Sentinels of the Lab: Ensuring Safety Across the Galaxy

Suspect BT Agents and Exposure Assessment

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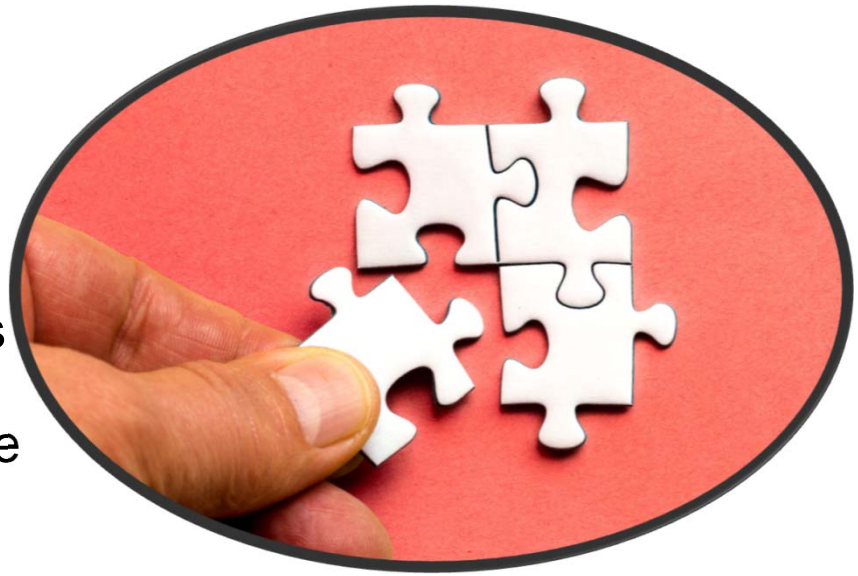
The Rebel Alliance Strategic Safety Plan

- A strategic plan is part of any initiative
- Keeping our Jedi and all other rebel alliance warriors safe as they battle the dark side of the force is a critical part of our strategic plan
- In the laboratory we call this a **biosafety plan**

Assembling the Biosafety Plan

- A biosafety plan is a tool every laboratory must have and utilize
- Laboratories often lack a specific plan for the laboratory and rely on a hospital or health system plan
  - Doesn't have the laboratory specifics needed
- Laboratories typically have many of the pieces of a great biosafety plan, but they haven't assembled the pieces to view the entire picture
- **If you don't know where your plan is, ask your supervisor and ask if it contains information on what to do after an exposure**



Contents of a Biosafety Plan

- Vaccinations
- Biosafety Training
- Competency Assessment
- Risk Assessments
- Mitigation Measures
- **Contact Information of Partners and When to Contact**
- **Incident Reporting**
- **Exposure Assessment and Monitoring Tool**
- **Root Cause Analysis Tool**
- **Outreach and Strong Effective Communications with Partners**
- **After Action Reports**

Make sure all employees know where the Biosafety Plan is kept!

Jedi Training – Staying Safe

What sources are you most likely to recover a select agent from?

A. Blood culture, sterile body fluids, upper respiratory specimens
B. Lower respiratory specimens, sterile body fluids, tissues
C. Lower respiratory specimens, wounds, blood culture
D. Wounds, sterile body fluids, urine
E. Blood culture, wounds, sterile body fluids

What sources are you most likely to recover a select agent from?

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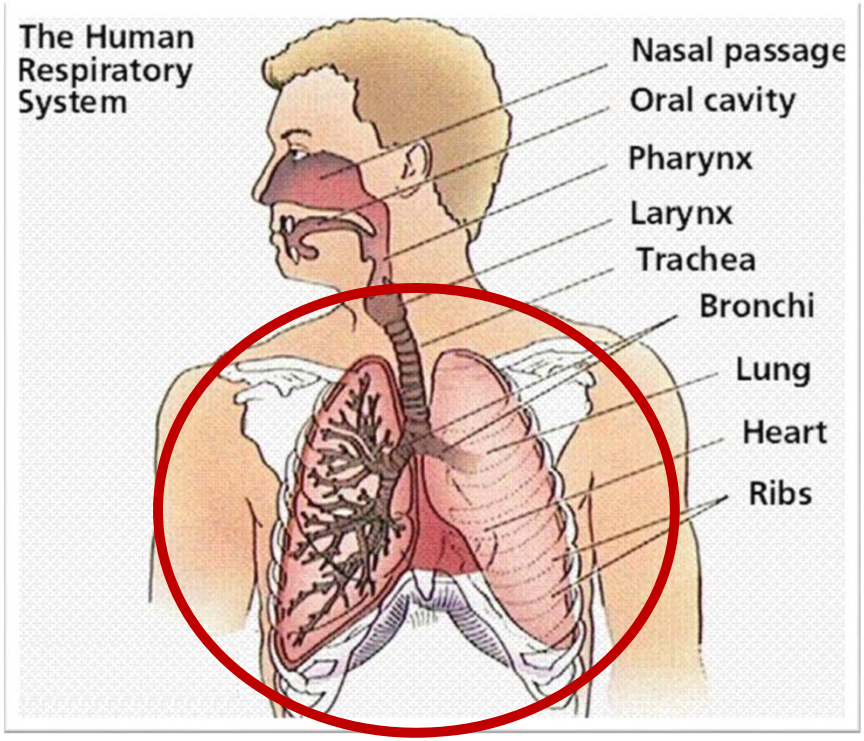
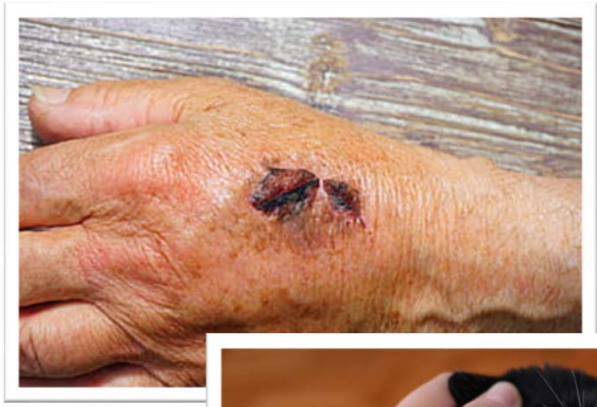
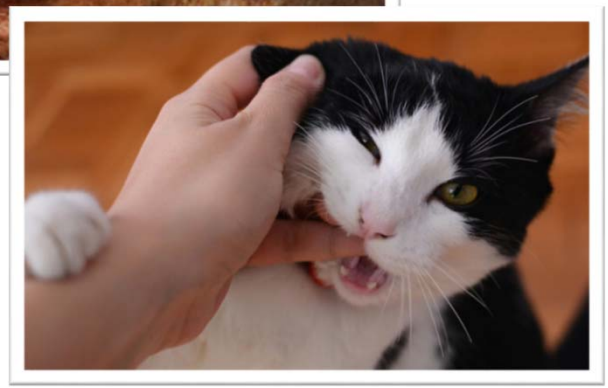
Key Sources to Stop and Ask "Could This be a BT Agent?"



Lower Respiratory tissue and fluid

Blood and possibly sterile fluid





Wounds, inclusive of animal bites

You are reading plates and you have a joint fluid culture with no growth on BLD or MAC and slight growth on Chocolate, what do you do?

