
NLTC-9

Supporting Your Sentinel Laboratories

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Outline

- Communication & Relationships
- State Specifics
- Sentinel Laboratory Site Specifics
- Trainings & Resources
- Helping With Identified Items

*ENGAGE → **SUPPORT** → MAINTAIN*

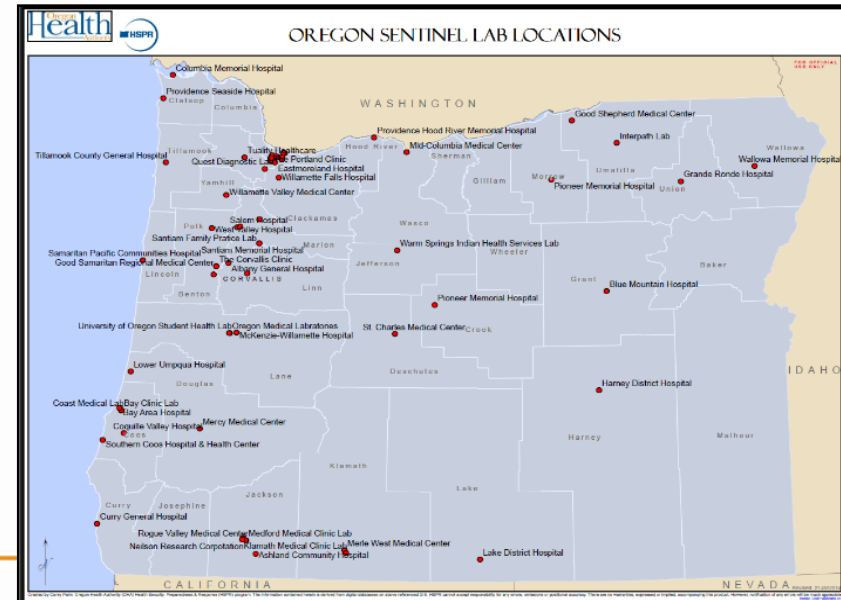
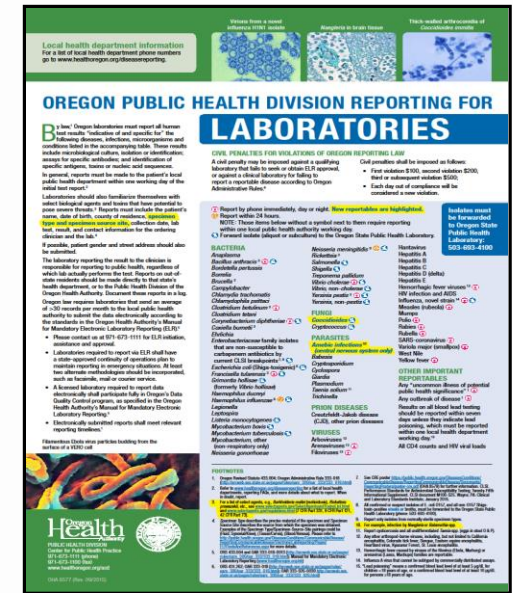
Communication & Relationships

- Established and current database
 - Distribution lists
 - Routine and urgent, alerts, messages, and training announcements
 - Consistent messaging style, and do not overburden
- Relationship building takes time!
 - Professional and personal relationships
 - Face to face introductions increase communication
 - Provide consistent, reliable guidance, results, and products
- Inspection vs. consultation approach
 - Supportive, not regulatory tone

State Specifics

- Geographic variability affecting site visits and scheduling
- Disease reporting requirements
- PH systems, infrastructures and partners
 - Epidemiology
 - Preparedness
 - Centralized vs. decentralized local public health departments
 - Sentinel Lab Healthcare Systems
 - Other Partners

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Sentinel Laboratory Site Specifics

