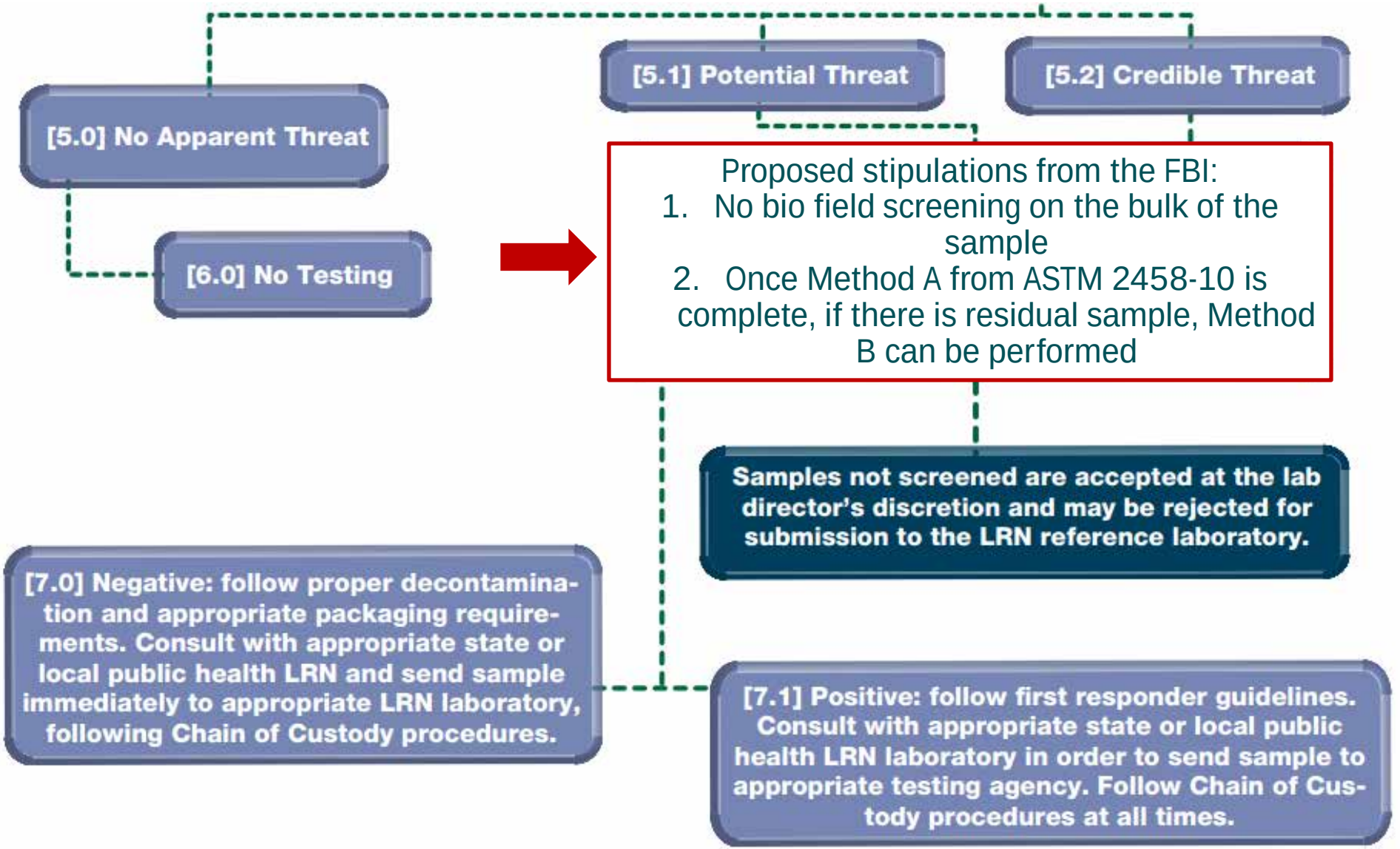
