

Bioterrorism Agents and Responsibilities of Sentinel (Level "A") Laboratories ***Methodist Medical Center Sentinel Laboratory***

Principle

On September 11, 2001, the CDC issued a Terrorist Activity Response Alert to public health agencies to monitor for any possible unusual disease patterns associated with the terrorist attack, including chemical and biological agents.

In a suspected or confirmed bioterrorism (BT) event, immediate and effective communication with all appropriate institutional and medical personnel, and public health officials is imperative. The laboratory is most likely to be the first to recognize that an organism isolated is a possible agent of bioterrorism.

The Illinois Department of Public Health began training programs in 2002 entitled "Response to Bioterrorism: Laboratory Methods for the Detection of Microbial Agents." The goals of the program were to educate Level A or Sentinel laboratories in the role of screening potential bacterial bioterrorism agents, referral of possible agents to other laboratories in the Laboratory Response Network for identification confirmation, and proper shipment of infectious agents in general.

The Laboratory Response Network for Bioterrorism (LRN) is a consortium and partnership of laboratories that provide immediate and sustained laboratory testing and communication in support of public health emergencies, particularly in response to acts of BT. The LRN is currently comprised of local, state, and federal public health laboratories in addition to private and commercial clinical laboratories, and selected food, water, agricultural, military, and veterinary testing laboratories. Other key federal partners are the FBI, Department of Defense, EPA, USDA, Department of Justice, Department of Energy, the FDA, the APHL, the NIH and the American Association of Veterinary Lab Diagnosticians, and the ASM. Their goals are to provide prompt and rapid initial response.

Clinical laboratories play a critical role in the LRN. Their heightened awareness to the possibility of recovering the agents of BT from patient specimens and referral of suspect isolates to the appropriate public health reference laboratory is crucial.

Hospitals and communities have also prepared for possible BT events. Methodist Medical Center has developed a policy (82A) titled Terrorism Preparedness Plan-Plan Eagle. It is written in conjunction with the Homeland Security Act and the laboratory participates in this plan utilizing the LRN as necessary.

UnityPoint Methodist/Proctor Microbiology laboratory is defined as a Sentinel (Level A) laboratory. We follow Biosafety Level 2 guidelines. Our primary responsibility is to recognize and rule out or refer suspicious bacterial agents by following standardized Sentinel laboratory guidelines provided on the ASM web site using the following link: http://asm.org/index.php?option=com_content&view=article&id=6342&Itemid=639. All suspicious isolates would be shipped to the Illinois Department of Public Health for complete identification. The Sentinel laboratory is not responsible for and should not make the decision that a BT event has occurred; that responsibility rests with local, state, and federal health and law enforcement officials.

Clinical Significance

Bioterrorism (BT) is defined as the "intentional use of microorganisms, or toxins, derived from living organisms, to produce disease and death in humans, animals, or plants." A bioterrorism (BT) event may be either overt or covert.

An **overt** attack would be accompanied by an announcement that a specific agent was released. These attacks elicit an immediate response by law enforcement and HAZMAT personnel. Public health officials will also be involved to assist in evaluating the risk and control of the disease. Samples (environmental, food, water, and animals) for testing would be submitted directly to a public health reference laboratory, usually a state health laboratory.

A **covert** attack involves the release of an organism or toxin without an announcement. Days or weeks may pass before the release is noticed. A cluster of disease appearing after the incubation period would probably signal the event. Emergency departments may be the first to observe unusual patterns of illness, while clinical laboratories would almost certainly detect the first case of disease and raise suspicion of a possible event. Organisms isolated by the clinical laboratory must be forwarded to the appropriate LRN reference laboratory, and public health officials are to be notified of the suspicious event that may be indicative of a bioterrorism incident. Public health officials in concert with law enforcement officials would determine if an attack has occurred, in addition to confirming the identification of the agent, and institute protective and preventive measures designed to minimize the spread of disease.

Specimen

Refer to the Specimen section of each Bioterrorism agent including: Bacillus anthracis, Brucella species, Yersinia pestis, Francisella tularensis, Botulinum toxin. (Check web site, favorites ASM Policy for other possible agents)

Also refer to comprehensive tables in Appendix C.

Reagents

Refer to the Specimen section of each Bioterrorism agent including: Bacillus anthracis, Brucella species, Yersinia pestis, Francisella tularensis, Botulinum toxin. (Check web site, favorites ASM Policy for other possible agents)

Instrumentation/Equipment

Bactec FX
Biological Safety Cabinet
Incubators 35-37C Ambient and CO2
Incinerators
Light Microscope with 10X, 40X and 100X objectives and 10X eyepiece
Inoculating loops
Microscope slides and coverslips
Slide warmer

Quality Control

Quality control requirements are listed with each reagent or identification system used in our laboratory. Also refer to quality control suggestions for some seldom performed testing procedures listed in the quality control section of the procedure for each BT agent.

The CAP Laboratory Preparedness Survey is a non-graded survey utilized to familiarize and train technologist in microbiology to recognize characteristics of BT agents.