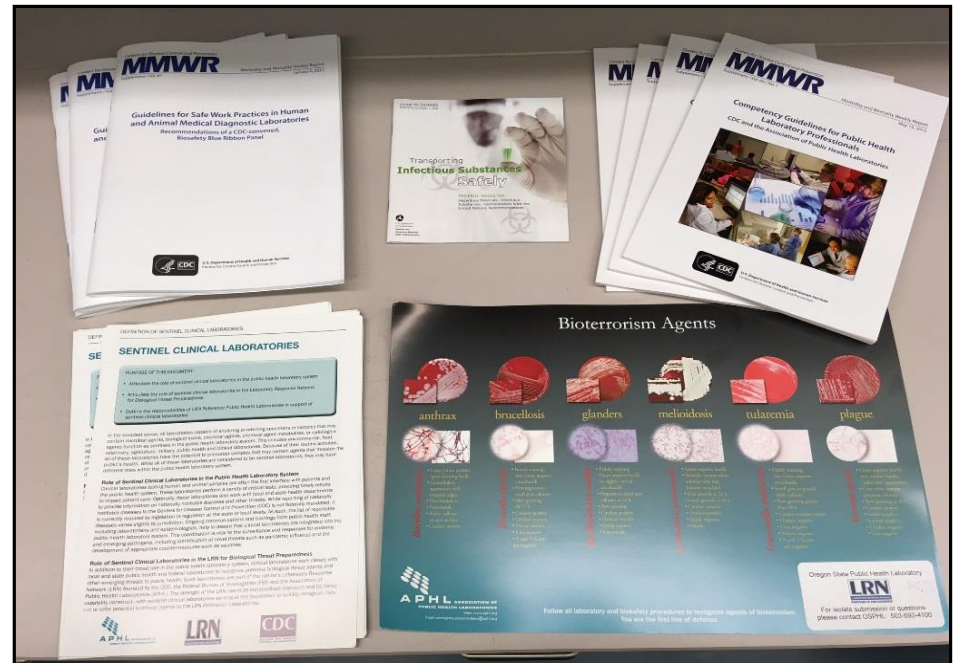
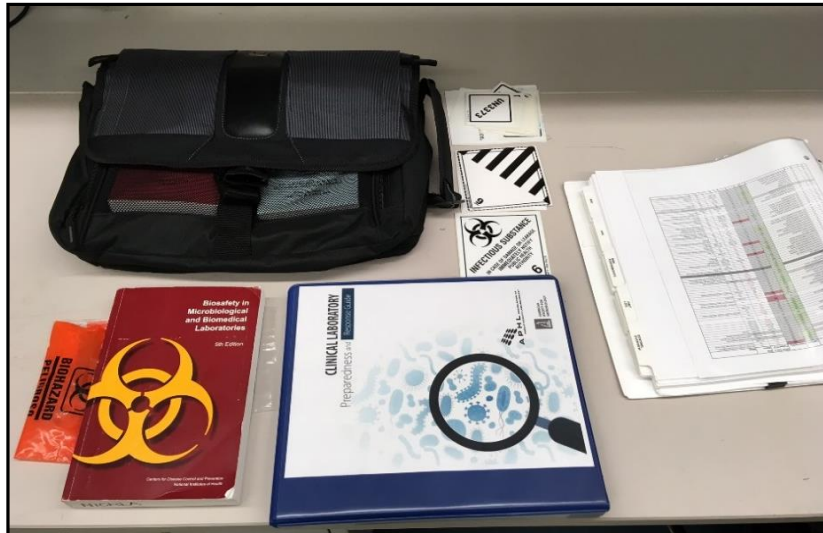
- Variety of clinical healthcare systems
- Frontline clinical
- Core & regional microbiology laboratories
- Academic / Research
- Animal or Veterinary
- Select agent registered
- Small rural vs. large metro
- County or city HDs
- Available resources, depth of staff, turn overs, availability and scheduling...
- Participation:
 - Leadership and management
 - Lead microbiologists and techs
 - Safety
 - Facilities
 - Infection prevention
 - Quality assurance
 - Emergency preparedness
 - Shipping/receiving

What Kind of Training?

- Training needs assessments, surveys, previously identified, follow up items
- Sentinel Lab requirements
- Online, e-learning, webinars and teleconferences
- In-person trainings
 - At PHL
 - At Sentinel Lab
 - Regional host site
- PHL developed
- Partner resources
 - ABSA, APHL, ASM, CDC, Eagleson, PHF, WHO
 - DOT, FedEx Pack/Ship Technical Support
 - OSHA trainings & consultations
- Commercial and private
- Competency assessments..

Outreach & Trainings

- Provide resources
 - Printed copies of guidance material, job aids, posters, handouts, updated pack/ship stickers, extra Category A box
- Offer and provide trainings as needed
 - General or “One Size Fits All”
 - Tailored trainings
 - Adjustable and scalable



Site Visit Agenda

- Share structured and custom agenda prior to visit & seek input
- Review current contacts and appropriate notifications
- Discuss general sentinel lab requirements
- Discuss site specific history:
 - LPX results, rule-outs sent in, exposures or other incidents, past questions or concerns, any follow ups, etc.
- Discuss biosafety & risk assessments
 - Their process, plans, personnel
- Lab tour
 - Biothreat sample walk thru
 - Observe and discuss biosafety practices and potential hazards
 - Gives you future frame of reference
- Closing discussion

APHL Training & Resources



APHL | ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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APHL | APHL PROGRAMS | PUBLIC HEALTH PREPAREDNESS & RESPONSE | BIOSAFETY & BIOSECURITY | LAB BIOSAFETY & BIOSECURITY RESOURCES

Lab Biosafety & Biosecurity Resources

Biosafety & Biosecurity Training

Lab Biosafety & Biosecurity Resources

APHL, working in partnership with the US Centers for Disease Control and Prevention, offers tools and resources to strengthen biosafety and biosecurity practices in public health and clinical laboratories.

APHL Resources for Public Health Labs
APHL guidelines and materials for public health labs

BIOSAFETY CHECKLIST APRIL 2015

A Biosafety Checklist: Developing A Culture of Biosafety

Background

There is an inherent risk in a laboratory handling any infectious agents. Biosafety practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Recent incidents involving biosafety lapses highlight the need to enhance the culture of biosafety across the laboratory community in the United States. The Association of Public Health Laboratories (APHL) has developed A Biosafety Checklist: Developing A Culture of Biosafety to assess the biosafety measures that they have in place.