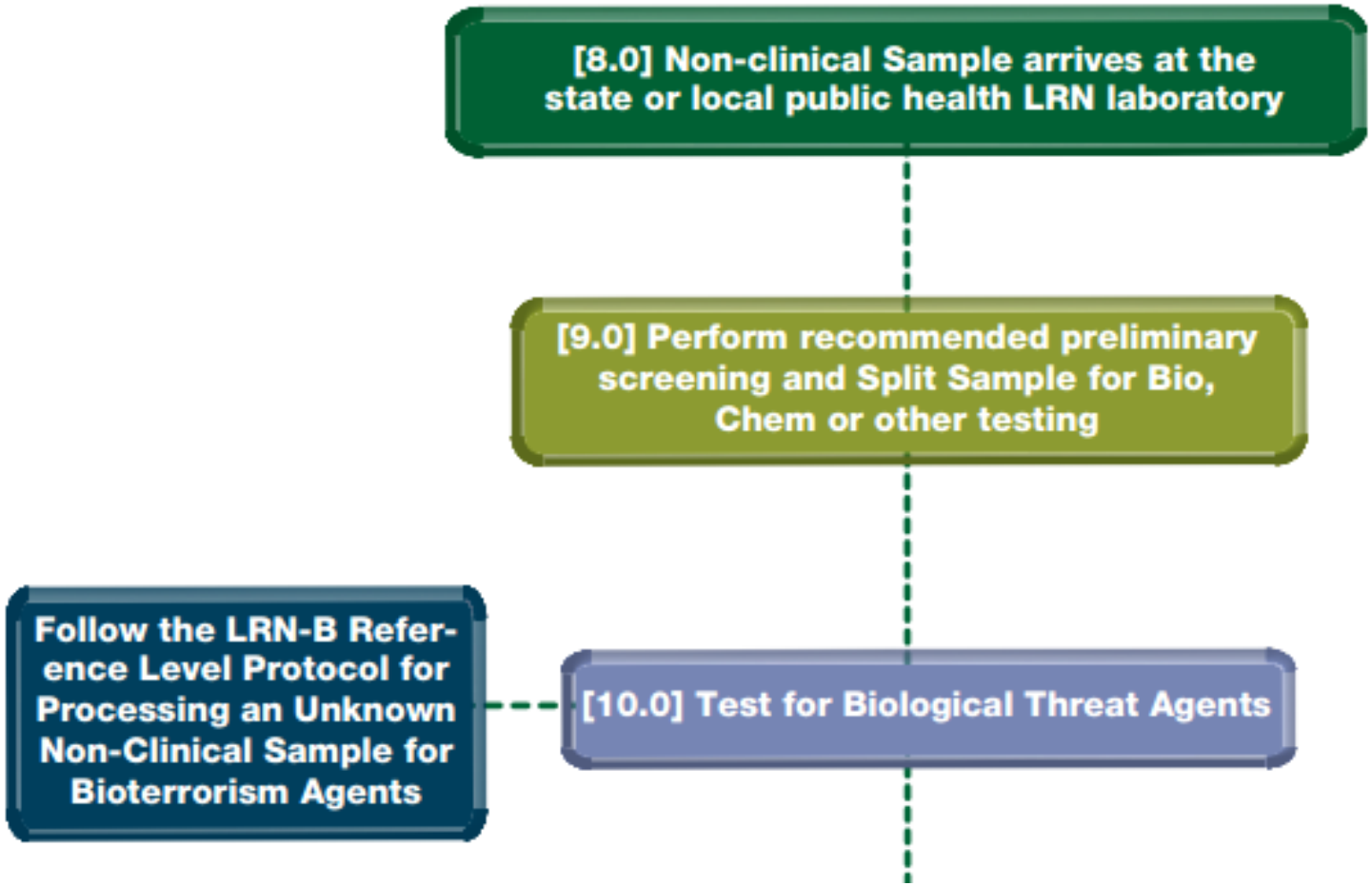
