

Michigan 2011 CAP LPX-B Survey Analysis

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Introduction

The College of American Pathologist (CAP) Laboratory Preparedness Exercise (LPX) survey provides clinical laboratories with an educational exercise that can be used to help prepare for the detection of pathogens of public health importance, including pathogens that might be used as biothreat (BT) agents. Another purpose of the LPX is to prepare participant laboratories for effective and efficient communication of critical information related to potential BT agents to public health authorities.

This report summarizes the results of the Michigan Laboratory Response Network (LRN) Sentinel Laboratories on the 2011 LPX-B survey panel in aggregate and compares Michigan lab responses to those of participating labs throughout the country.

Performance Summary

The LPX survey consists of organism identification (rule out) plus a notification component to test communications between LRN Sentinel Laboratories and LRN Reference Labs. In these exercises, LRN Sentinel Labs are required to contact their LRN Reference Lab if, after following the established Sentinel Laboratory Guidelines on a challenge isolate, they are unable to rule out an agent of bioterrorism. Both organism rule out and notification are summarized below.

Approximately 40% of Michigan sentinel labs participated in the 2011 LPX-B survey. We congratulate participating laboratories for a job well done and encourage all laboratories to consider enrolling in this worthwhile educational exercise.

The 2011 LPX-A survey contained the following samples:

LPX-04	<i>Burkholderia thailandensis</i>
LPX-05	<i>Yersinia pestis</i>
LPX-06	<i>Listeria monocytogenes</i>

Correct Result Reporting LPX-A		N = 43
Sample Number	% of MI Labs with Intended Response	
LPX-04	76.74% (33/43)	
LPX-05	81.39% (35/43)	
LPX-06	95.35% (41/43)	

Notification Drill Results

Notification Drill LPX-A			
Sample Number	Notification Required	% MI Labs Indicating Would Notify the LRN Ref Lab	% MI Labs Actually Notified the LRN Reference Lab
LPX-04	Yes	100% (34/34) ^	73.53% (25/34) ^
LPX-05	Yes	100% (35/35) #	80% (28/35) #
LPX-06	No	7.3% (3/41) ▽	2.4% (1/41)

^ All laboratories unable to rule out a BT agent in this sample indicated they would notify their LRN Reference Lab. N = 34 as 34 labs could not rule out a BT agent.

All laboratories unable to rule out a BT agent in this sample indicated they would notify their LRN Reference Lab. N=35 as 35 labs could not rule out a BT agent.

▽ Although notification was not necessary in these cases, it is great that sentinel labs are willing and able to communicate with their LRN Reference Lab. N=41 as 41 labs reported this challenge as Non-BT culture.

Analysis by Sample

LPX-04: <i>Burkholderia thailandensis</i>		
Submitted Answers	Michigan Participants	All Participants
§ <i>Burkholderia</i> sp., refer to rule out <i>Burkholderia pseudomallei</i>	12/43 27.91%	263/1357 19.4%
§ Gram-negative bacillus, rule out <i>Burkholderia pseudomallei</i>	21/43 48.84%	594/1357 43.8%
Non-BT Culture	9/43 20.93%	198/1357 14.6%
Gram-negative coccobacillus, refer to rule out <i>Brucella</i> sp.	1/43 2.33%	-

§ Acceptable response for Sentinel Laboratories

LPX-05: <i>Yersinia pestis</i>		
Submitted Answers	Michigan Participants	All Participants
§ <i>Yersinia pestis</i> , confirmed	0/43 0%	57/1356 4.2%
§ <i>Yersinia pestis</i> , refer for confirmation	4/43 9.3%	148/1356 10.9%
§ <i>Yersinia</i> sp., refer to rule out <i>Yersinia pestis</i>	6/43 13.95%	286/1356 21.1%
§ Gram-negative bacillus, refer to rule out <i>Yersinia pestis</i>	25/43 58.14%	661/1356 48.8%
Non-BT Culture	8/43 18.6%	157/1356 11.6%

§ Acceptable response

LPX-06: <i>Listeria monocytogenes</i>		
Submitted Answers	Michigan Participants	All Participants
§ Non-BT culture	41/43 95.35%	1314/1353 97.1%
<i>Bacillus</i> sp., rule out <i>Bacillus anthracis</i>	1/43 2.33%	-
Gram-negative bacillus, refer to rule out <i>Yersinia pestis</i>	1/43 2.33%	-

§ Acceptable response

Discussion

LPX-04

This challenge contained *Burkholderia thailandensis* in pure culture. *B. thailandensis* is a mimic for *Burkholderia pseudomallei*, the two species being indistinguishable using the Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases screening tests. Thus the intended response would differ depending upon the participant's role within the LRN. The intended response for Sentinel Laboratories was either *Burkholderia* sp., refer to rule out *Burkholderia pseudomallei* or Gram-negative bacillus, refer to rule out *Burkholderia pseudomallei*. The intended response for LRN Reference Laboratories was Non-BT Culture.