Intended Use

A Biosafety Checklist: Developing A Culture of Biosafety is intended for specimens that could contain infectious agents in the United States. It components that should be considered for inclusion in any laboratory's

1. Risk Assessment
2. Selection of Safety Practices
 - Biosafety Level
 - Engineering Controls
 - Personal Protective Equipment (PPE)
 - Laboratory Practices
3. Biosafety Competencies
4. Safety Orientation and Training
5. Audits, Monitoring and Safety Committee
6. Administrative Controls

This checklist is for your laboratory's internal use only. The questions in laboratory and do not address biosecurity practices. Some questions want to add additional questions to perform their risk assessments. The and information gained from this tool can be used to help laboratories

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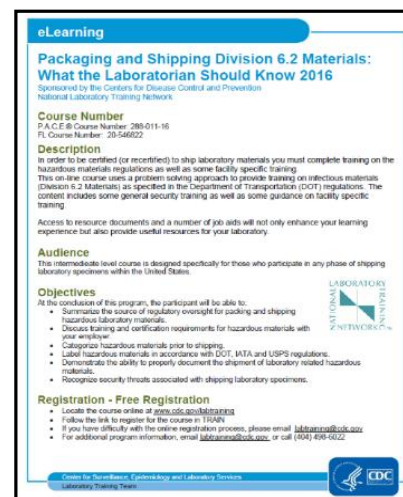
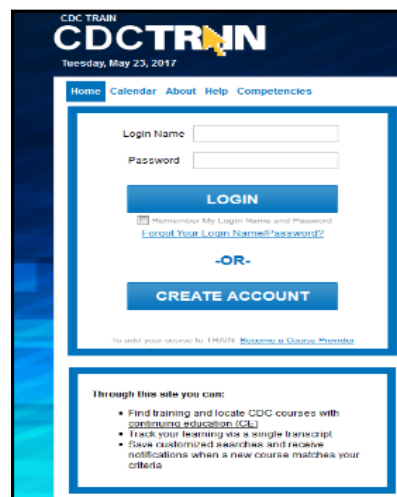
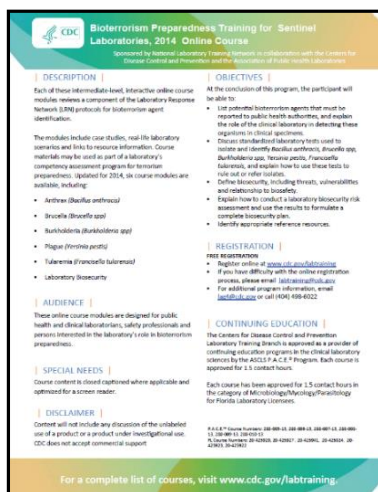
- Biosafety & Biosecurity
- Document library
- Checklists
- Trainings
- SharePoint Sites
- Active Listserv

RISK ASSESSMENT				RESOURCES	COMMENTS
Yes	No	Not Applicable			
☐	☐	☐	Is there a written policy and/or a standard operating procedure (SOP) for performing risk assessments?	Biological Risk Assessment Guidelines can be found on pages 7-12 of CDC's Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories	It is recommended that at a minimum risk assessments include: • an assessment of risks associated with specimen source and likely organisms • method of transmission, route of exposure, infectivity and infectious dose • test requested from submitter • epidemiological information such as symptoms, travel history, and occupation • risk factors and experience of individual performing the assay • when assays require inactivating BSL3/4 agents and bringing them out to a BSL2 for testing
☐	☐	☐	Do risk assessments consider both agent hazards and laboratory procedure hazards?	An example Risk Assessment form can be found on CDC's Biosafety Website .	
☐	☐	☐	Has the person performing the risk assessment received training and are they experienced in risk assessments?		Examples of trainings include the American Society of Clinical Pathology's "Using Risk Analysis to Assess Biosafety" and the American Biological Safety Association's "ABSA Advanced Biosafety Training Series Module 1"
☐	☐	☐	Is a risk assessment performed when: • new assays are introduced? • new methods are introduced? • equipment is moved? • new equipment is introduced? • the potential for aerosolization is introduced? • the potential for needledsticks is introduced? • a laboratory is physically moved? • a new pathogen is detected? • staffing changes?		
☐	☐	☐	Are risk assessments conducted annually for assays performed in the laboratory?		

<https://www.aphl.org/programs/preparedness/Biosafety-and-Biosecurity/Pages/BB-Resources.aspx>