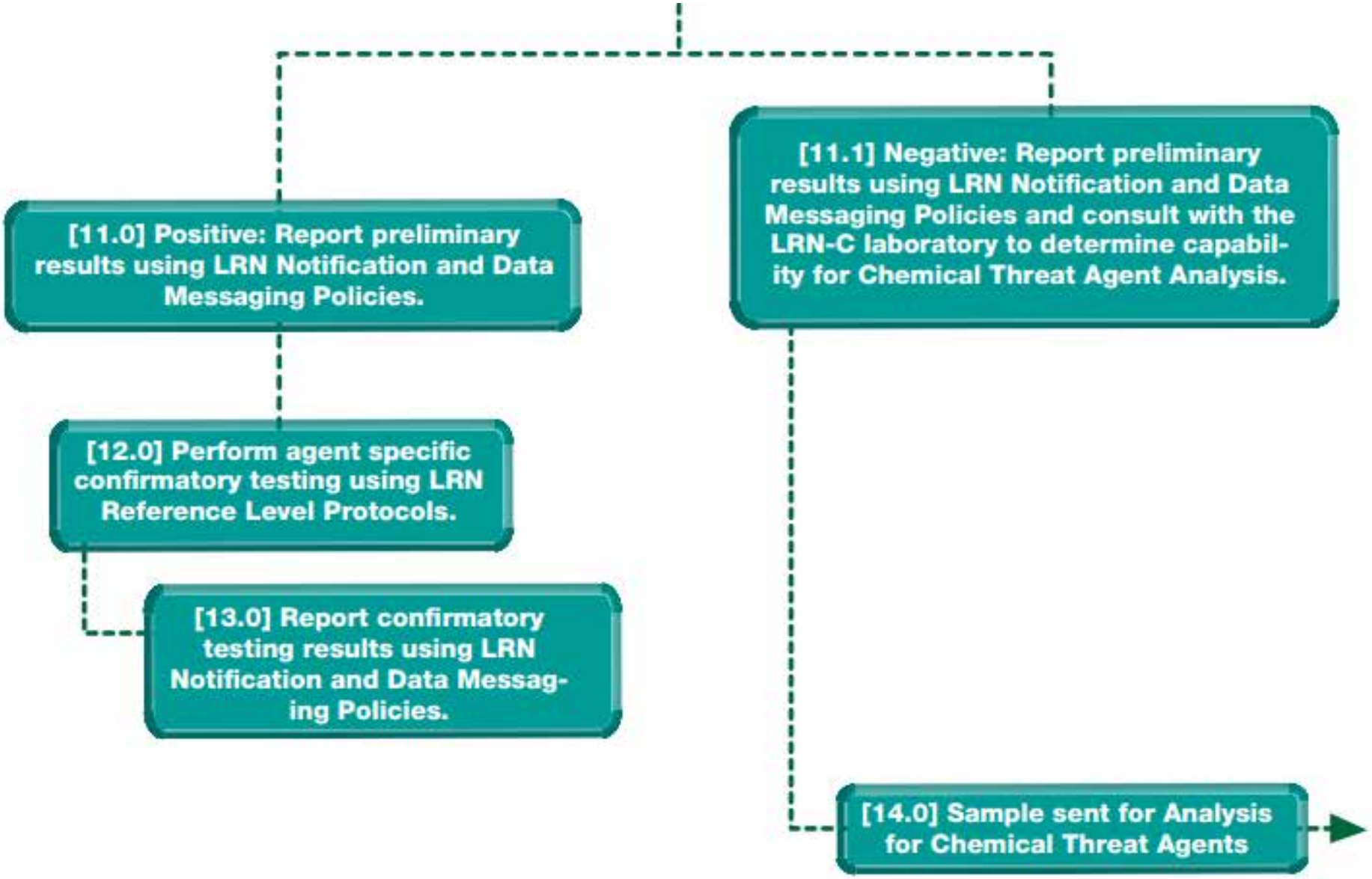
APHL Unknown Algorithm




