"Clinical Laboratory Preparedness and Response Guide – What's New?"…

(1/18/17 WCLN Webinar)

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Objectives

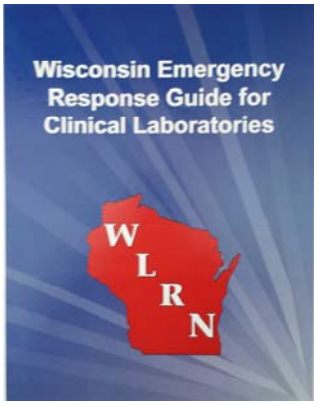
1. Explain what the "*Clinical Laboratory Preparedness and Response Guide"* is and where it can be accessed.
2. Describe at least 3 situations when your laboratory would find it useful to refer to the "Clinical Laboratory Preparedness and Response Guide.
3. Discuss some of the content that can be found in the "*Clinical Laboratory Preparedness and Response Guide"* and why it is useful for all states to use the same guidance document.

What is the Clinical Laboratory Preparedness and Response Guide?

- A reference to assist laboratories by providing guidance on the responsibilities and practices that are recommended when working with possible or known biothreat agents.
  - Tools and standards
  - Basic laboratory safety
  - Packaging and shipping
  - Regulations

Replaces the Wisconsin Emergency Response Guide for Clinical Laboratories

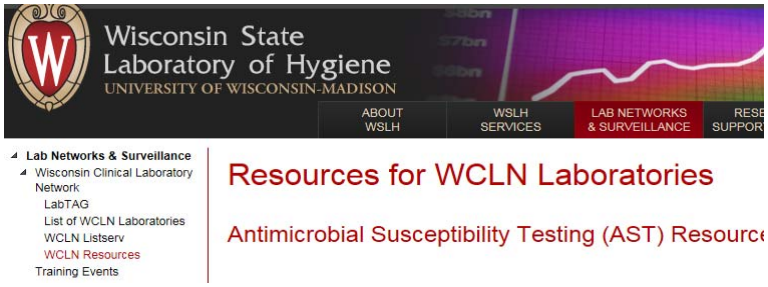
Old



New

Where Can I Access the New Document?

- Access the document on the WSLH website on the WCLN Resources webpage at:
  http://www.slh.wisc.edu/wcln-surveillance/wcln/wcln-resources/
- You will find it under the 'Emergency Response' section.

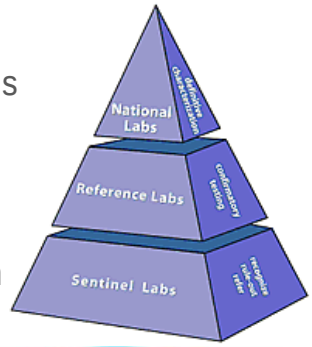


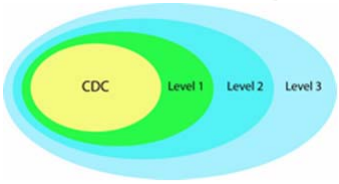
State Specific Information

- Pages 7 – 9 contain state specific emergency response information for WI
  - WSLH address
  - Link to WSLH website
  - Routine and emergency contact phone numbers
  - Links to other emergency response partners

Organization of the Document

- Table of Contents
  - Publication Date and Revisions
- State Information
- Introduction
  - How to Use
  - Sentinel Laboratory Definition & Responsibilities
  - LRN Information
  - Chemical and Radiologic Information
  - Food Safety, etc.





Biosafety Basics

Definition of Biosafety:

Biosafety is the combination of appropriate work practices, safety equipment (including PPE), and facility design employed to contain potentially infectious microorganisms and hazardous biological materials (e.g., toxins) to reduce exposure risk to workers, the environment and the public and to prevent laboratory acquired infections.

Biosafety Levels:

- There are 4 biosafety levels.
- At a minimum laboratories performing high complexity microbiology testing should be BSL-2 labs.
- For more information see the BMBL, 5th edition http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

Laboratory Exposures and Laboratory Acquired Infections (LAIs)

Routes of Infection:

- Sticks or cuts with contaminated sharps
- Spills or splashes
- Ingestion
- Indirect exposure from touching mouth or eyes with contaminated fingers or objects
- Animal bites or scratches
- Inhalation
  - **Aerosol and Droplet Production**

More Biosafety Basics

- BSL-3 Practices and When to Use in a BSL-2 Laboratory
- Biosafety Cabinet (BSC) Usage and Training
  - When to Use a BSC
  - Where to Place Your BSC
  - Safe Usage Parameters
  - BSC Clean-up
  - Demonstrating Proper Inward Airflow
- Disinfecting Work Surfaces
- Spill Clean-up
- Creating a Culture of Safety
- Decontamination of Select Agents
- Risk Assessment

Biosecurity

Biosafety	Biosecurity
Protects people from dangerous pathogens.	Protects pathogens from dangerous people.