Seventy-six percent of Michigan laboratories responded with the intended response. Nine laboratories ruled out all BT agents. One laboratory suspected the challenge contained a *Brucella* species.

Burkholderia pseudomallei is a cause of naturally occurring infections with endemic areas in Southeast Asia through Northern Australia and an increasing number of naturally occurring infections on the India subcontinent, and Central and South America. With increasing travel to these areas of the world, clinical laboratories may encounter *B. pseudomallei* as naturally occurring infections.

Since *B. pseudomallei* has the potential for use as a BT agent, notification of Public Health as soon as possible is needed for epidemiologic investigation. Use of the Sentinel Laboratory Guideline will facilitate timely reporting and minimize the potential for laboratory acquired infections. Automated and kit systems are not recommended for use as they are not particularly accurate and may increase the risk of laboratory acquired infection.

Participants who did not achieve the expected results for this challenge should review their laboratory protocols and QC records. If participants did not perform key tests as outlined in the Sentinel Laboratory Guideline, their protocols should be reviewed for the application of appropriate testing for potential BT agents. If your laboratory desires refresher training on any of the LRN Rule Out Procedures, please contact the Michigan Department of Community Health Bureau of Laboratories Bioterrorism Coordinator, Valerie Reed, via e-mail at ReedV@michigan.gov.

The results of this challenge required notification of the LRN Reference Laboratory. All Michigan participating laboratories who could not rule out a biothreat agent, stated they would complete this notification. However, only 73% of Michigan participating laboratories actually did notify their LRN Reference Laboratory. **Remember, Sentinel Labs MUST actually contact their LRN Reference Laboratory when a biothreat agent cannot be ruled out. It is not sufficient to simply state you would make that contact.**

LPX-05

This challenge was a simulated blood specimen from a patient presenting with inguinal lymphadenopathy and fever after cleaning a chicken coop in New Mexico. The specimen contained *Yersinia pestis* in pure culture. The intended response would differ by the participant's role within the LRN. The intended response for Sentinel Laboratories was either *Yersinia pestis*, refer for confirmation; *Yersinia* sp., refer to rule out *Yersinia pestis*; or Gram-negative bacillus, refer to rule out *Yersinia pestis*. The intended response for LRN Reference Laboratories was *Yersinia pestis*, confirmed.

Yersinia pestis has the potential for development as a BT agent, so notification of Public Health authorities to further epidemiologic investigation as soon as possible is needed.

Michigan Department of Community Health
Bureau of Laboratories
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With endemic areas within the United States, participant laboratories may encounter *Y. pestis* as naturally occurring zoonotic infections. Using the Sentinel Laboratory Guideline will facilitate timely reporting to Public Health authorities and minimize the potential for laboratory acquired infection.

Over 80% of Michigan labs participating in this survey responded with an acceptable response indicating they were not able to rule out *Yersinia pestis*. However, eight Michigan laboratories indicated they had ruled out all agents of bioterrorism and reported this challenge as “Non-BT Culture.” Participants in LPX exercises are required to contact their LRN Reference Laboratory if, after performing the established Sentinel Laboratory Guidelines on a challenge isolate, they are unable to rule out an agent of bioterrorism. This challenge required notification of the LRN Reference Laboratory. All Michigan laboratories who could not rule out a biothreat agent indicated they would contact their LRN Reference Laboratory. However, only 80% of participating Michigan laboratories actually contacted their LRN Reference Laboratory. **Remember, Sentinel Labs MUST actually contact their LRN Reference Laboratory when a biothreat agent cannot be ruled out. It is not sufficient to simply state you would make that contact.**

Participants who did not achieve expected results on this challenge should review their laboratory protocols and QC records. Participants who did not perform key tests outlined in the Sentinel Level Clinical Microbiology Laboratory Guideline should review their protocols for the application of appropriate testing for potential BT agents. If your laboratory desires refresher training on any of the LRN Rule Out Procedures, please contact the Michigan Department of Community Health Bureau of Laboratories Bioterrorism Coordinator, Valerie Reed, via e-mail at ReedV@michigan.gov.