[5.0] No Apparent Threat
[6.0] No Testing
[5.1] Potential Threat
[5.2] Credible Threat
Proposed stipulations from the FBI:
1. No bio field screening on the bulk of the sample
2. Once Method A from ASTM 2458-10 is complete, if there is residual sample, Method B can be performed
Samples not screened are accepted at the lab director's discretion and may be rejected for submission to the LRN reference laboratory.
[7.0] Negative: follow proper decontamination and appropriate packaging requirements. Consult with appropriate state or local public health LRN and send sample immediately to appropriate LRN laboratory, following Chain of Custody procedures.
[7.1] Positive: follow first responder guidelines. Consult with appropriate state or local public health LRN laboratory in order to send sample to appropriate testing agency. Follow Chain of Custody procedures at all times.


[8.0] Non-clinical Sample arrives at the state or local public health LRN laboratory
[9.0] Perform recommended preliminary screening and Split Sample for Bio, Chem or other testing
Follow the LRN-B Reference Level Protocol for Processing an Unknown Non-Clinical Sample for Bioterrorism Agents
[10.0] Test for Biological Threat Agents


[11.0] Positive: Report preliminary results using LRN Notification and Data Messaging Policies.
[11.1] Negative: Report preliminary results using LRN Notification and Data Messaging Policies and consult with the LRN-C laboratory to determine capability for Chemical Threat Agent Analysis.
[12.0] Perform agent specific confirmatory testing using LRN Reference Level Protocols.
[13.0] Report confirmatory testing results using LRN Notification and Data Messaging Policies.
[14.0] Sample sent for Analysis for Chemical Threat Agents

FiRST Subcommittee

- Composed of 10 BT/CT personnel: AZ, DE, FL, IA, MA, MN, NY, TX, VA
  - Phase I: public health laboratory-only focus
  - Phase II: expand to include federal reps
- Key activities:
  - Outreach best practices
  - Survey PHLs on knowledge of first responder capabilities
  - Database template to contact first responders
  - Opportunities for collaboration with other organizations (e.g., International Association of Fire Chiefs)

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Quick Reference Guide for Trained Public Safety Responders (Non-Hazmat) On Collecting & Submitting Suspicious Substances to the Hinton State Laboratory for Biological and Chemical Testing

1. Call the BT/CT on-call phone upon arrival at the incident (617-590-6390)
2. Perform a risk assessment (no apparent risk, low risk, or high risk)
3. Notify the FBI WMD Coordinator if the specimen is associated with a threat/high profile target (617-742-5533)
4. Notify the Postal Inspector if the specimen is associated with mail that has gone through the postal system (617-839-1043)
5. Don appropriate Personal Protective Equipment (PPE)
6. Perform field screening (radiation screening on all specimens and x-ray for explosive device on sealed items is mandatory)
   - Request additional resources (hazmat, bomb squad) if you don't have the capability to field screen or collect a specimen
7. Collect specimen

Suspicious Mail/Threat Letter		Visible/Bulk Powder	Trace Amounts of Powder	Liquids
Opened	Unopened			
				
Collect loose powder in a sterile plastic container. Lab needs at least 1-mL quantity. If sterile container is unavailable, try to contain the powder within the envelope. Carefully place the letter and envelope into a zip lock bag. Limit handling of the letter and envelope to minimize the destruction of DNA and latent prints. Seal the zip lock bag.	Do not open a sealed item without prior consultation with the BT/CT lab. Carefully place the envelope into a zip lock bag. Limit handling of the envelope to minimize the destruction of DNA and latent prints. Seal the zip lock bag.	Sterile tools such as scoops, spatulas and laminated cards can be used to gather powder. Gathered powder should be placed into a sterile plastic container. The plastic container should be placed in a zip lock bag and sealed. Refer to the ASTM-E2458 "Standard Practices for Bulk Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces" for further guidance.	Sterile tools such as swabs and gauze sponges can be used to gather powder. Do not use wooden shafted or cotton tipped swabs. Swab or gauze pad should be placed in a sterile plastic container. The plastic container should be placed into a zip lock bag and sealed.	Perform pH to rule-out strong acid/base. Collect the liquid using a sterile pipette. Transfer liquid to a sterile plastic container. Use glass for strong chemicals. Seal container with parafilm to prevent leakage. Place container in a zip lock bag and seal.

8. Place the sealed zip lock bag into an outer container such as another zip lock bag, paint can or small bucket
9. Complete the BT/CT Specimen Submission form. Paperwork must be placed on the outside of the outer container
10. Determine who will transport specimen to the laboratory (i.e., local police, fire, FBI, Postal Inspector)
11. Call the BT/CT on-call phone at 617-590-6390 to notify the laboratory that the specimen is being transported
12. Transport specimen to the Hinton State Laboratory Institute, 305 South Street, Jamaica Plain, MA 02130

Triage and Test Prioritization of Suspicious Environmental Specimens

Assess Level of Risk: First Responders should assess the incident to determine the level of risk based on the following categories:

No Apparent Risk

Specimens in this category include powder, particulate matter or liquid found in a likely location with an obvious explanation and no evident threat (i.e., white powder in a coffee shop).

➔ **Testing is Not Recommended**. These samples can be disposed of in the regular trash.

Low Risk

Specimens in this category include unusual powders, particulate matter or liquid found in a location with no obvious explanation, but no known threat.

➔ **Routine Testing is Recommended**.