A. Run it on Maldi
B. Gram stain and then run it on Maldi
C. Run it on Maldi and then do a Gram stain
D. Close the plate, check the age of the culture, check the patient history, Gram stain, and then run it on Maldi
E. Close the plate, check the age of the culture, check the patient history, move into a biosafety cabinet to do a Gram stain, and dependent on the gram stain result - **STOP** - perform rule-out testing

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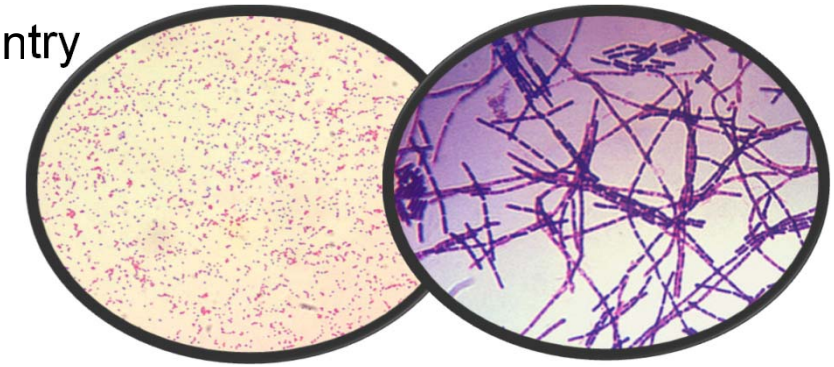
E. **Close the plate, check the age of the culture, check the patient history, move into a biosafety cabinet to do a Gram stain, and dependent on the gram stain result - STOP - perform rule-out testing**

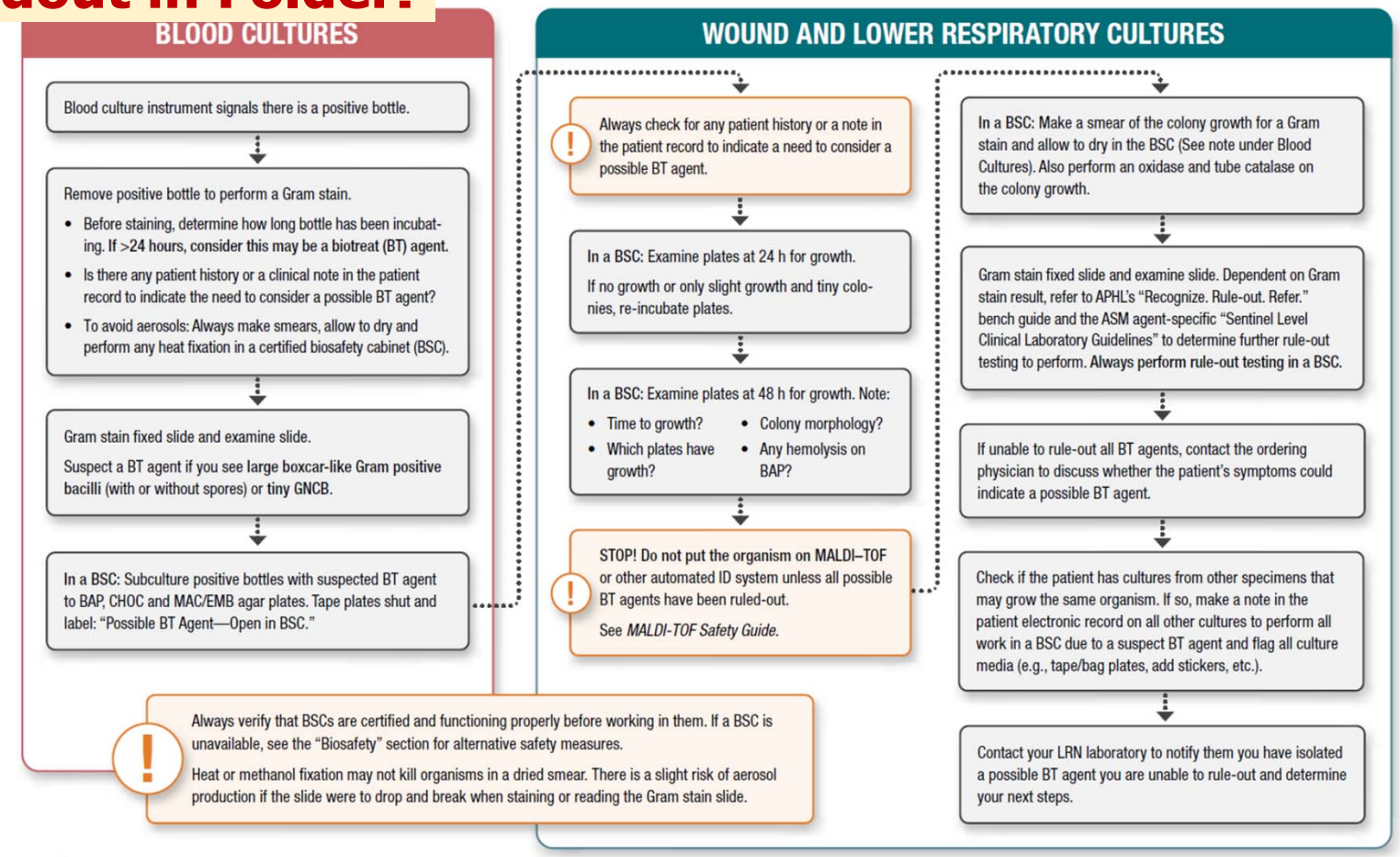
Clues You Could Be Working With a BT Agent

- Blood culture takes longer than 24 hours to grow
- No growth or just a slight haze of growth at 24 hours
- Better growth on CHOC than BLD
- Gram stain shows tiny gram-variable coccobacilli
- Gram stain shows large boxcar shaped gram-positive bacilli
- Check the patient history:
  - Patient history notes travel to or has lived in a country where BT agents are endemic
  - Patient has had an insect bite or an animal bite
  - Patient works with animals



See Handout in Folder!

BIOTHREAT AGENT BIOSAFETY AWARENESS FLOW CHART



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8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910 | www.aphl.org | 240.485.2745 (P)

Do not use MALDI until all BT agents are ruled-out!

Perform Rapid Blood Culture Identification inside a Biosafety Cabinet!

Verigene

BioFire

Remember:

When forwarding positive cultures to another laboratory for work-up, warn lab if sending a possible BT agent!

Rule-out Testing

- Work in BSC using BSL-3 biosafety practices:
  - Safety eyewear
  - N-95 or PAPR
  - Back opening gown
- Minimal rule-out testing you must perform:
  - Catalase (tube method is safest)
  - Oxidase
- Additional rule-out testing that is helpful to perform:
  - Motility (tube method is safest)
  - Urea
  - Indole
  - B-lactamase
  - Satellite

Photo courtesy of John Maniaci, UW Health

What would you do if you realized you were working outside of containment with a possible BT agent and had been exposed?

A. Call for help from the Rebel Alliance
B. Ask your coworker what to do
C. Notify a supervisor and ask for help
D. Go to your Biosafety Plan and turn to the “Laboratory Contact” section to find the list of who to contact and how to reach them
E. Go to the Emergency Department at the end of your shift

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Contact Information of Partners and When to Contact

It Takes a Team of Partners

Determine Who is Responsible for What

Connect and Communicate with Partners

- How will you communicate
- Look at the big picture
- Ask questions
- Provide guidance
- Determine action plan for follow-up treatment or prophylaxis
- Discuss disposal of any remaining organism
- Determine who is responsible for what actions
- Evaluate and determine what changes need to be made to prevent further occurrences

In the event an incident occurs, do you know what to report, what forms you need to complete, and where they are kept?

