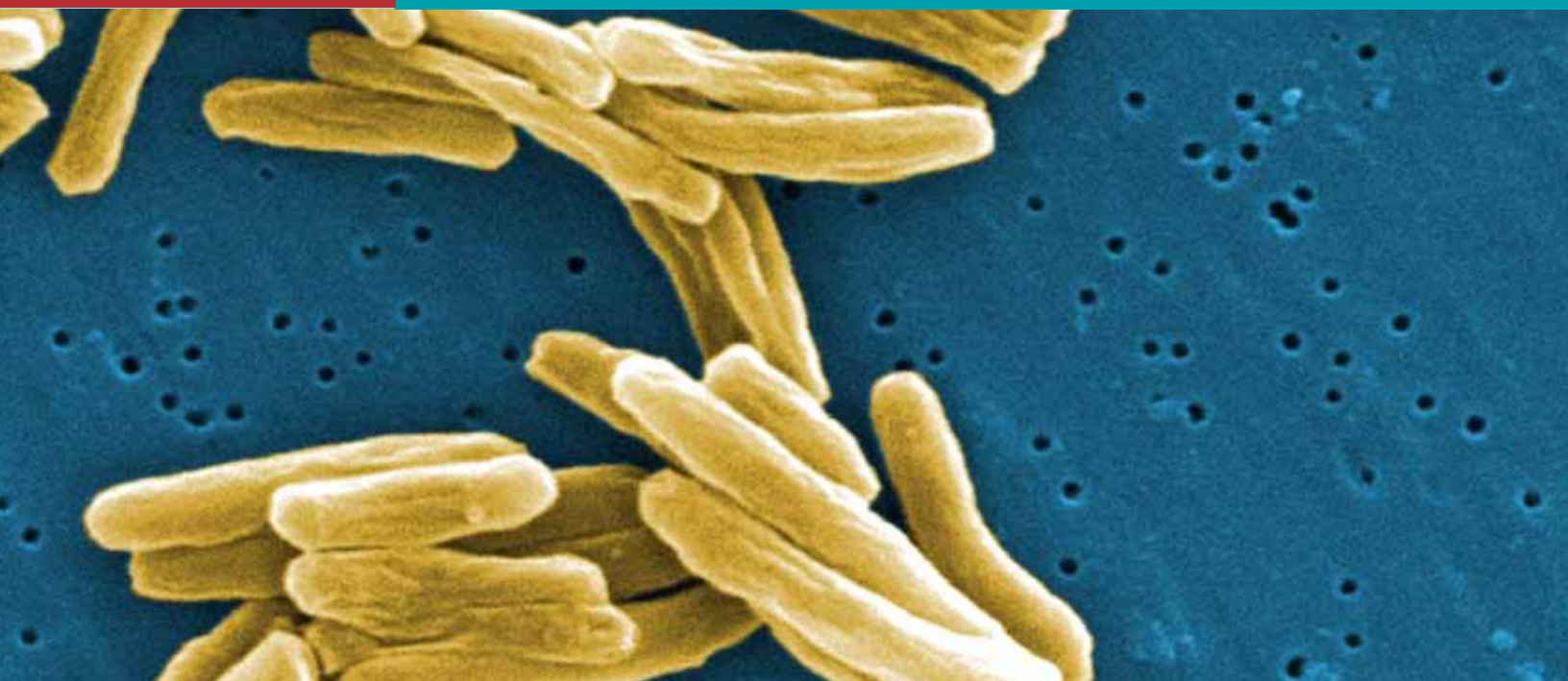


NATIONAL TB SERVICES SURVEY REPORT

APHL Report



Diagnosing TB

JUNE 2012

The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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BACKGROUND AND PURPOSE

Diagnosis of tuberculosis (TB) in the United States involves a network of private and public laboratories with different levels of service. As a result, specimens from a single patient may be referred to several laboratories for more complex tests including drug susceptibility testing. Without excellent coordination and communication between public and private sector laboratories, diagnosis and treatment of TB patients may be delayed.

As the number of TB cases in the US has fallen, the number of laboratories offering the full menu of TB diagnostic services has eroded. In 2002, the Association of Public Health Laboratories (APHL) and the US Centers for Disease Control and Prevention (CDC) convened the Task Force on the Future of TB Laboratory Services to develop recommendations to assure continued availability of high-quality, cost-effective TB laboratory services. The Task Force formulated three principle benchmarks of which one was a comprehensive assessment of available TB laboratory services in the public and private sector to fill gaps in knowledge about the capabilities and capacities of US laboratories and the structure of jurisdictional laboratory networks.