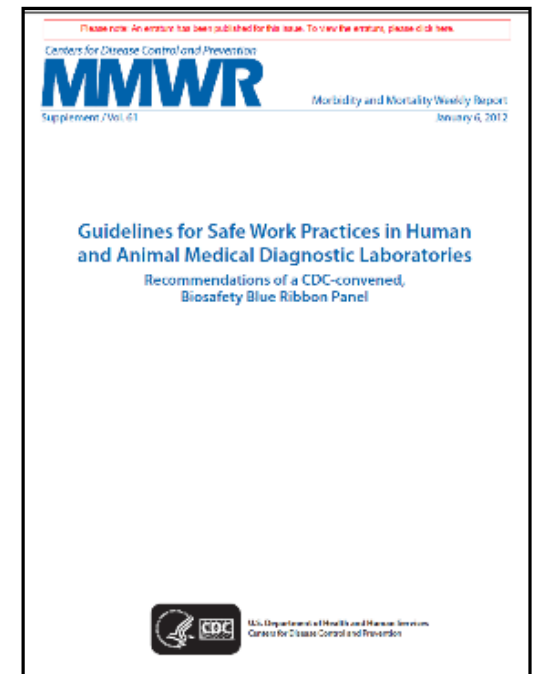
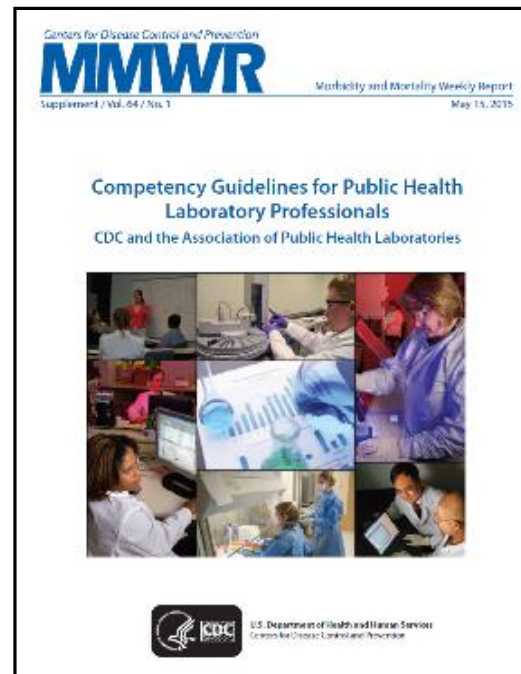
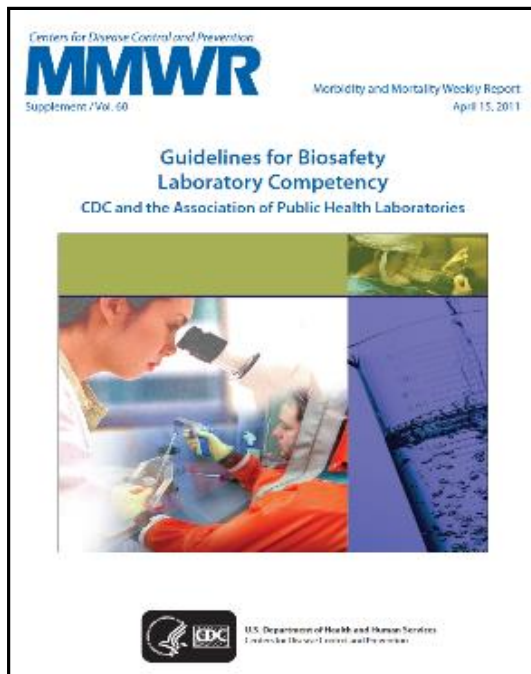
CDC TRAIN

- Free registration and online course
- 6.2 Packaging & Shipping
- Basic Microbiology Curriculum
- BT organism awareness
- Environmental & occupational safety



Relevant MMWRs

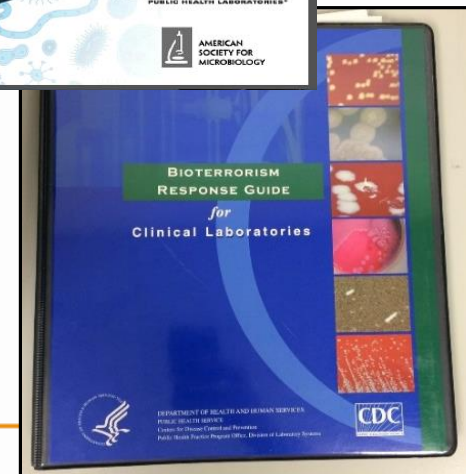
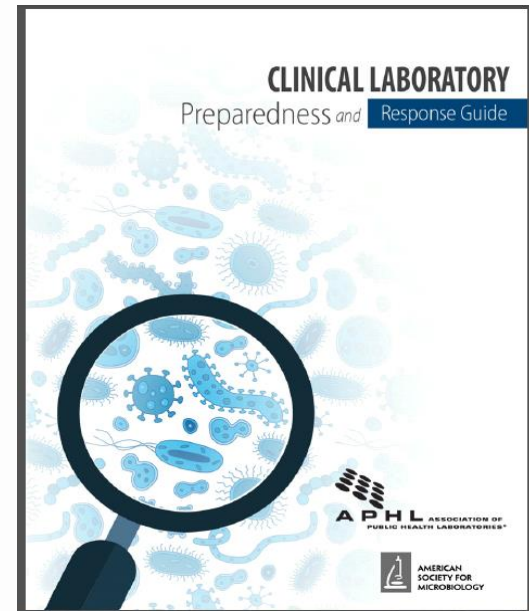
- *Guidelines for Biosafety Laboratory Competency*
- *Competency Guidelines for Public Health Laboratory Professionals*
- *Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories*



Clinical Laboratory Preparedness and Response Guide

- Updated LRN Program information
- Expanded all-hazard clinical lab preparedness scope
- Clinical laboratory regulatory references
 - Pack/Ship, Biosafety, Biosecurity, Risk Assessments, OSHA, etc.
- Valuable job aids and checklists!!!

Standardized guidance and reference manual for all sentinel labs



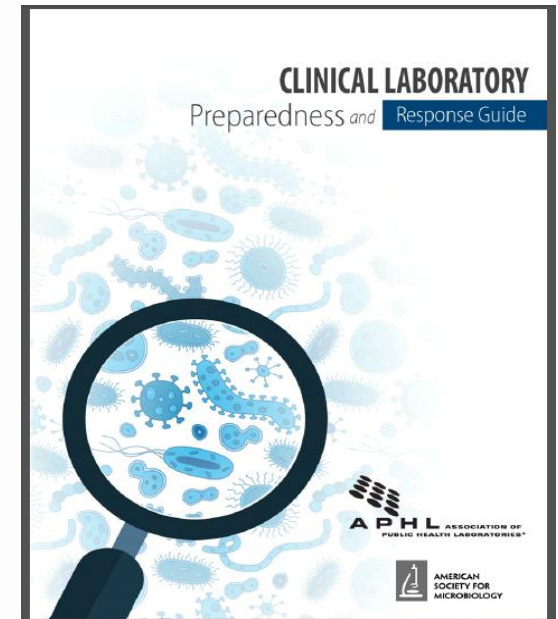
Clinical Laboratory Preparedness and Response Guide