A. Yes, I know what to report, the forms I need to complete, and where they are kept.
B. Yes, I know there are forms I need to complete, but I don't know where they are kept, and I'm not sure what I need to report.
C. I don't know anything about reporting or what forms I need to complete or where I should even look for them.
D. That information is classified.
E. My supervisor will take care of this and I don't need to know.

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Incident Reporting

Never assign blame!

- What do you report?
  - Actual incidents
  - Near misses
- Who do you report to?
- How long do you have to file your report?
- What forms do you use?
- Where are the forms kept?
- Where do you go if medical follow-up is necessary?
- How do you get there?
- What do you need to bring with you?

Learning From Stories of Past Incidents

Call for Help!

The phone rings and we hear:

- “I think we have a possible BT agent…..”

Our response:

- What is the specimens source and how old is the culture?
- What media/plates is it growing on?
- What do the colonies look like?
- What is the Gram stain result?
- What testing have you done so far?
- Did you do any work outside of the biosafety cabinet?
- What do you know about the patient history?
- **Have you contacted the physician to ask about patient history and to see if the patients symptoms are consistent with an infection with this suspect agent?**
- Do you have someone who is certified in packaging and shipping to package the specimen and do you have any questions about how to package and ship a suspect Category A specimen?
- When should we expect the specimen?
- What is the patient’s name and date of birth?
- Do you have any other questions for me?

Packaging and Shipping Suspect BT Agent Isolates

- Ship as a suspect Category A package
  - Note: This requires someone who is certified in packaging and shipping Category A specimens to package and ship the specimen
- Must use proper Category A labels and shipping materials
- Must include a shippers declaration form
- Don’t forget responsible person emergency contact information
  - Must be available and answer a phone call immediately for the entire time the package is in transport
  - Must be knowledgeable of the contents of the package
  - Must be able to provide information for safe clean-up if the package breaks open or leaks

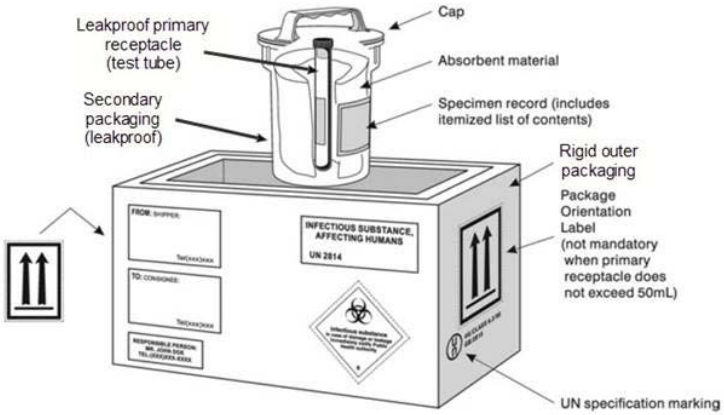
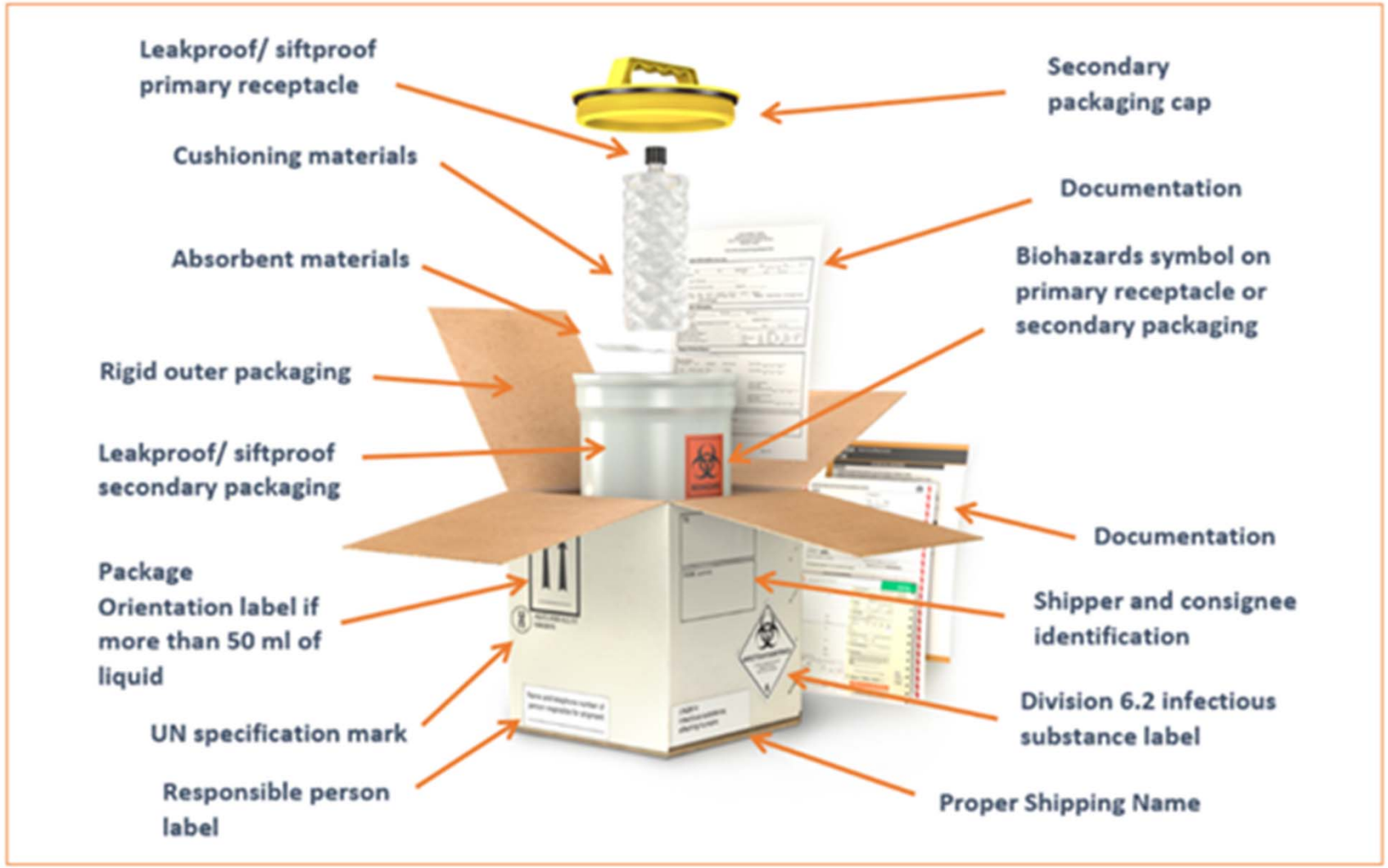


Diagram 1: Example of Category A, Ambient Temperature Shipment.



What Happens at the WSLH?