High Risk

Specimens in this category include any substance or object associated with (a) written or verbal **threat**; (b) a high profile target; (c) an unusual event determined by public safety and/or public health officials to be of high risk; and/or (d) occurrence of human exposure or illness associated with the incident.

➔ **Priority Testing is Required!**

Field Screening Suspicious Environmental Specimens

Field Screening for Acute Hazards is Required Prior to Laboratory Submission
Minimum Requirement: Radiation (preferably before the item is packaged) and screen for Explosive Device (x-ray) if the item is sealed and has a thickness greater than a folded sheet of paper

Specimen Testing/Results Reporting

Low Risk Specimens Submitted to HSLI:

Monday-Friday 8am-5pm: Testing will begin no later than an hour following receipt.

Evening or weekend hours: Testing will begin on the next business day.

- Final results will be mailed to the submitter no earlier than 5 days.

High Risk Specimens Submitted to HSLI:

Monday-Friday 8am-5pm: Testing will begin immediately upon receipt.

Evening or weekend hours: Testing will begin immediately upon receipt.

- Preliminary test results will be called out to the submitter within 6 hours.
- Final test results will be called out and mailed to the submitter no earlier than 5 days.

Hinton State Laboratory
305 South Street
Jamaica Plain, MA 02130
617-590-6390

Field Screening Policy

- *The Need for a Quality Assurance Program for Kits and Devices Used in the Field to Screen for Hazardous Biological and Chemical Warfare Agents*
  - Revised and approved by APHL membership in March 2013

- Quality Assurance Program should incorporate:
  - Performance verification
  - Field validation
  - Proficiency testing
  - Training
  - Competency assessment
- DHS designated as the lead agency

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D. Implementation

1. **DESIGNATE THE DEPARTMENT OF HOMELAND SECURITY (DHS) AS THE LEAD FEDERAL AGENCY**: DHS must establish uniform guidelines for the performance standardization and validation of all kits and devices for use in the field by first responders to screen for hazardous biological and chemical warfare agents.
    a. **DEVELOP AND IMPLEMENT PERFORMANCE STANDARDS**: Establish guidelines for performance standardization of all kits, assays, and devices for use in the field by first responders to screen for hazardous biological and chemical warfare agents.
    b. **VALIDATE FIELD DEVICES (MEASURE WHETHER THE DEVICES DO WHAT THEY SAY THEY DO)**: Perform validation studies under variable conditions that may be less than favorable: location (laboratory vs. field), varying levels of experience with such devices and/or laboratory testing by end-users. Engage an independent third party to conduct such evaluations and involve state and local public health LRN member laboratories in validation studies, as appropriate.
    c. **DEVELOP AND IMPLEMENT A QUALITY ASSURANCE PROGRAM**: The program should encompass training and certification on the use of all devices and kits that screen for biological and chemical warfare agents and ensure that personnel participate in a proficiency testing program and undergo regular annual competency assessment.
    d. **ESTABLISH PROCESS FOR PURCHASE OF APPROVED FIELD KITS AND DEVICES**: Once kits and devices meet the performance standards and have been validated, they should be placed on a federally-approved list. Only items on this list should be approved for purchase with DHS Federal Emergency Management Agency (FEMA) and other federal funds.

Collaborations with Stakeholders

- Department of Homeland Security Standards and Technology Directorate (DHS S&T)
- National Guard Bureau (NGB)
- Federal Bureau of Investigation (FBI)
- National Institute of Standards and Technology (NIST)
- U.S. Strategic Command (USSTRATCOM)

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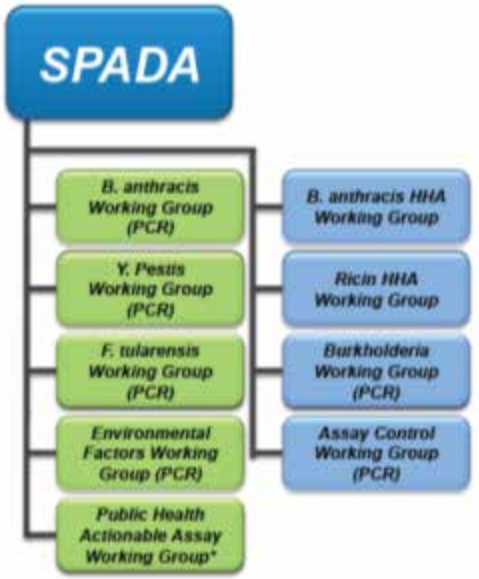
Stakeholder Panel on Agent Detection Assays (SPADA)