- Budget allocation to print and distribute a copy to ALL state sentinel laboratories
- Outreach and training tool
 - Increase awareness for biosafety, biosecurity, risk assessments, packaging & shipping, clinical laboratory preparedness
 - Current, standard guidance
 - Contact updates
 - Sentinel lab resource
 - On-site discussions



Intended Sentinel Lab Use

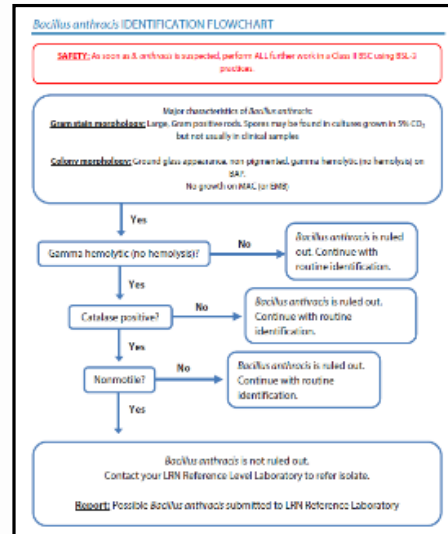
- Share the new resource internally with lab staff & with clinical partners
Lab → Epi → Infection Control → Preparedness → Other Partners
- Increase & strengthen:
 - Communications and networks
 - Plans, policies and procedures
 - Biosafety & biosecurity awareness
 - Risk assessment processes
 - Biothreat organism familiarization
 - Pack/ship capabilities
 - Regulatory awareness
 - BSL-2 & BSL-3 laboratory inspections
 - Generate ideas for well designed laboratory drills and exercises



Job Aids!!!

- Biochemical Reference Charts
- BSL-2 & BSL-3 Checklists
- Job Hazard Analysis Chart
- OSHA Poster
- Select Agent Algorithm Guide
- Select Agent Forms 2, 3 & 4
- Select Agent Suspected ID
- Pack/Ship Checklists & Guidance

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Yersinia pestis DIFFERENTIATION CHART
DIFFERENTIATION OF *Y. pestis* FROM OTHER ORGANISMS BY CONVENTIONAL MICROBIOLOGY PROCEDURES

Organism	Gram Stain	Growth on BAP	Growth on MacConkey	Oxidase	Catalase	Urease
<i>Yersinia pestis</i>	Gram negative	Slow	Non-Lactose Fermenter	Negative	Positive	Negative
<i>Yersinia pseudotuberculosis</i>	Gram negative	Slow	Non-Lactose Fermenter	Negative	Positive	Positive
<i>Yersinia enterocolitica</i>	Gram negative	Slow	Non-Lactose Fermenter	Negative	Positive	Variable
<i>Escherichia coli</i>	Gram negative	Good	Lactose Fermenter	Negative	Positive	Negative
<i>Klebsiella pneumoniae</i>	Gram negative	Very good, full non-fermenter (4h)	Lactose Fermenter	Negative	Positive	Positive/Negative
<i>Enterobacter cloacae</i>	Gram negative	Good	Lactose Fermenter	Negative	Positive	Variable
<i>Pseudomonas maltophilia</i>	Gram negative	Good	Variable	Positive	Positive	Negative

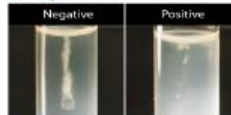
SENTINEL LABORATORY BIOCHEMICAL REFERENCE CHART

Catalase Test



3% Hydrogen peroxide: Look for bubbles.
Safety Warning: To contain potential aerosols perform in a BSC, covered petri dish or tube.
 Negative Control: *S. pyogenes* ATCC® 29635
 Positive Control: *S. aureus* ATCC® 33592/25923

Motility



Compare the uninoculated tube with the inoculated tube.
Negative: See only growth in the line of inoculum (no fuzziness or spreading and media is clear).
Intermediate: Just starting to see growth out from the line of inoculum (fuzzy) but media is still clear.
Positive: See distinct growth out from line of inoculum into the media (not clear).
Negative Control: *K. pneumoniae* ATCC® 23883/27736
Positive Control: *E. coli* ATCC® 25922

Spot Indole Test



Cinnamaldehyde reagents: Look for blue color.
Negative Control: *E. coli* ATCC® 25922
Positive Control: *P. aeruginosa* ATCC® 27853

Arginine Decarboxylase



Compare the uninoculated Base with the inoculated Base and Arginine tubes to determine color changes.
1st Step - Base only (no Arginine): Look for color change inoculated base to yellow, golden or grey yellow (see NF Base) to indicate that the organism utilized the glucose and pH decreased.
2nd Step - Arginine: Look for color change in inoculated base and arginine back to purple indicating decarboxylation of Arginine occurred and pH increased.
Negative Control - Arginine tube yellow indicating no decarboxylation: *E. coli* ATCC® 25922
Positive Control - Arginine tube purple indicating decarboxylation: *P. aeruginosa* ATCC® 27853
Non-Fermenters that are Arginine positive (suspect *Burkholderia* spp.): Color change is more subtle.