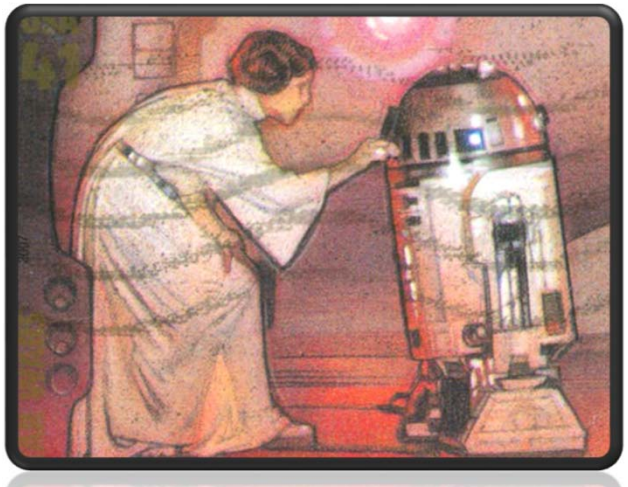
- Specific testing and the order it is performed in at the WSLH is varied and dependent on the following:
  - Likelihood of an isolate being a true BT agent
  - Age, pureness, and quality of the isolate growth
  - Urgency of testing due to possible lab exposures
- If testing is not available at WSLH, we forward to the appropriate National lab. (i.e. Botulinum toxin)

WSLH SA Testing

- WSLH subcultures the submitted isolate
- WSLH repeats rule-out testing
  - To confirm submitters results
  - To complete any rule-out testing the submitting lab may not have been able to do
  - To confirm the correct isolate was submitted
- WSLH performs agent specific PCR
  - From sub-culture in most cases
  - Directly on submitted isolate if suspicion is high
    - Only if growth is sufficient, pure, and consistent with suspected agent
- WSLH performs other conventional testing
  - Part of the definitive identification protocol
  - Depends on the organisms
  - Could include phage testing, additional biochemicals or media, motility, metabolism, etc.

*We use the CDC LRN protocols, many have FDA approval.

WSLH Notification - Positives



- WSLH will call a positive results upon identification of a specific agent
  - This may be a final or preliminary report as we work to identify the agent
    - e.g. Preliminary report - call with positive *Brucella* spp. PCR result
    - e.g. Final report - call with positive *Francisella tularensis* PCR result
  - Note the exception of *Bacillus* spp. which is never speciated, but only reported as a final report of *Bacillus anthracis,* or *Bacillus* spp. not *anthracis*
- Final Positive Report – You will receive a written report via ELR, fax, or other standard method
  - You have 24 hours to report any laboratory exposures
  - You have 7 days to complete and submit required forms to FSAP
    - We will send you a FSAP Form 4 to complete sections C and D
    - Additionally, if there were laboratory exposures, complete FSAP Form 3
  - You have 7 days to gather and destroy all cultures and media growing the organism

WSLH Notification - Negatives

- WSLH will call a negative result when we have ruled out the following select agents and toxin:
  - *Burkholderia mallei* and *B. pseudomallei*
  - *Yersinia pestis*
  - *Brucella abortis, B. mellitensis, and B. suis*
  - *Francisella tularensis*
  - *Bacillus anthracis*
  - Ebola
  - Orthopoxviruses
  - Ricin toxin
- Final Negative report– you will receive a written report telling you SAs have been ruled out
  - In rare cases, we may report the identification for a non- SA bacteria if we are able to ID by MALDI.
  - Additional identification using 16S sequencing or advanced biochemical testing is available upon request.
    - Testing is fee for service
    - May take 10-14 days for results
    - Never performed on *Bacillus* species (doesn't work)

Exposure Assessment and Monitoring Tool

CLINICAL LABORATORY BIOLOGICAL EXPOSURE EVALUATION TOOL

Potential Exposure Event Summary

Date of Potential Exposure: _____ Exposure Location(s): _____

Multiple people exposed? ☐ No ☐ Yes. *Complete this form for each person to determine individual exposure risk.*

Name/Identifier of Person Potentially Exposed: _____

Individual's Predispositions: ☐ Pregnant ☐ Immunocompromised ☐ Other: _____

What work was done by whom, where and what PPE was worn? Who else was present and how close were they?

Interactions with Organism

Individual worked with organism: ☐ Within BSC ☐ Outside BSC ☐ Did not work directly with organism

Individual did not work with organism, but was: ☐ Within five feet ☐ M

Individual wore: ☐ Gloves ☐ Lab coat/gown ☐ Safety glasses ☐

Individual performed the following activities or types of manipulation wit

- ☐ Removed caps or swabs from culture containers, opened lyophilized cultures or cryotubes
- ☐ Manipulated needles, syringes or sharps
- ☐ Flamed a loop
- ☐ Wet preps
- ☐ Rapid antigen testing
- ☐ Blood culture bottle
- ☐ Exa me
- ☐ Snif
- ☐ Cat

Exposure Event Follow-up

Treatment and Monitoring

Post Exposure Prophylaxsis (PEP): ☐ Will begin PEP ☐ Declined PEP ☐ N/A

Serological Monitoring: ☐ Will begin serological monitoring ☐ Declined ☐ N/A

Fever Watch: ☐ Yes ☐ No ☐ N/A

Other Notes:

What treatment is needed and who will be monitoring the treatment?

Corrective Actions and Mitigations

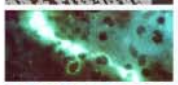
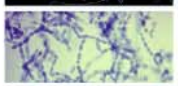
Use the risk assessment determinations above to evaluate the overall risk of exposure according to the likelihood of occurrence and severity of consequences.

[Laboratory Exposure Assessment and Symptom Monitoring Guide]

Exposure Monitoring Guide

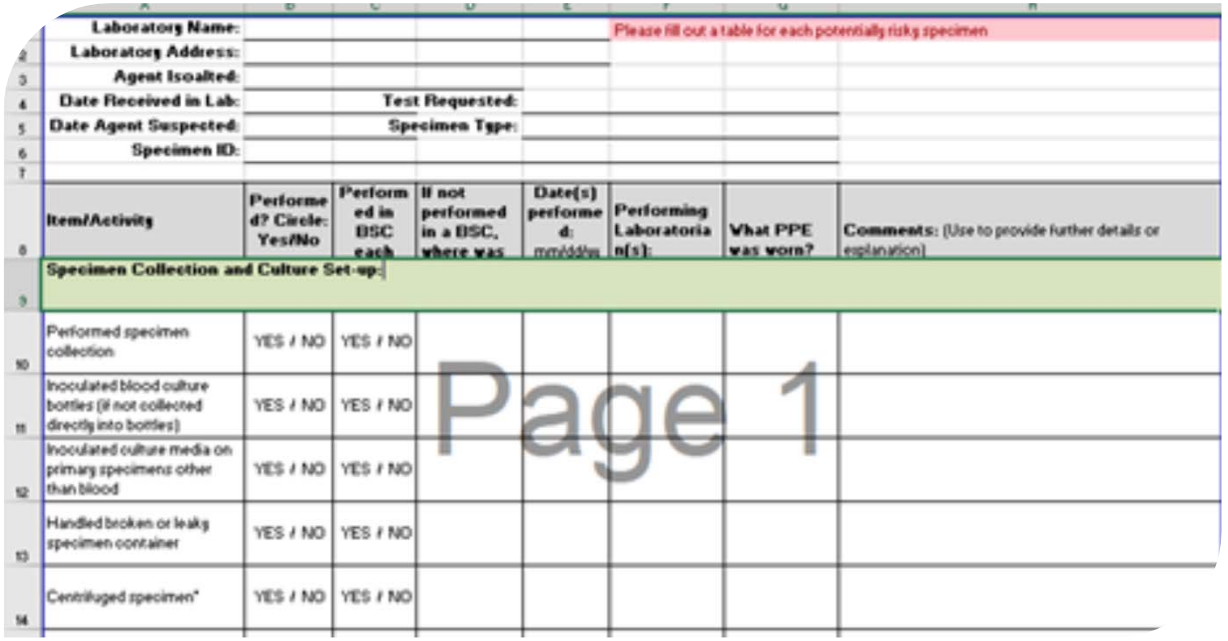
PHPR_Clinical_Laboratory_Biological_Exposure_Monitoring_Guide.pdf (aphl.org)