- Standards body
  - DHS S&T with AOAC International
  - Based on the PSAA architecture
- Standard Method Performance Requirements (SMPRs) for:
  - PCR: Ba (aerosols), Yp, Ft
  - HHA: Ba (spores), ricin
  - Pending : PCR for Ba (powders), Bp, Bm
- APHL representation:
  - Dr. Christina Egan (NY)
  - Dr. Dee Pettit (NC)
  - Ms. Chris Mangal (APHL)

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Federal Stakeholders
- Centers for Disease Control and Prevention
- Department of Defense
- Dept of Homeland Security
- Environmental Protection Agency
- Federal Bureau of Investigation
- Food and Drug Administration
- Intelligence Community
- Lawrence Livermore National Laboratory
- National Institute of Standards and Technology
- Office of Science and Technology Policy
- United States Postal Service

Organizational Stakeholders
- Association of Public Health Laboratories
- Interagency Board for Equipment Standardization and Interoperability
- International Association of Fire Chiefs
- National Association of County and City Health Officials

Academia Stakeholders
- Colorado State University
- Loyola University
- Northern Arizona University
- Rutgers University
- University of Medicine and Dentistry of New Jersey
- University of Nebraska Medical Center

International Stakeholders
- Cambridge and Wellcome Trust
- Ernst-Moritz-Arndt University of Griefswald
- Menzies School of Health Research
- Plymouth Hospital NHS Trust
- University of Exeter

State and City Stakeholders
- Boston Fire Department
- Chicago Fire Department
- Commonwealth of Massachusetts Dept of Fire Service
- Commonwealth of Massachusetts Dept of Public Health
- Fairfax Fire Department
- Georgia Public Health Laboratory
- Minnesota Department of Health
- Nebraska Public Health Laboratory
- New York City Dept of Health and Mental Hygiene
- New York City Fire Department
- New York State Dept of Public Health
- Orlando Fire Department
- Troy Fire Department

Industry Stakeholders
- Alexeter
- American Type Culture Collection
- Applied Biosystems
- Battelle Memorial Institute
- BioRad Laboratories
- Cepheid
- HazTech Systems, Inc.
- Ibis Biosciences
- ICx Technologies
- Idaho Technologies
- Innovative Biosensors, Inc.
- Invitrogen Federal Systems
- Midwest Research Institute
- Northrop Grumman
- Qiagen
- Response Biomedical
- SAIC
- Smiths Detection
- Tauri Group
- Tetracore
- US Genomics

National Institute of Standards and Technology (NIST)

- Reference material for confidence assessments of users
  - *Saccharomyces cerevisiae* with a unique DNA "barcode"
  - **NOT** a validation of biothreat detection assays
- Inter-laboratory comparison study
  - Determine LOD, repeatability
  - Participating PHLs: FL-Tampa, MI, MN, NY, WA
- Next steps:
  - Development of powder format
  - Ensure PHLs are engaged in future lab studies