Oxidase Test



Tetramethyl reagent: Look for purple color.
Negative Control: *E. coli* ATCC® 25922
Positive Control: *P. aeruginosa* ATCC® 27853

Motility with TTC



Triphenyltetrazolium chloride (TTC): A colorless dye in the medium that turns red when bacteria reduce it.
Warning: TTC inhibits some bacteria. Look for evidence of spreading of growth away from the line of inoculum.
Negative: See only the red in the line of inoculum (no fuzziness or spreading and media is clear).
Intermediate: Just starting to see growth out from the line of inoculum (fuzzy) but media is still clear.
Positive: See distinct growth out from line of inoculum into the media (not clear).
Negative Control: *K. pneumoniae* ATCC® 23883/27736
Positive Control: *E. coli* ATCC® 25922

Packaging & Shipping

- Update and integrate technical resources for regulatory compliance
- Supply references
- Biothreat sample referral
- Job aids and checklists!!!



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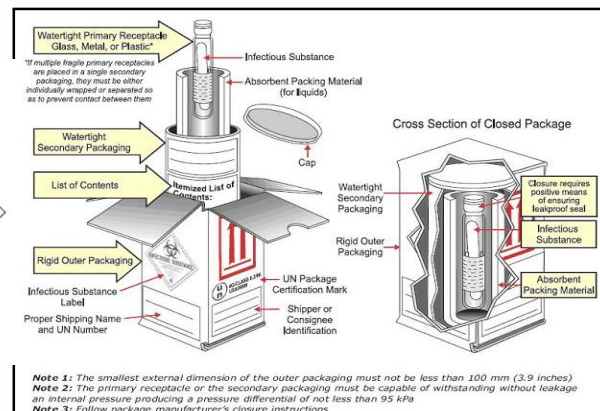
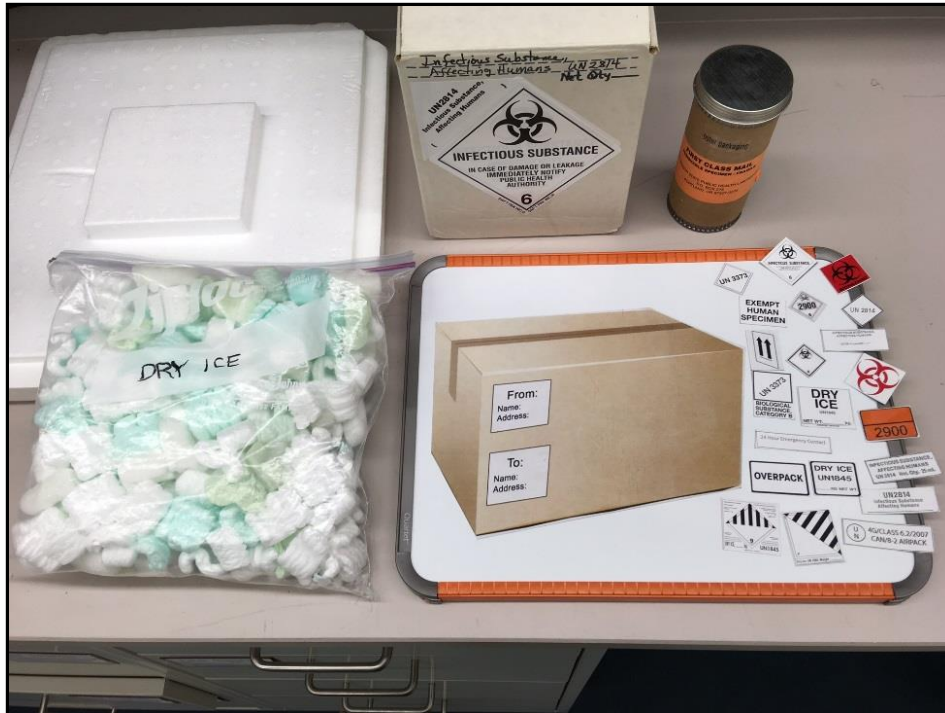


TABLE 8. SUMMARY TABLE

SHIPMENT CLASSIFICATION		Summary Table of Shipping Information							
Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Hazard Label	Packing Instruction	Max Net Qty/Plg	Packing Group	IATA Packing Instruction	AIR Transport
Category A Infectious Substance, Affecting Humans (Note: and possibly animals)	Infectious Substance, Affecting Humans (technical name of organism)	UN 2814	6.2		620	No Limit	None	620	Passenger Aircraft Max Net Qty/plg: 50ml or 50g; Cargo Aircraft Max Net Qty/plg: 4L or 4kg
Category A Infectious Substance, Affecting Animals (Note: affecting animals only and not humans)	Infectious Substance, Affecting Animals (technical name of organism)	UN 2900	6.2		620	No Limit	None	620	Passenger Aircraft Max Net Qty/plg: 50ml or 50g; Cargo Aircraft Max Net Qty/plg: 4L or 4kg
Category B Infectious Substance	Zoonotic Infectious Substance, Category B	UN 3373	6.2		650	No Limit	None	650	Passenger Aircraft Max Net Qty/plg: 4L or 4kg; Cargo Aircraft Max Net Qty/plg: 4L or 4kg
Dry Ice	Dry Ice, UN 1845, Class 9	UN 1845	9		954	200kg	None	954	Passenger Aircraft Max Net Qty/plg: 200kg; Cargo Aircraft Max Net Qty/plg: 200kg
Non-Infectious, transducing genetically modified organisms or microorganisms (GMOs)	Genetically modified microorganisms	UN 2245	9		959	No Limit	None	912	No Limit; Passenger Aircraft Max Net Qty/plg: No Limit; Cargo Aircraft Max Net Qty/plg: No Limit

NOTE: GMOs & GMOs which meet the definition of an infectious substance Category A or D and the criteria for inclusion in Class 6.2 must be transported as UN 2814, 2900 or 3373 as appropriate instead of UN2245.