Procedure

1. The manager or microbiology staff must be notified immediately that a suspected BT specimen or agent is in the laboratory. Laboratory workers are to be informed promptly of the name and medical record number of the person(s) with the suspected infection and, if appropriate, to treat other specimens from the patient(s) appropriately. This must be done in a manner that is in compliance with the Health Insurance Portability and Accountability Act (HIPAA).
2. All suspected BT specimens are to be processed in the biological safety cabinet located in microbiology section while wearing appropriate personal protective equipment, such as gown, gloves, and mask.
3. Each of the plates, tubes, and blood culture bottles for which this applies must be labeled prominently: **“Possible highly infectious agent: Suspect [fill in name of agent]”**
4. All plates that have been streaked for culture or subculture will be sealed with parafilm and labeled as in step 3 above.
5. Any growth from specimens is to be manipulated in the biological safety cabinet while wearing appropriate personal protective equipment, such as closed-front gown, gloves.
6. As the culture is being worked up, the technologist(s) working on the culture(s) must be in close touch with the microbiology supervisor and medical director.
7. An identification of the organism is **NOT** the role of the Sentinel microbiology laboratory. An organism that is consistent with, for example, *Yersinia pestis*, will be forwarded to a LRN Reference or higher laboratory (IDPH Springfield) for definitive identification. **Do not perform any more manipulation of the cultures than is absolutely essential.**
8. Key characteristics for each of the BT agents is listed in **Appendix A** or refer to AMS.org website using the following link:
http://asm.org/index.php?option=com_content&view=article&id=6342&Itemid=639

9. Additional information can be found at the Illinois Department of Public Health website idph.state.il.us/bioterrorism.
10. When a BT agent is suspected, then the isolate is referred to the Illinois Department of Public Health. Notification that the isolate is being sent is essential. Notify IDPH Springfield when sending any suspect isolate.
11. Follow the Shipping and Handling Guidelines for Infectious Materials. Our referral specialists are trained to ship infectious and diagnostic specimens and are re-trained every two years. (documentation on file)
12. Therapy of BT Agents: In the setting of a BT event, the specific treatment and prophylaxis will likely be forthcoming from the Public Health Authorities. In absence of this information, a good source for treatment and prophylaxis is:
Gilbert DN, Moellering RC, Sande MA. The Sanford Guide to Antimicrobial Therapy. 34th ed. Table 1B: Prophylaxis and treatment of organisms of potential use as biological weapons, page 46. (A copy of this guide is available in our laboratory and can also be accessed on the follow web site: (<http://www.sanfordguide.com/>))

Reporting Results

1. If a possible BT agent is grown in the laboratory or detected by other laboratory means, place phone calls to the responsible physician and the following individuals noted below immediately.
OR
2. If a specimen is submitted for detection of a BT agent as the result of a possible BT event, place phone calls to the individuals noted below immediately.

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|---|---|
| A. Theresa King, Manager | 671-2547 |
| B. Richard Borge, Administrative Director | 671-8218 |
| C. Devendra Trivedi, Medical Director | 672-4919 or Clinical Pathologist (check rotation)
Methodist Campus |
| D. Adam Quinn, DO Medical Director | 691-1060 Proctor Campus |
| E. Tammy Cooper, Infection Preventionist | 671-2192 |
| F. Terry Schadt, Hospital Safety Officer | 672-4250 |
| G. Peoria Health Department | 679-6022 |
| H. Illinois Department of Public Health | (217) 782-7860 (Springfield) - 24 hour (217) 782-6562 |

Procedural Notes/Problem-Solving Tips

- A. In no case should the Sentinel laboratory accept environmental (powders, letters, packages), animals, food, or water specimens for examination, culture, or transport for bioterrorism associated agents. Follow outline in Hospital policy 82A - Plan Eagle
- B. All Powders with threats call the FBI (312) 431-1333 (Chicago)
- C. Technical consults with Roman Golash, Bioterrorism unit IDPH,(312) 793-1571
- D. Shipping questions 217-524-6222 (Springfield Lab)
- E. IEMA Hotline 800-782-7860
- F. State Infectious Diseases (217) 782-6562
- G. CDC Biosafety 404-639-3883

- H. Appendix A –Biosafety in Microbiological and Biomedical Laboratories 5th Edition
- I. For additional information on BT agents not include in this procedure refer to ASM Policy web site which is stored in Favorites on the computer in Microbiology and the manager's office.

References

- A. Sentinel Laboratory Guidelines for Suspected Agents of Bioterrorism. ASM Policy web site. http://asm.org/index.php?option=com_content&view=article&id=6342&Itemid=639
- B. Basic Diagnostic Testing Protocols for Level A Laboratories. CDC, ASM, APHL. ASM Policy web site.
- C. Packaging & Shipping of Infectious and Hazardous Materials, Terry W. Oldfield, MBA, MT (AMT) IDPH. Update 2002 Bioterrorism Level A tests, Roman G. Golash, Bioterrorism unit, IDPH

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REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
0	Reviewed and signed	T Smith	6/24/11
0.1	Contact info updated	T King	6/30/13
0.2	Updated personnel contact information and Appendix A- to include all relevant information (replacing prev A-F)	J Corpus	4/20/2015
0.3	Previously labeled: Microbiology: 19 -	L. Racsa	9/9/15

Reviewed

Reviewed by	Date	Coordinator	Date	Medical Director	Date
		<i>T Smith</i>	6/24/11	<i>Dmckrogh MD</i>	7/1/11
		<i>Theresa R King</i>	6/30/13	<i>Dmckrogh MD</i>	6/30/13
		<i>Jan Corpus MT (ASCP)</i>	4/20/15	<i>Dmckrogh MD</i>	4/20/15