LPX-06

This challenge was a simulated blood specimen which contained *Listeria monocytogenes* in pure culture. The intended response was “Non-BT Culture.” Nationally, the majority of participants appropriately managed this sample. 97.1% of all laboratories replied with an intended response.

Over ninety-five percent of the 43 Michigan laboratories who participated in this survey responded with an acceptable response indicating this was not a potential biothreat agent. One Michigan laboratory indicated the presence of a gram-negative bacillus and said they would refer to an LRN Reference Laboratory for rule-out of *Yersinia pestis*. Another Michigan laboratory reported this challenge as containing a *Bacillus* species and said they would refer it to an LRN Reference Laboratory to rule out *Bacillus anthracis*. The Gram stain of *L. monocytogenes* would show small, non-spore forming gram-positive bacilli, distinct from the Gram stain of *B. anthracis*, which shows large gram-positive bacilli. Spores may be seen with *B. anthracis*.

Participants who did not achieve expected results on this challenge should review their laboratory protocols and QC records. If your laboratory desires refresher training on any of the LRN Rule Out Procedures, please contact the Michigan Department of Community Health Bureau of Laboratories Bioterrorism Coordinator, Valerie Reed, via e-mail at ReedV@michigan.gov.

This challenge should not have triggered a communication with participant's LRN Reference Laboratory. However, in Michigan, *Listeria monocytogenes* is a reportable disease. As such, if isolated from a patient sample, it would require reporting to your local health department and patient isolates of *L. monocytogenes* would be required to be submitted to MDCH BOL.

A complete list of Michigan Reportable Diseases can be found on the MDCH BOL webpage at http://www.michigan.gov/documents/Reportable_Disease_Chart_2005_122678_7.pdf

Comparison between Michigan 2009, 2010, and 2011 Notification Drill Results

Michigan Notification Results		
Year	Lowest % of MI Labs that Actually Notified the LRN Reference Lab When Notification Required	Highest % of MI Labs that Actually Notified the LRN Reference Lab When Notification Required
2009	41.9%	53.5%
2010	56.8%	72.7%
2011	67.4%	80%

It is great to see the upward trend in percent of participating Michigan laboratories who actually notify their LRN Reference Laboratory when a BT agent cannot be ruled out.

Participation in Drills and Exercises

As noted in the 2011 LPX-A final critique, the lack of laboratory participation in drills and exercises is a concern. Drills and exercises provide an opportunity to determine preparedness and practice response. BT drills can be performed in multiple ways, paper-based table-top exercises, computer simulation, and/or operational drills.

National BT Drill Participation Over the Last Two Years		N=1360
	Drill Type	% ∞
	Internal (within your laboratory)	20.5
	Internal (within your institution)	29.2
	External (involving outside agencies)	32.6
	Did not participate in BT drill in past two years	42.4

Michigan BT Drill Participation Over the Last Two Years		N=43
	Drill Type	% ∞
	Internal (within your laboratory)	9.3
	Internal (within your institution)	37.2
	External (involving outside agencies)	23.3
	Did not participate in BT drill in past two years	48.8

∞ Does not total 100% as some laboratories participated in multiple types of drills.

Our concern still exists for the lack of participation in drills and exercises in Michigan laboratories. Of the 45 Michigan laboratories participating in the 2011 LPX-A survey, 17 (37.7%) did not participate in drills or exercises in the last two years. Of the 43 Michigan laboratories participating in the 2011 LPX-B survey, 21 (48.8%) did not participate in drills or exercises in the last two years. If your laboratory wishes to discuss participation in a bioterrorism drill or exercise, please contact the Michigan Department of Community Health Bureau of Laboratories Bioterrorism Coordinator, Valerie Reed, via e-mail at ReedV@michigan.gov.

Thank you for participating in the CAP LPX Exercise. Over time, improvement has been made by participating laboratories in both the testing and notification components of these exercises providing Michigan with improved biothreat agent detection and preparedness status.