- **Biosecurity objective:**
  To prevent loss, theft or misuse of microorganisms, biological materials, and research-related information.
- **Accomplished by:**
  Implementing policies and procedures, tracking inventory, and limiting and monitoring access to facilities, biological materials and information.
- **Risk Management:**
  Helps establish if any agents require biosecurity measures and helps ensure that the protective measures provided, and the costs associated with that protection, are proportional to the risk.

Regulations

- Select Agent Regulations
- APHIS/CDC Forms
- What To Do If You Suspect or Have a Confirmed Identification of a Select Agent
- OSHA Bloodborne Pathogens Regulations
- Clinical Laboratory Improvement Act (CLIA)

Agents
(pages 62 – 187)

- Quick Reference Guides:
  - Specimen Collection of Suspected Agents of Bioterrorism and Emerging Infections
  - Specimen Collection of Unknown Viruses
  - Specimen Collection for Botulism
  - Specimen Collection for Staphylococcal Enterotoxin B

DISEASE/ AGENT	SPECIMEN SELECTION		Time & Temp		SPECIMEN PLATING AND PROCESSING				
			Transport	Storage	BAP	CHOC	MAC	Stain	Other
Anthrax *(Bacillus anthracis)*	Cutaneous	**Vesicular Stage:** collect fluid from intact vesicles on sterile swab(s). The organism is best demonstrated in this stage.	≤2 h RT	≤24 h RT	X	X	X	Gram Stain	India Ink and slide motility NOT recommended due to safety considerations
		Eschar Stage: without removing eschar, insert swab beneath the edge of eschar, rotate and collect lesion material.	≤2 h RT	≤24 h RT	X	X	X	Gram Stain	India Ink and slide motility NOT recommended due to safety considerations
	Gastro-intestinal	**Stool:** collect 5-10 g in a clean, sterile, leakproof container.	≤1 h RT	≤24 h 4°C	Inoculate routine stool plating media plus CNA or PEA				Minimal Recovery
		Blood: collect per institution's procedure	≤2 h	Incubate per lab	Blood Culture Bottles				Positive in late stages

Agent Specific Information

Agent Specific Information (cont.)

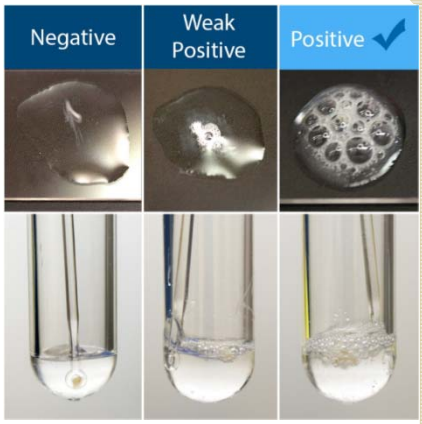
- Recommendations for Safe Laboratory Practices:
  - Blue box of Safety Considerations
  - **Warnings** posted right at the beginning
  - Links to biosafety/biosecurity publications are provided
- Disease Transmission and Clinical Presentation:
  - Symptoms

SAFETY CONSIDERATIONS:
As soon as Brucella is suspected in the laboratory, perform ALL further work within containment such as a Class II Biological Safety Cabinet (BSC) and follow BSL-3 practices

Anthrax eschar

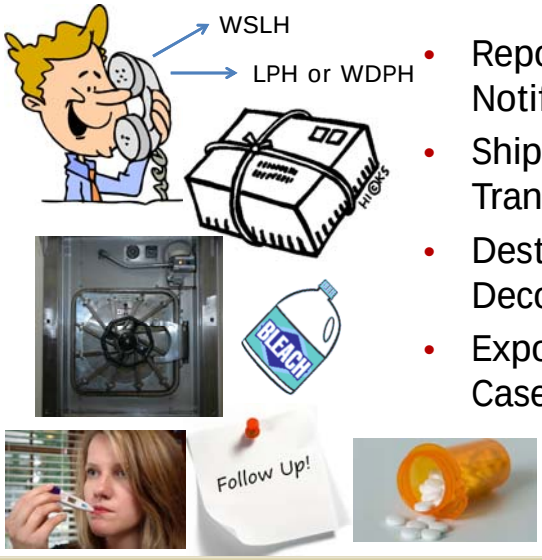
Agent Specific Information (cont.)