CLINICAL LABORATORY BIOLOGICAL EXPOSURE MONITORING GUIDE

	Disease (Organism/Agent)	Notes	Exposure Risks and Routes of Transmission in the Laboratory Setting [8]	Incubation Period	Symptoms (Will depend on route of transmission)
	Anthrax, Woolsorter's disease *(Bacillus anthracis)*	1, 5*, 8, 14	Direct and indirect contact of broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, exposure to infectious aerosols. LD50 is 2,500-55,000 for spores and will depend on the route of exposure. < 10 spores necessary for cutaneous anthrax infection.	Typically 1–6 days, with a range up to 60 days	**Cutaneous:** painless sore with black eschar. **Inhalational:** Fever and chills, chest discomfort, body aches. **Gastrointestinal:** Fever, chills, swelling of neck and neck glands, sore throat, painful swallowing, stomach pain, fainting, abdominal swelling. **Injection anthrax:** Fever, chills, blisters or bumps that may itch, painless skin sore with black eschar, swelling around sore.
	Blastomycosis *(Blastomyces dermatitidis)*	3, 14	Accidental parenteral inoculation with infected tissues or cultures of yeast form. Pulmonary infections from inhalation of conidia from mold-form cultures.	3 weeks – 3 months	Flu like symptoms, fever, cough, night sweats, myalgia (muscle pain) and arthralgia (joint pain), weight loss and anorexia, chest pain, fatigue.
	Brucellosis, Undulent fever, Malta fever, Mediterranian fever *(Brucella abortus, B. suis, B. melitensis)*	1, 5, 14	*Brucella spp.* have a very low infectious dose and are easily aerosolized. Ingestion, inhalation, accidental parenteral inoculation or contact with broken skin or mucosa. Direct exposure to samples or cultures (outside containment). ID is 10-100 organisms by aerosol or subcutaneous exposure.	5 days – 5 months	**Initial symptoms:** fever, sweats, malaise, anorexia, headache, pain in muscles, joint, and/or back, fatigue. **Chronic symptoms:** recurrent fevers, arthritis, swelling of the testicle and scrotum area, swelling of the heart (endocarditis), neurologic symptoms (in up to 5% of all cases), chronic fatigue, depression, swelling of the liver and/or spleen.
	Glanders *(Burkholderia mallei)*	1, 5*, 14	Ingestion, inhalation, accidental parenteral inoculation, and contact with broken skin or mucosa with cultures and infected tissues, purulent drainage, blood and sputum. There is increased risk for individuals with diabetes.	1–14 days	Fever with chills and sweating, muscle aches, chest pain, muscle tightness, headache, nasal discharge, light sensitivity (sometimes with excessive tearing of the eyes), ulceration at the site of localized infection, lymphadenopathy, abscess formation.
	Meliodosis, Whitmore's disease *(Burkholderia pseudomallei)*	1, 5*, 14	Ingestion, inhalation, inoculation, and direct contact via skin abrasions and mucous membranes.	1 day – years	**Localized:** Localized pain or swelling, fever, ulceration, abscess. **Pulmonary:** Cough, chest pain, high fever, headache, anorexia. **Bloodstream:** Fever, headache, respiratory distress, abdominal discomfort, joint pain, disorientation. **Disseminated:** Fever, weight loss, stomach or chest pain, muscle or joint pain, headache, seizures.
	Psittacosis *(Chlamydia psittaci)*	1, 14	Infectious aerosols in the handling, care, or necropsy of naturally or experimentally infected birds, mice and eggs.	5–14 days	Abrupt onset of fever and chills, headache, muscle aches, nonproductive cough, splenomegaly, rash.
	Botulism *(Clostridium botulinum toxin)*	1, 5*, 13	Exposure to toxin, and especially associated with activities that have high potential for aerosol or droplet formation. 0.7-0.9 µg of inhaled aerosolized toxin is likely enough to kill a 70 kg / 150 lb person.	6 hours – 10 days	Double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, difficulty breathing, thick-feeling tongue, dry mouth, muscle weakness.
	C. diff *(Clostridioides difficile)*	1, 14	Infectious aerosols are the most likely route of laboratory-associated infections (LAI) and could serve as a reservoir for vegetative cells and spores.	2–3 days	Severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea.
	Coccidiomycosis, Valley Fever *(Coccidioides immitis, C. posadasii)*	3, 14	Inhalation of spores. Rarely, contact with broken skin can cause cutaneous infection.	1–3 weeks	Fatigue, cough, fever, shortness of breath, headache, night sweats, muscle aches or pains, rash on upper body or legs.
	Q fever *(Coxiella burnetii)*	1, 5, 9, 14	Inhalation of infectious aerosols. Accidental parenteral inoculation. Exposure to experimentally or naturally infected animals, their tissues, or body fluids. ID by inhalation is ~10 organisms.	9–39 days	**Acute:** Fever, chills, myalgia, arthralgia, headache, pneumonia, hepatitis.
	Dermatophytosis, Ringworm *(Microsporum, Epidermophyton and Trichophyton)*	3, 14	Contact with skin, nail lesions, contact with contaminated surfaces.	4–14 days after skin comes in contact with fungus	Ringworm can affect skin on almost any part of the body as well as fingernails and toenails. The symptoms of ringworm often depend on which part of the body is infected, but they generally include itchy skin, ring-shaped rash, red, scaly, cracked skin and hair loss.
	Encephalitis, EEE (Eastern Equine Encephalitis virus)	2, 5, 6, 12	Inhalation of infectious aerosols, accidental parenteral inoculation. Exposure to infected animals and mosquitoes in the lab.	1–10 days	Sudden onset of headache, high fever, chills, and vomiting; severe cases may progress to disorientation, seizures, or coma.

Complete the Exposure Assessment Form

- WSLH will send an exposure assessment form to the clinical laboratory to complete and return if they get a presumptive positive for a select agent organism.
- The WSLH reviews the completed form and contacts the clinical laboratory to provide guidance on the next steps.



1	**Laboratory Name:**					Please fill out a table for each potentially risky specimen		
2	**Laboratory Address:**							
3	**Agent Isolated:**							
4	**Date Received in Lab:**		**Test Requested:**					
5	**Date Agent Suspected:**		**Specimen Type:**					
6	**Specimen ID:**							
7								
8	**Item/Activity**	**Performed? Circle: Yes/No**	**Performed in BSC each**	**If not performed in a BSC, where was**	**Date(s) performed:** mm/dd/yy	**Performing Laboratorian(s):**	**What PPE was worn?**	**Comments:** (Use to provide further details or explanation)
9	**Specimen Collection and Culture Set-up:**							
10	Performed specimen collection	YES / NO	YES / NO					
11	Inoculated blood culture bottles (if not collected directly into bottles)	YES / NO	YES / NO					
12	Inoculated culture media on primary specimens other than blood	YES / NO	YES / NO					
13	Handled broken or leaky specimen container	YES / NO	YES / NO					
14	Centrifuged specimen*	YES / NO	YES / NO					

Completion of Federal Select Agent Program (FSAP) Forms

Form 3

(Only complete if there were exposures)

- Submitting lab must notify FSAP of exposures within 24 hours of confirmed BT agent identification by WSLH
- Submitting lab completes form 3 and submits to FSAP

Form 4

(Must always complete)

- WSLH notifies FSAP of identification of a select agent.
- WSLH completes their section of Form 4 as the identifying laboratory and submits to FSAP
- Submitting lab completes their section of Form 4 as the submitting laboratory and submits to FSAP

What does the Federal Select Agent Program (FSAP) expect laboratories to do with any cultures growing a select agent?