In response to that recommendation, APHL and CDC developed and launched the National TB Laboratory Services Survey in 2010. The purpose of the survey was to assess the overall ability of commercial, clinical, and public health laboratories in the United States to provide quality TB diagnostic services. The results will be used to identify gaps in the capabilities and capacities of TB testing services and identify opportunities to strengthen laboratory systems.

METHOD

The National TB Laboratory Services Survey was developed by an APHL-led workgroup that consisted of representatives from CDC's Division of Tuberculosis Elimination (DTBE) and public health laboratories. The final product was reviewed by a larger workgroup that included representatives from clinical and commercial laboratories.

The 118-question survey was launched September 7, 2010, and officially closed in February 2011. The questions were divided into 11 different categories, including: demographics; testing methodologies and volume; referral strategies; specimen collection, handling and transport; turnaround-times; reporting practices; laboratory staff and training; safety practices; proficiency testing and quality assurance; public health and epidemiology; and planning for the future.

The survey was distributed electronically to 1,444 clinical, commercial, public health, and Department of Defense laboratories via MRInterview, a web-based survey instrument. The survey participants were identified based on a list of laboratories enrolled in a mycobacteriology proficiency testing program in 2009. The list was quality-checked by APHL, and points of contact were identified for each laboratory. The point of contact for each laboratory received a link to an electronic version of the survey as well as a PDF file on September 7, 2010. Reminders were sent out on September 14 and twice more, biweekly. Of the 1,444 laboratories receiving the survey, 656 (45%) responded. Of those that responded, 580 (88%) performed some level of TB service in-house and were included in the analysis for this first of a series of issue briefs describing the survey results.

RESULTS

Figure 1: Respondents by Laboratory Type (n=580)