Packaging & Shipping Training



- Twice a year at PHL
- At sentinel laboratories
- Regional host sites
- APHL, Pat Payne
- Free CDC online course



Biosafety & Biosecurity Training

- Biosafety & biosecurity overview
 - Risk groups and biosafety levels
 - PPE don/doff
 - Exposures and laboratory acquired infections (LAIs)
 - Biological safety cabinets (BSC)
 - Chain of custody
 - Biohazardous waste
 - BSL-3 practices in a BSL-2 lab
- Increase awareness & capacity



Biothreat Awareness Training

RECOGNIZE → RULE-OUT → REFER

- **Recognize**
 - Familiarity with biothreat organism warning signs and appropriate safety precautions
- **Rule-Out**
 - Safe, prompt, presumptive recognition steps in accordance with ASM Sentinel Lab Guidelines
- **Refer**
 - Category A shipping materials and trained staff



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Burkholderia pseudomallei CHARACTERISTICS CHART

GRAM STAIN:

- Small, straight, or slightly curved Gram negative rods (1-3 x <2.0µm)
- Smooth form arranged in long, parallel bundles
- Rough form arranged irregularly
- Bipolar staining

COLONY MORPHOLOGY:

- Smooth, creamy on Sheep Blood and CHOC agar at 24 h; may display metallic sheen on BAP, CHOC at 48 h; some become either mucoid or dry and wrinkled after 48-72 h; no violet pigment
- Pink on MAC/EMB agar at 24-48 h; will become dry and wrinkled after 48-72 h

GROWTH:

- Heavy at 42°C, at 48 h
- Resistant to colistin and polymyxin B
- Resistant to penicillin
- Susceptible to amoxicillin/clavulanic acid
- No pigment on MH agar
- Distinctive moldy or earthy odor

BIOCHEMICALS:

- Oxidase, catalase, and arginine dihydrolase positive
- Indole negative
- Glucose non-fermenter

MOTILITY:

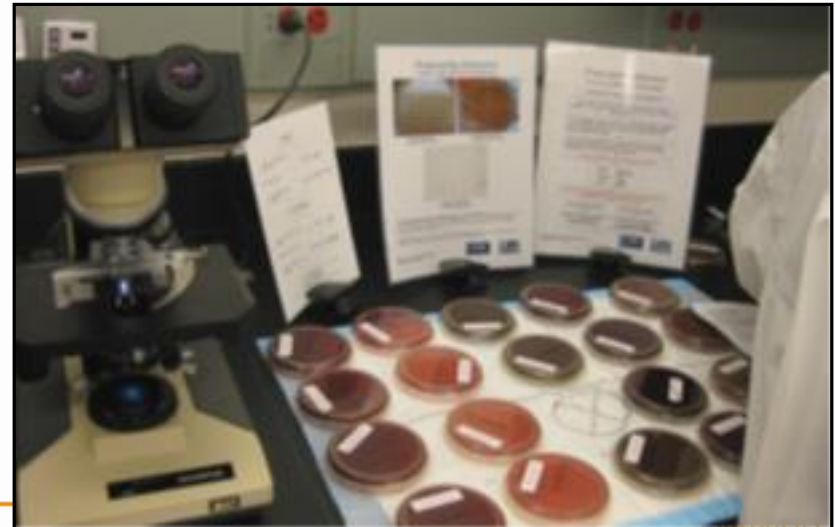
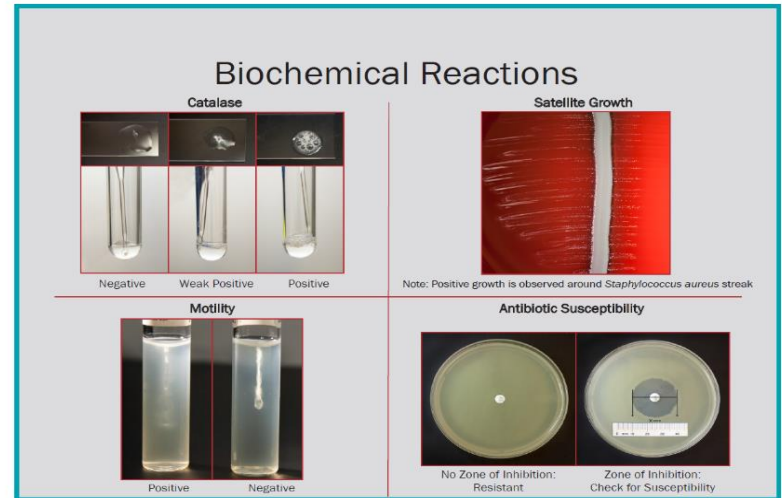
- Motile

↓

Refer Cultures to your LRN Reference Laboratory

Biothreat Awareness Training

- Provide communications, guidance & resources
 - ASM Sentinel Laboratory Protocols
 - CDC TRAIN BT courses
 - Biannual CAP LPX
 - Electronic case studies
 - Share newsworthy events
 - Wet Lab rule-out course
 - CDC Form 4 instruction
 - Select Agent algorithm