A. Dispose of culture media in a biohazard container and follow your facilities routine disposal of biohazardous waste
B. Package and ship all positive culture media to your LRN laboratory
C. Spray cultures with a disinfectant and then place in biohazardous waste and follow your facilities routine disposal of biohazardous waste.
D. Use a validated method (autoclaving or overnight chemical disinfection with bleach) to ensure you've killed all organisms, then dispose of as you would normal biohazardous waste.
E. Call your biohazardous waste handler to see if they can autoclave the plates for you.

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Destruction of All Positive Culture Media

- Check if patient has other cultures
  - If does, warn about positive BT isolate
- Gather all positive culture media
- **All isolates and positive cultures must be killed in your facility before transporting off site for disposal**
  - **Note: medical waste hauler can't destroy for you**
- Destruction methods:
  - Autoclave – solids and liquids
  - Chemical destruction
- Destruction must occur within 7 days of confirmation of a select agent

APHL Resource: "*Clinical Laboratory Preparedness and Response Guide*"

- *Decontamination of Select Agents Isolated in the Clinical Laboratory* **(see handout)**

Decontamination of Select Agents Isolated in the Clinical Laboratory

www.aphl.org

Select Agent regulations detailed in 7 CFR 331, 9 CFR 121 and 42 CFR 73 require that material containing an identified select agent must either be **destroyed or transferred** to a select agent registered facility within 7 days from confirmation (unless an extension is granted from CDC). Select agents may only be held more than 7 days from confirmation by facilities that are registered and approved by CDC and/or USDA to possess those specific select agents. Once an isolate from a patient specimen in a non-select agent registered clinical lab has been confirmed by a registered Laboratory Response Network (LRN) reference laboratory as a select agent, within 7 days the non-registered clinical lab must either **destroy** all other relevant patient specimens and cultures remaining in their possession **or obtain permission from CDC to transfer** them to the nearest LRN reference laboratory that is registered to possess the specific select agent.

If a clinical lab chooses to **transfer the relevant specimens and cultures** after organism confirmation, the lab personnel will need to work with their LRN reference laboratory to ensure the proper paperwork (e.g., APHIS/CDC Form 2) and transfer protocols are followed in compliance with all applicable local, state, and federal shipping regulations, and carrier/courier requirements **prior to transport**. Transfer considerations should be discussed between clinical laboratories and LRN reference laboratories *before* LRN reference testing is conducted to avoid some potential shipping restrictions or dilemmas. If a facility does not have an autoclave on-site and chooses not to chemically decontaminate the cultures, all positive cultures including blood culture bottles must be transferred to an appropriate select agent registered laboratory approved and willing to accept the specific select agent material.

Please Note These Items!

"**If a non-registered clinical lab decides to destroy the relevant specimens and cultures in-house, inactivation using an on-site autoclave or chemical decontamination method must be performed before final disposal or transferring the items to a contracted medical waste hauler for destruction and final disposal.** Specimens associated with an identified select agent cannot be directly discarded into the biohazardous waste stream like other regulated infectious medical waste materials because the material would be classified as Category A waste and restricted according to both the select agent regulations and the US Department of Transportation Hazardous Material Regulations (49 C.F.R., Parts 171-180). **Autoclaving is the preferred method of destruction, however when an autoclave is not available, chemical decontamination may be the only feasible option.** For both chemical inactivation decontamination procedures below, the clinical laboratory should **note the date, amount/quantity of material being destroyed, method of destruction, and the laboratorian(s) performing the procedures for record keeping purposes."**

"Non-registered clinical labs are not required to have a validated select agent inactivation protocol but may use these decontamination and destruction procedures as a recommended best practice."

Chemical Inactivation Decontamination Process for Samples and Cultures

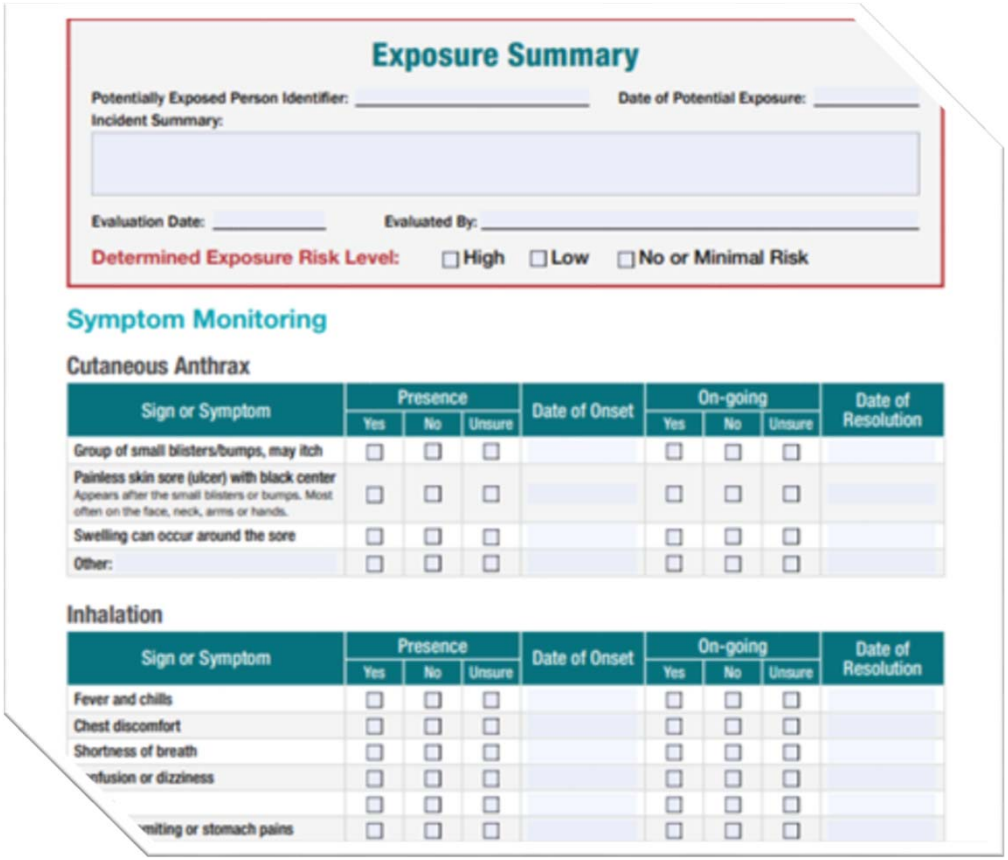
1. Prepare a fresh (daily) **10% (1:10) solution** of household bleach in a receptacle large enough to submerge all containers/plates containing the select agent specimen(s).
2. Working in a biological safety cabinet (BSC), **slowly** and completely immerse open sample/culture containers in the bleach solution.
3. Leave the open and submerged containers in the bleach solution overnight in the BSC and post a warning/safety sign for it.
4. Once overnight inactivation is complete, turn the sink faucet on and discard the bleach solution down the drain with running tap water.
5. Place the inactivated sample/culture plates and containers in a biohazard bag and discard them with the other biohazardous waste that is transported off site by a medical waste management contractor for final treatment and disposal.