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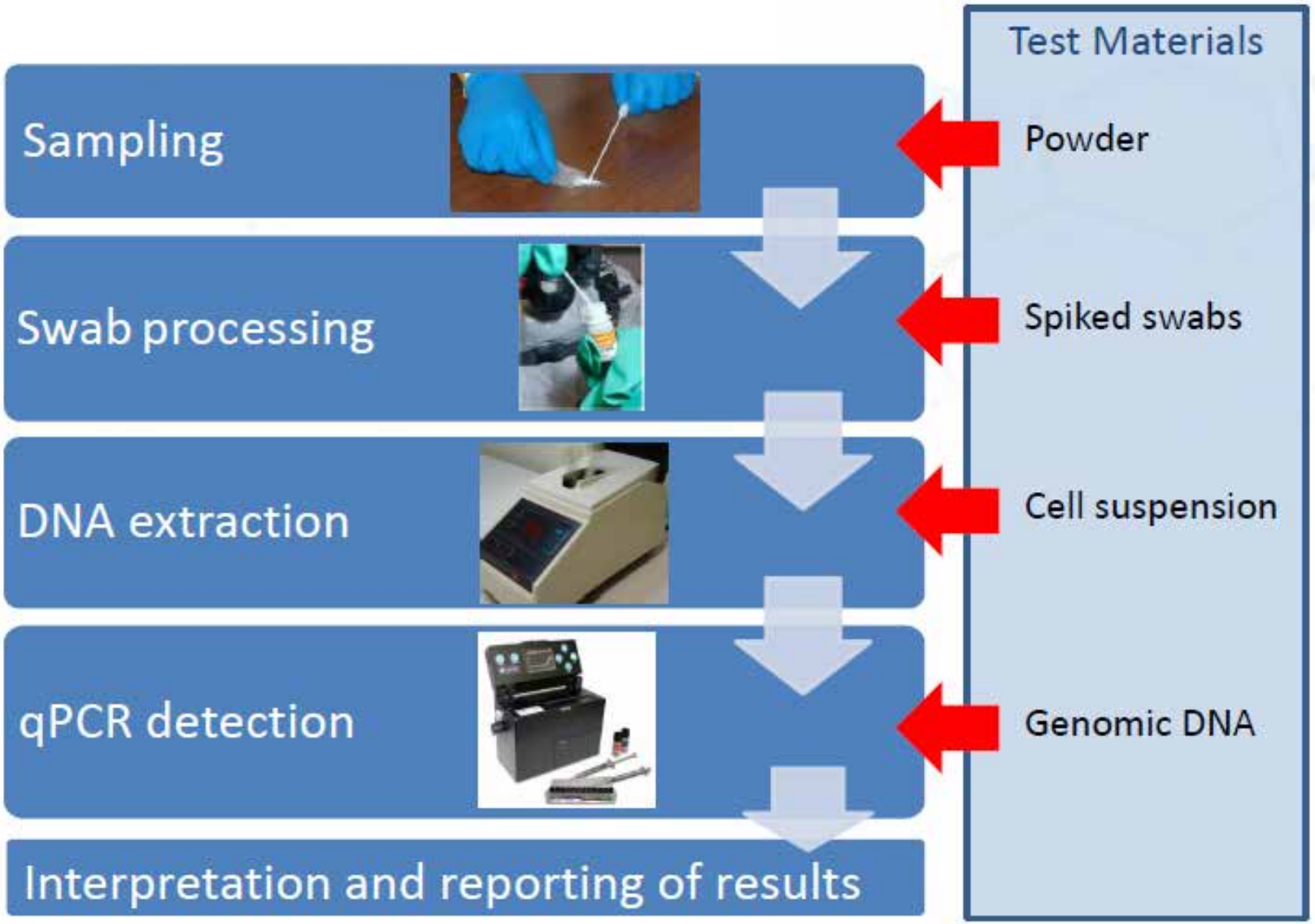
Test Materials
Sampling
Powder
Swab processing
Spiked swabs
DNA extraction
Cell suspension
qPCR detection
Genomic DNA
Interpretation and reporting of results

Next Steps

- Continue outreach to stakeholders to ensure PHLs are involved
- Engage FBI, DHS, and other partners in discussion on technology and training needs
- Contribute to ongoing exercises and the development of templates and standards
- Connect with FEMA to learn more about their grants process

Discussion

- Outreach to first responders in Texas
  - o Activities
  - o Lessons learned
  - o Needs

Contact Information

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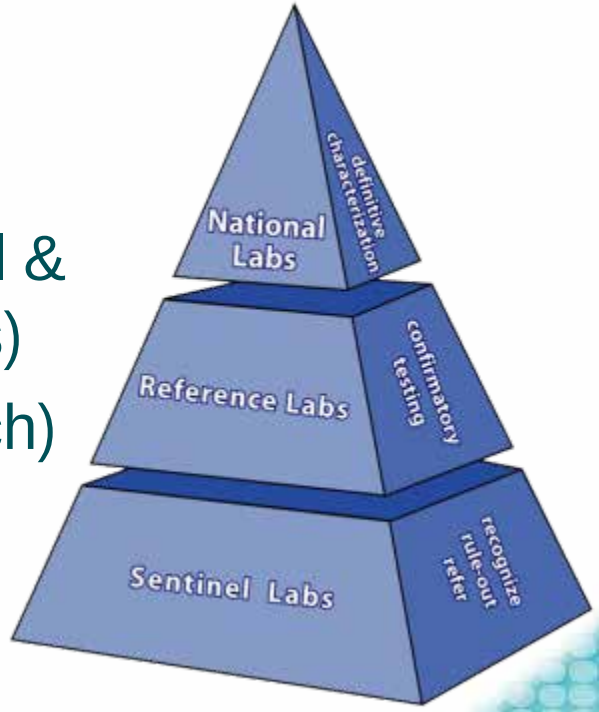
kara.mackeil@aphl.org (LIMSi)