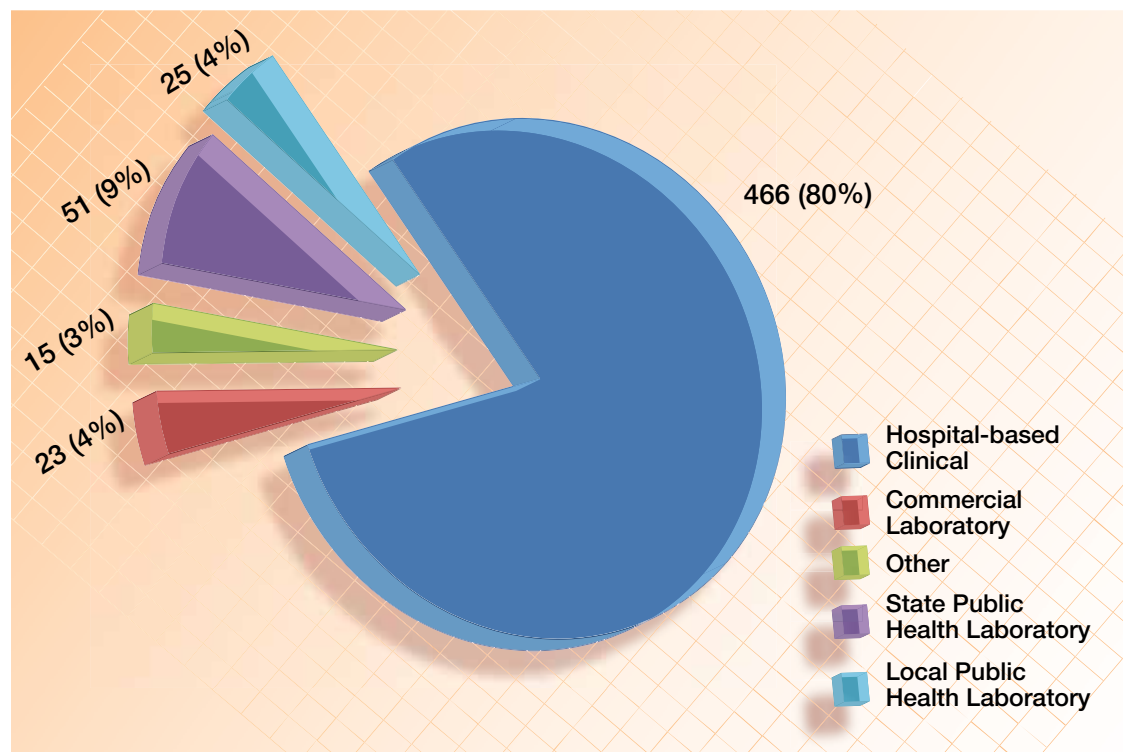


Table 1

In-house service performed	NO. OF LABORATORIES BY TYPE					Total (%)
	Hospital-based Clinical	Commercial	State Public Health	Local Public Health	Other	
AFB-smear Microscopy	466	23	51	25	15	580 (100)
AFB Culture	364	23	50	25	12	474 (81.7)
MTBC Identification	121	19	50	21	4	215 (37.1)
First-line DST	26	8	44	16	0	94 (16.2)
Second-line DST	4	2	19	4	0	29 (5.0)
Direct Detection	33	6	37	11	0	87 (15.0)
IGRA	35	8	17	14	5	79 (13.6)

Figure 2: Primary AFB Staining Method (n=575)

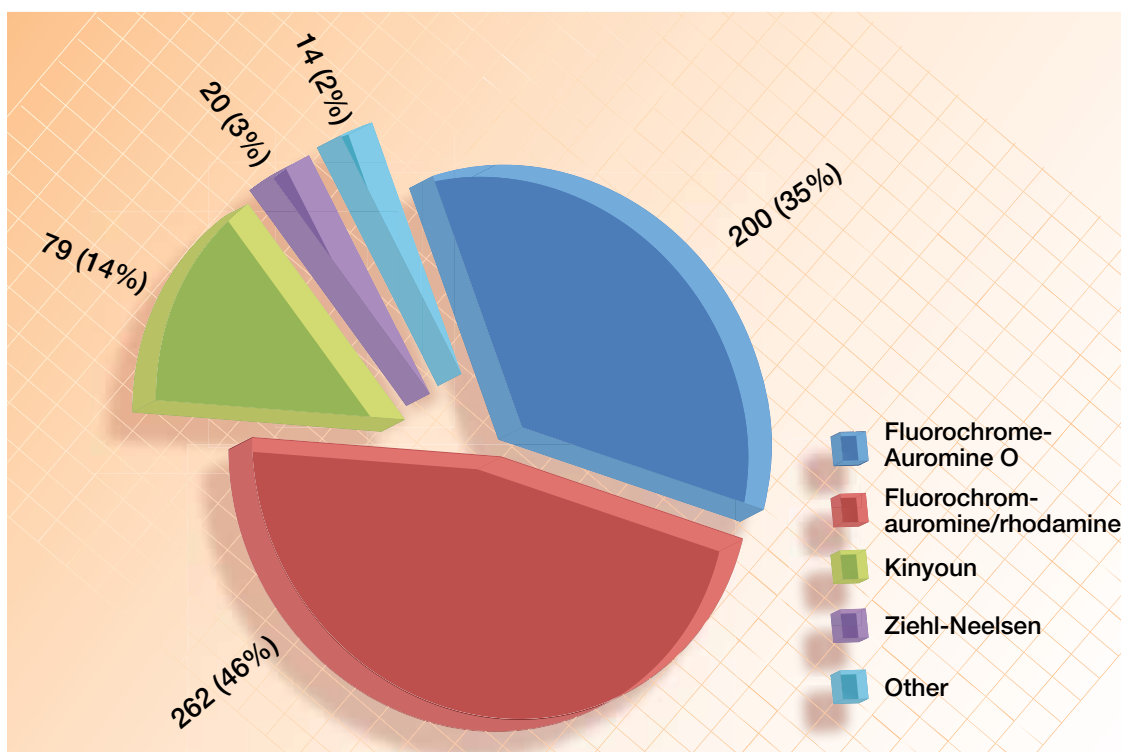


Table 2

No. of AFB smears processed per week	NO. OF LABORATORIES BY TYPE					Total (%)
	Hospital-based Clinical	Commercial	State Public Health	Local Public Health	Other	
<5	93	0	1	1	2	97 (16.8)
6-14	115	0	4	4	4	127 (22.0)
15-25	80	3	7	6	4	100 (17.3)
26-50	87	4	9	9	3	112 (19.4)
51-100	60	5	15	0	1	81 (14.0)
>100	28	11	15	5	1	60 (10.4)
Total	463	23	51	25	15	577

Figure 3: Primary Direct Detection Method of MTBC from Clinical Specimen (n=85)