Chemical Inactivation Decontamination Process for Blood Culture Bottles

1. Bring all needed materials into a BSC including the blood culture bottle(s), a syringe, and a small amount of **undiluted household bleach (e.g., ~50mL per blood culture bottle to decontaminate).**
2. Working in a BSC, the blood culture bottles can be chemically decontaminated by adding straight (not diluted) household bleach to the bottle to obtain a final concentration of 1-2% sodium hypochlorite (20 - 40% household bleach and ~10,000 ppm available chlorine) within the bottle. The higher undiluted bleach concentration works well for inactivation and accounts for the large amount of organic material present.
3. Cover the top of the bottle with a disinfectant soaked gauze pad (e.g., 10% bleach) to contain any splashes and slowly inject the undiluted bleach into the bottle(s) through the gauze pad.
4. Discard the used syringe in the sharps container inside the BSC.
5. Let the bottle(s) sit overnight in the BSC and post a warning/safety sign for it.
6. Package the inactivated bottle(s) with other biohazardous waste that is transported off site by a medical waste management contractor for final treatment and disposal.

Exposure Monitoring and Prophylaxis

- APHL guide and poster are very useful for exposure monitoring
- Provides specific information on some of the most common disease organisms/agents
- Prophylaxis may be a choice that is offered to those who have been exposed.
  - Employee may want to consult with their personal physician to weigh the pros and cons
- If only monitoring, who will be responsible for tracking and keeping records?



Exposure Summary

Potentially Exposed Person Identifier: _____ Date of Potential Exposure: _____

Incident Summary:

Evaluation Date: _____ Evaluated By: _____

Determined Exposure Risk Level: ☐ High ☐ Low ☐ No or Minimal Risk

Symptom Monitoring

Cutaneous Anthrax

Sign or Symptom	Presence			Date of Onset	On-going			Date of Resolution
	Yes	No	Unsure		Yes	No	Unsure	
Group of small blisters/bumps, may itch	☐	☐	☐		☐	☐	☐	
Painless skin sore (ulcer) with black center Appears after the small blisters or bumps. Most often on the face, neck, arms or hands.	☐	☐	☐		☐	☐	☐	
Swelling can occur around the sore	☐	☐	☐		☐	☐	☐	
Other:	☐	☐	☐		☐	☐	☐	

Inhalation

Sign or Symptom	Presence			Date of Onset	On-going			Date of Resolution
	Yes	No	Unsure		Yes	No	Unsure	
Fever and chills	☐	☐	☐		☐	☐	☐	
Chest discomfort	☐	☐	☐		☐	☐	☐	
Shortness of breath	☐	☐	☐		☐	☐	☐	
nfusion or dizziness	☐	☐	☐		☐	☐	☐	
	☐	☐	☐		☐	☐	☐	
miting or stomach pains	☐	☐	☐		☐	☐	☐	

[Laboratory Exposure Assessment Guide (aphl.org)]

Does Your Laboratory Perform a Root Cause Analysis After a Laboratory Exposure Occurs?

A. Yes
B. No
C. I don’t know what management does
D. What is a root cause analysis?
E. Both C & D

Determine Root Cause

- **Ask 5 "whys" to get to the underlying root cause of the problem?**

Problem:
Why was there an exposure?

Why?

Aerosol created when spotting isolate for Maldi-TOF ID on open bench

Why?

Trying to get rapid results to physician for patient care and no Gram stain performed on isolate

Why?

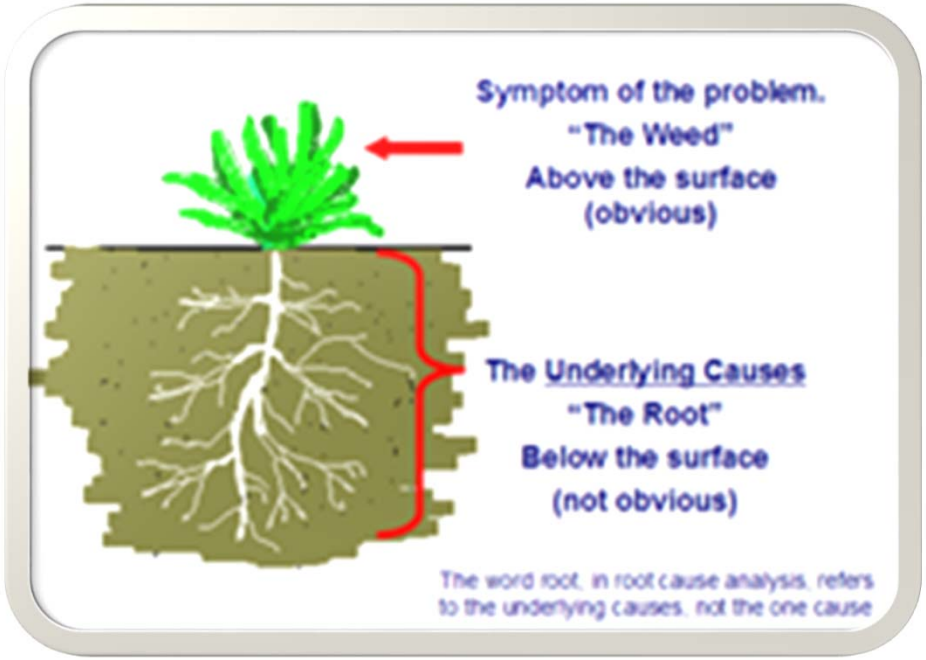
Didn't suspect a BT agent from a synovial fluid inoculated into a blood culture bottle

Why?

No policy in place to do a Gram stain routinely before performing Maldi-TOF

Why?

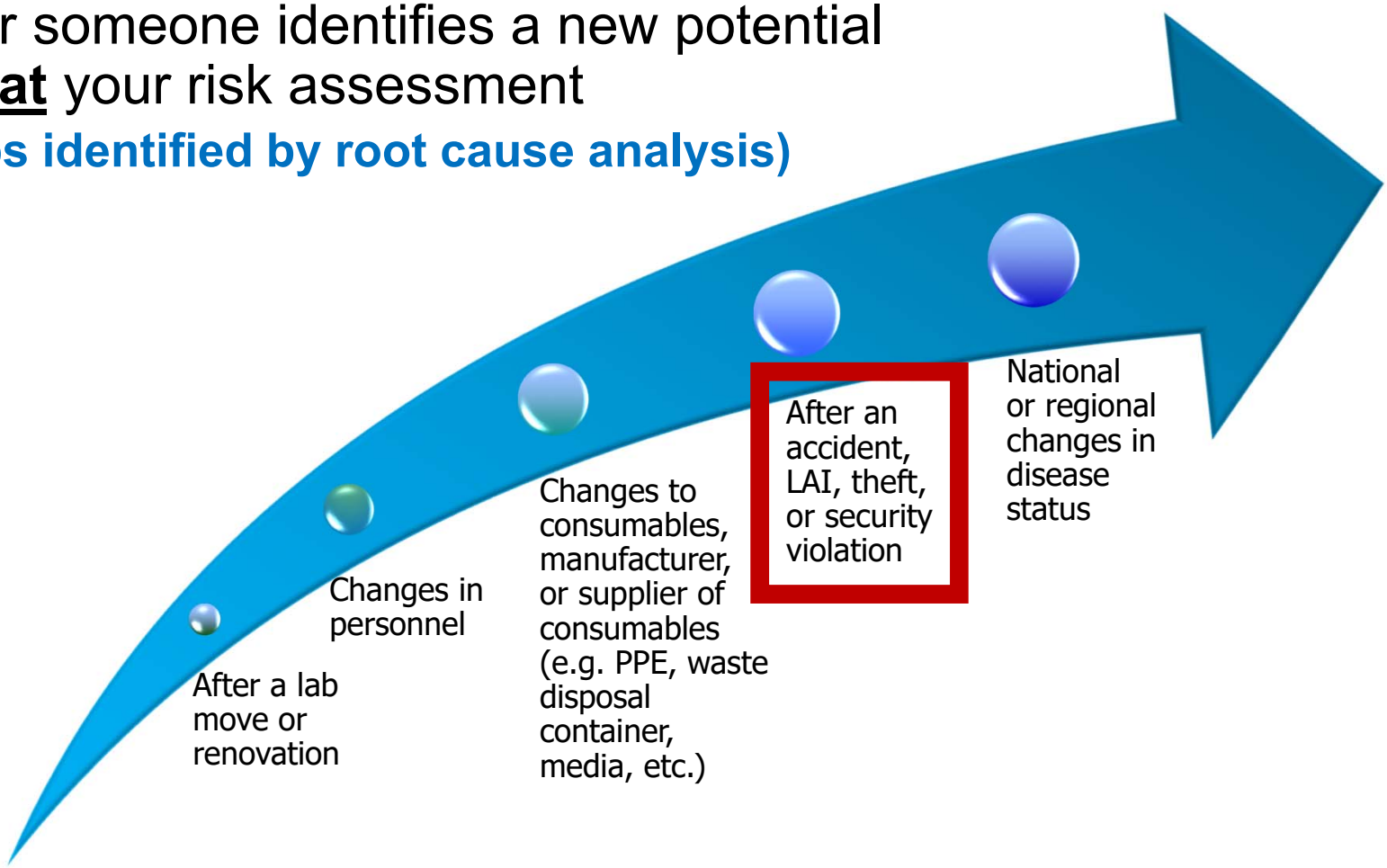
Missed clues of slow growth and never checked patient history