- Testing and Diagnostic Information:
  - Specimen Collection
  - Microscopic Characteristics (Gram stain)
  - Colonial Morphology and Growth Characteristics
  - Specific Rule-out Test Information
  - Possible Misidentifications
  - Rule-out Flowchart



Catalase testing

Agent Specific Information (cont.)



- Reporting and Notification
- Shipping and Transfers
- Destruction and Decontamination
- Exposures/Medical/ Case Definition

Agent Specific Information (cont.)

- Alphaviruses
  - Eastern Equine Encephalitis (EEE)
  - Venezuelan Equine Encephalitis (VEE)
  - Western Equine Encephalitis (WEE)
  - Chikungunya
- Botulinum Toxin (BoNT) *Clostridium botulinum*
- *Coxiella burnetii* (Q Fever)
- Orthopox Viruses (Smallpox)
- *Ricinus communis* (Ricinine)
- Staphylococcal Enterotoxin B (SEB) *Staphylococcus aureus*
- Viral Hemorrhagic Fevers (VHF)
  - Ebola

Packaging and Shipping
(pages 188 – 267)

- Introduction
- Regulatory Overview
- Required Trainings
- Transport
- Shipper's Declaration
- Transfers and Permits
- Guidance
- Supplies

Packaging and Shipping Tools

TABLE 8. SUMMARY TABLE

Summary Table of Shipping Information											
SHIPPING CLASSIFICATION					GROUND Transport		AIR Transport				
Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Hazard Label	Packing Instruction	Max Net Qty/Pkg	Packing Group	IATA Packing Instruction	Passenger Aircraft Max Net qty/pkg	Cargo Aircraft Max Net qty/pkg	Special Provisions and Restrictions
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	50mL or 50g	4L or 4kg	A81, A82, A140, (R)134
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	50mL or 50g	4L or 4kg	A81, A82, A140, (R) 134
Category B infectious substance	Biological Substance, Category B	UN 3373	6.2	UN 3373	650	No Limit	None	650	4L or 4kg	4L or 4kg	A82, (R) 134
Dry Ice	Dry Ice, or Carbon dioxide, solid	UN 1845	9		954	200kg	None	954	200kg	200kg	A48, A151, A805, (R)217
Non-infectious, transducing genetically modified	Genetically modified micro-	UN 3245	9		959	No Limit	None	913	No Limit	No Limit	A47

Appendices
(Pages 268 -332)

- Quick Reference Guide of Rule-out Flowcharts for BT Agents
- Decontamination of Select Agents in the Clinical Laboratory
- Instructions for Correctly Completing APHIS/CDC Select Agent Forms
- Select Agent Algorithm Guide
- Biosafety Checklists for Biosafety Level 2 and Biosafety Level 3 Clinical Laboratories

When Should I Use the Clinical Laboratory Preparedness and Response Guide?

- Isolate a suspect select agent
- Participate in BT challenge exercises
- Need to package and ship something outside the norm
- Looking for State specific contact information
- Looking for links to regulations

Problems Noted from October 2016 WSLH Educational Bioterrorism Proficiency Exercise

Table 1. BPE-3 Procedure Summary

Procedure	Referee Consensus	Expected Result	Participant Responses	No. of Participants
Growth on Blood agar	100%	24 hours	24 hours 48 hours	100 1
Growth on Chocolate agar	100%	24 hours	24 hours 48 hours No growth ^	98 1 1
Growth on MacConkey	96%	No growth	No growth 24 hours ^ 48 hours ^	93 6 1
Hemolysis description	100%	Not beta-hemolytic	Not beta-hemolytic	101
Gram stain	100%	Gram positive rods/bacilli	Gram positive rods/bacilli Gram negative rods/bacilli *	100 1
Catalase	96%	Positive	Positive Negative * Test not indicated *	95 1 5
Motility	82%	Negative	Negative Positive * Test not indicated *	61 13 2

* Incorrect response
^ Not scored

Use All Your Available Resources

http://www.asm.org/index.php/guidelines/sentinel-guidelines

Summary

- *The Clinical Laboratory Preparedness and Response Guide* replaces the *Wisconsin Emergency Response Guide for Clinical Laboratories* (Blue Book Binder).
- Many states collaborated on the document to ensure that all states have the exact same reference document and receive the same information to ensure a Nationwide coordinated response to an emergency situation.
- Multi-state collaboration on this project was cost effective and helpful to states that don't receive as much funding and that struggle to develop and provide training to their Sentinel Clinical Laboratories
- Laboratories are encouraged to use the on-line document that is hosted on the WSLH website on the WCLN Resources webpage under the heading 'Emergency Response'. This ensures you are always using the most up-to-date version of the document.

That's all folks!

Any Questions