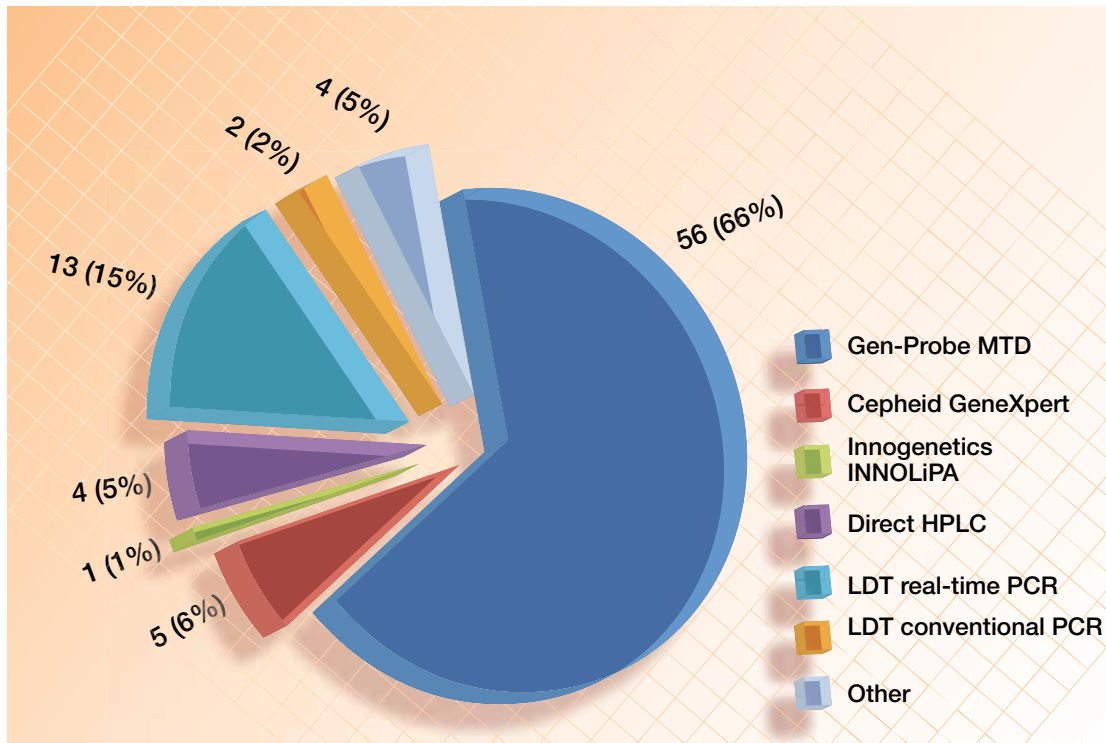


Figure 4: Primary Broth-based Culture System (n=466)