Root Cause: Speed more important than safety?

When Do You Repeat a Risk Assessment?

- Whenever someone identifies a new potential risk, **repeat** your risk assessment
  (e.g. Gaps identified by root cause analysis)



Repeat Risk Assessment

- What new hazards were identified in the root cause analysis?
  - Emphasis is on speed to ID in a high volume laboratory. People working in a hurry don't pay attention to age of culture and just spot any growth onto a Maldi plate and hope for a rapid ID
- Evaluate the risk
  - High risk
- What else can be done to mitigate the risk?
  - Spot all Maldi plates in a BSC on slow growing isolates
  - Make a Gram stain at the same time and let it dry in the BSC
  - Fix, stain and read the Gram stain before running the isolate on the Maldi
  - Provide training stating it is OK to slow down to assess specimen source, time to growth, and other clues that you may be working with a BT agents or high consequence pathogen
- Implement controls
- Review effectiveness and continue to adjust as needed

Always Keep in Mind the GOAL!

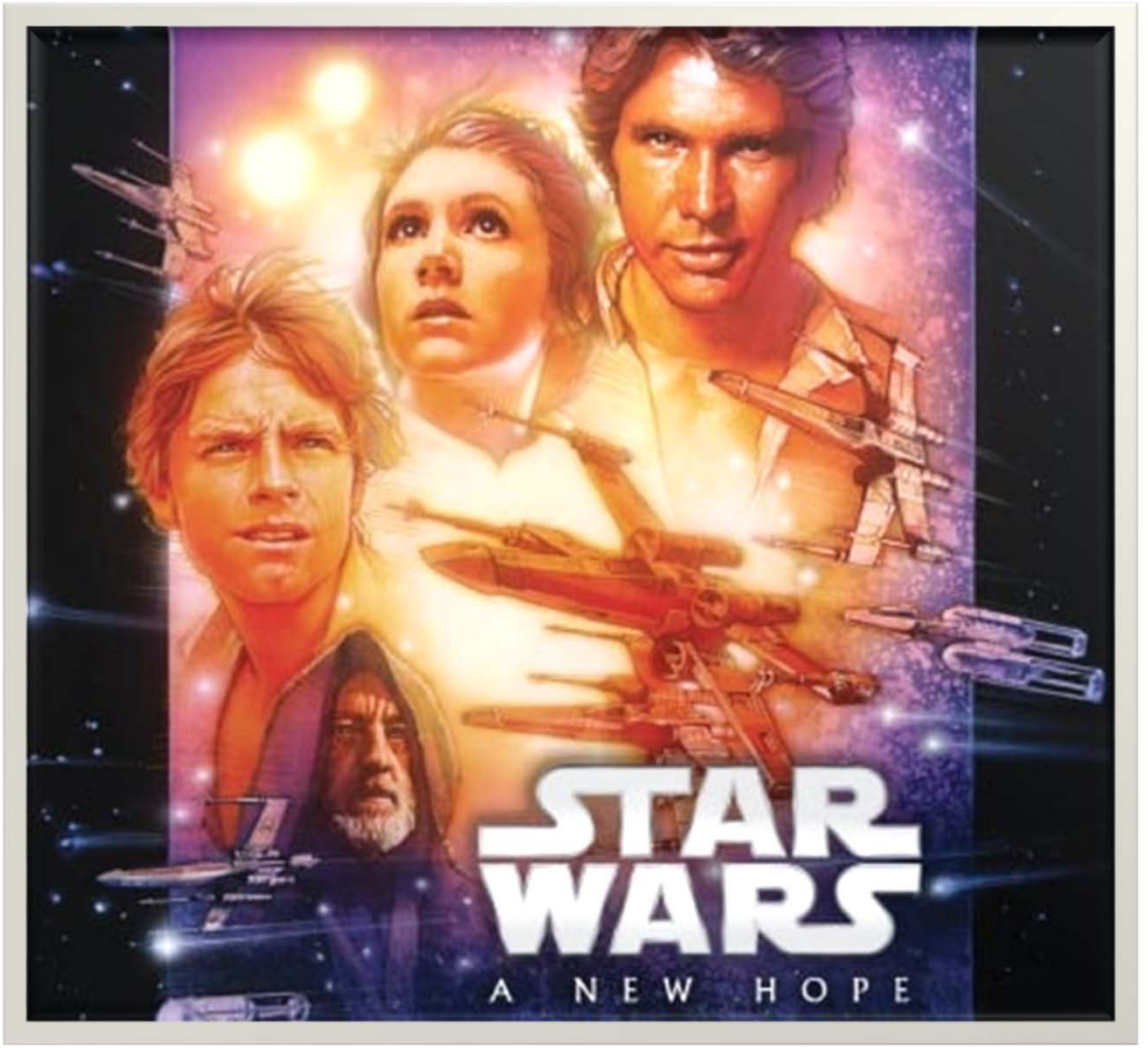
- No matter what the pathogen, protecting our most valuable asset:
  - Our lab professionals
- Preventing laboratory associated infections (LAIs)

Jedi and our Laboratory Rebels

Key Points to Remain with the Force

- A biosafety plan is a strategic plan for the laboratory that contains all the information on how we work to keep employees safe.
- Biothreat agent biosafety awareness training provided initially upon hire and thereafter as part of your yearly refresher training is critical in preventing laboratory exposures.
- Identify your exposure response team members in advance of an incident; detail each person's responsibilities, and keep their contact information in a location all employees know and can easily access.
- The WSLH is your LRN reference laboratory partner and a member of your exposure response team. Contact us during office hours at 800-862-1013. After hours contact our emergency pager at 608-263-3280.
- We assist you in the identification of suspect biothreat agents, the identification of lab exposures, and can provide guidance in completion of required forms and the destruction of the organism before disposal.
- Perform a root cause analysis after an exposure event to identify gaps and then repeat your risk assessment to determine further mitigations to address the gaps.


QUESTIONS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