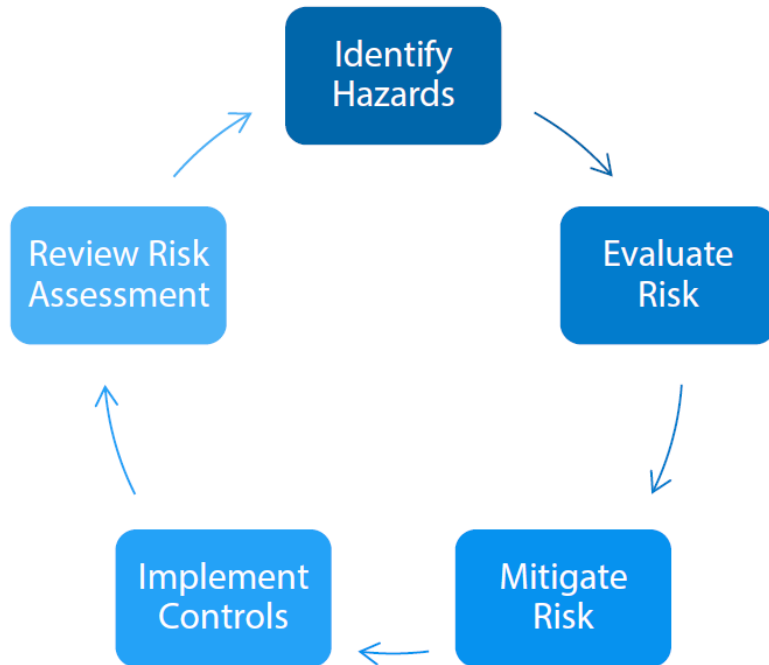


Biological Risk Assessments

- Requires management and key laboratory personnel involvement and support
- Multidisciplinary team (depending on the work)
 - Laboratorians
 - Management/supervisors
 - Health and safety specialists
 - Facility and maintenance
 - Scientists with unique expertise and experience
 - Veterinarians (if animal work)
- Reach out for support
 - OSHA, equipment manufacturers



Biological Risk Assessments



- Standardized approach, content and processes
 - Conduct, evaluate and review
- Site specific considerations!
 - Hazard identifications
 - Controls and mitigations
 - Minimize risks
 - LAI prevention
 - Infectious material handling
 - PPE, waste, BSCs, equipment, disinfection and decontamination

BSL-2 & 3 Laboratory Inspections

NLTN BIOSAFETY CHECKLIST FOR CLINICAL LABORATORIES* BIOSAFETY LEVEL 2

Facility Name: _____

Date: _____

Laboratory Name/Location: _____ Supervisor: _____

Items are based on the Biosafety Level 2 (BSL-2) Section of the *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, 2009.

Check the response that best describes the laboratory in which work will be performed.

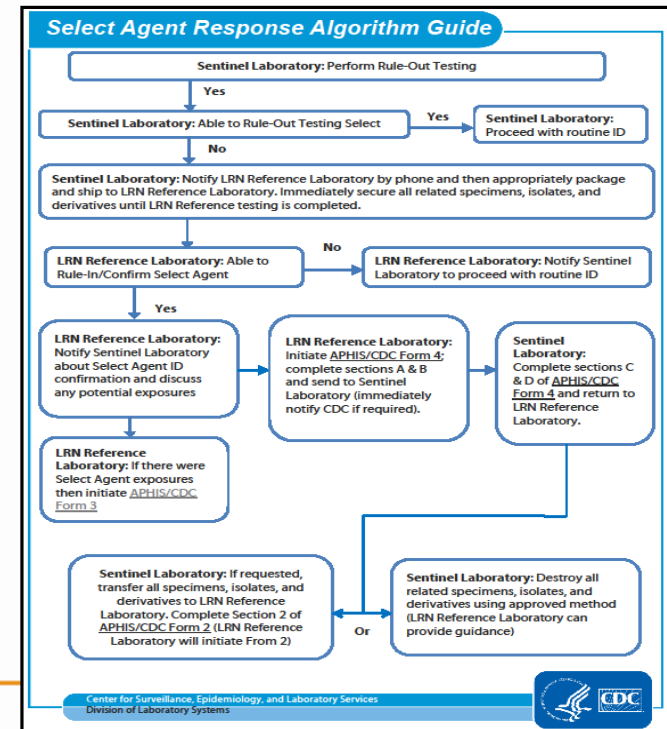
*Adapted from the Select Agent BSL-2 Checklist on the Select Agent website: <http://www.selectagents.gov/>

NA = not applicable

Reference	Statement	Response			Comments
		Yes	No	N/A	
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition HHS Publication No. (CDC) 21-1112 Revised December 2009	In developing a biosafety plan, an individual or entity should consider: The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories (BMBL)." This document is available on the National Select Agent Registry website at http://www.selectagents.gov/ and on the CDC website at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm Biosecurity should be part of a biosafety plan. The BMBL has a section on biosecurity.				
BMBL	Security should be considered and implemented to protect pathogenic agents from misuse. If a select agent has been confirmed contact your LRN reference laboratory.				
BMBL	Drills or exercises should be conducted at least annually to test and evaluate the effectiveness of the plan.				
BMBL	The plan should be reviewed annually and revised, as necessary, after any drill or exercise and after any incident.				

Enlist Support From Your Partners!

- Offer collaboration ideas and create opportunities!
 - Chemical, radiological, and food safety threats
- Exposures
 - Risk determinations, symptom monitoring, PEP follow ups
- Joint trainings, drills and exercises
 - Intelligent design and planning
- **Epi, Preparedness, Local HDs, HAI programs, Infection Preventionists, CLIA programs, HPP, PH Liaisons, HazMat**



RESOURCES!



Thank You