Share best practices:

emergency.preparedness@aphl.org



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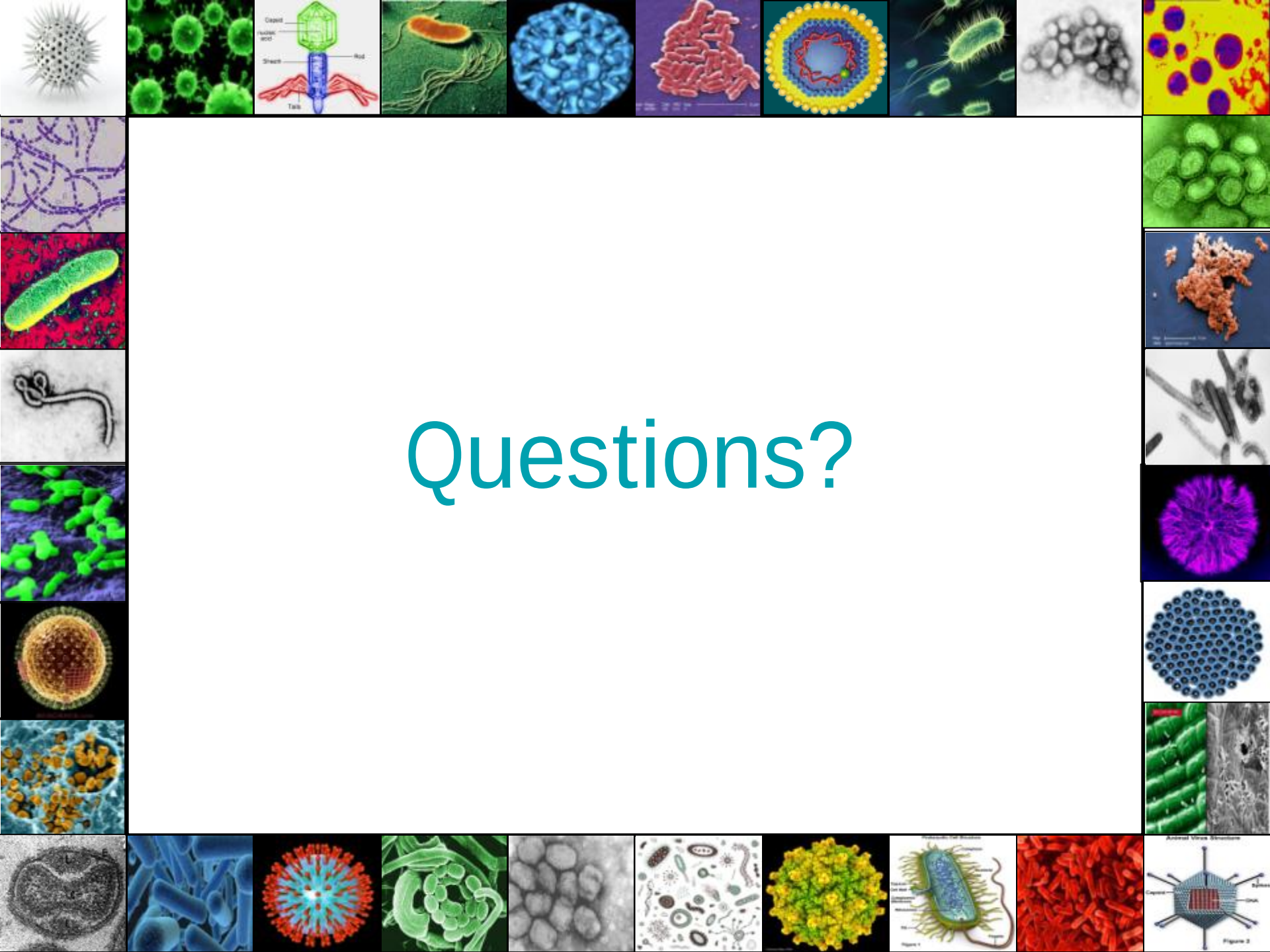
Questions?