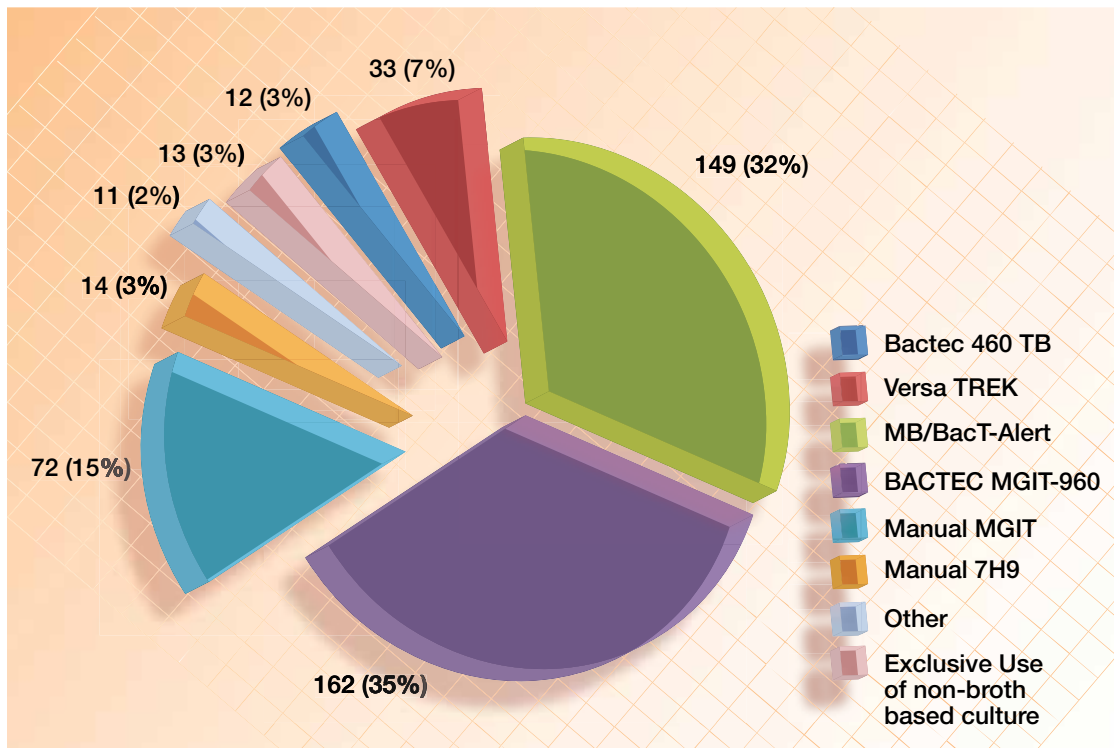


Table 3

No. of AFB cultures inoculated per week	NO. OF LABORATORIES BY TYPE					Total (%)
	Hospital-based Clinical	Commercial	State Public Health	Local Public Health	Other	
<5	29	0	0	0	0	29 (6.3)
5-9	46	0	3	2	1	52 (11.2)
10-15	54	1	2	3	2	62 (13.4)
16-20	34	1	2	3	2	42 (9.1)
21-30	52	3	6	3	2	66 (14.2)
31-40	34	2	3	4	1	44 (9.5)
41-100	81	5	20	3	3	112 (24.1)
101-250	23	6	11	3	0	43 (9.3)
251-500	3	2	3	2	1	11 (2.4)
>500	0	3	0	0	0	3 (0.7)
Total	356	23	50	23	12	464

Figure 5: Primary Method for ID of MTBC from Culture (n=213)

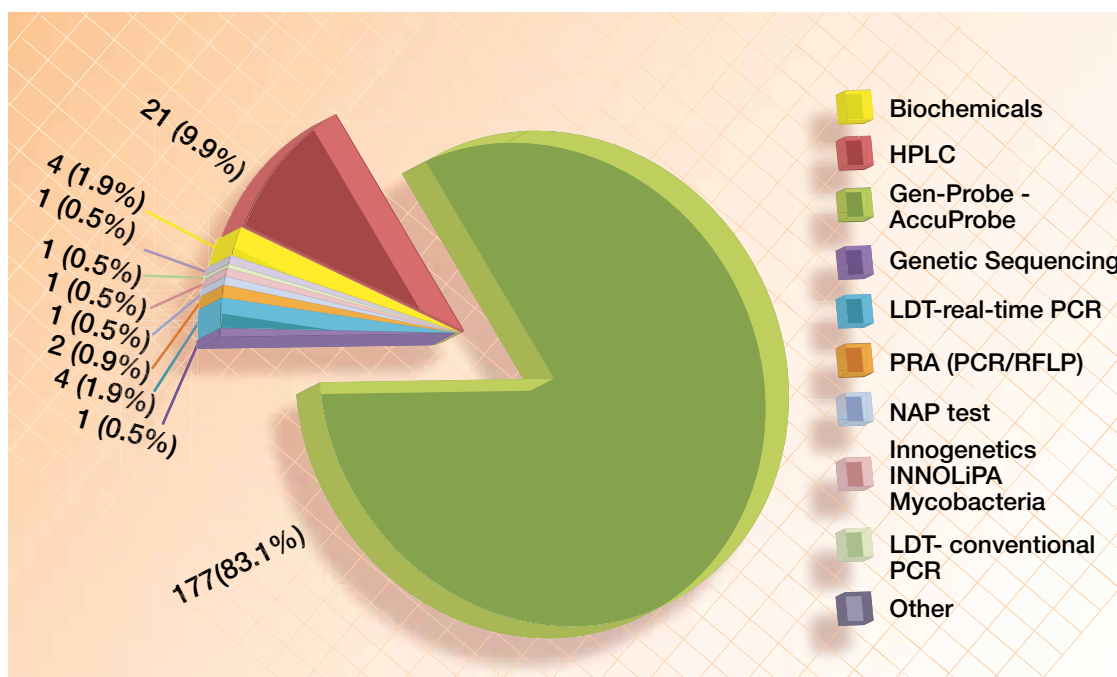


Figure 6: Culture Positivity for MTBC (n=212)

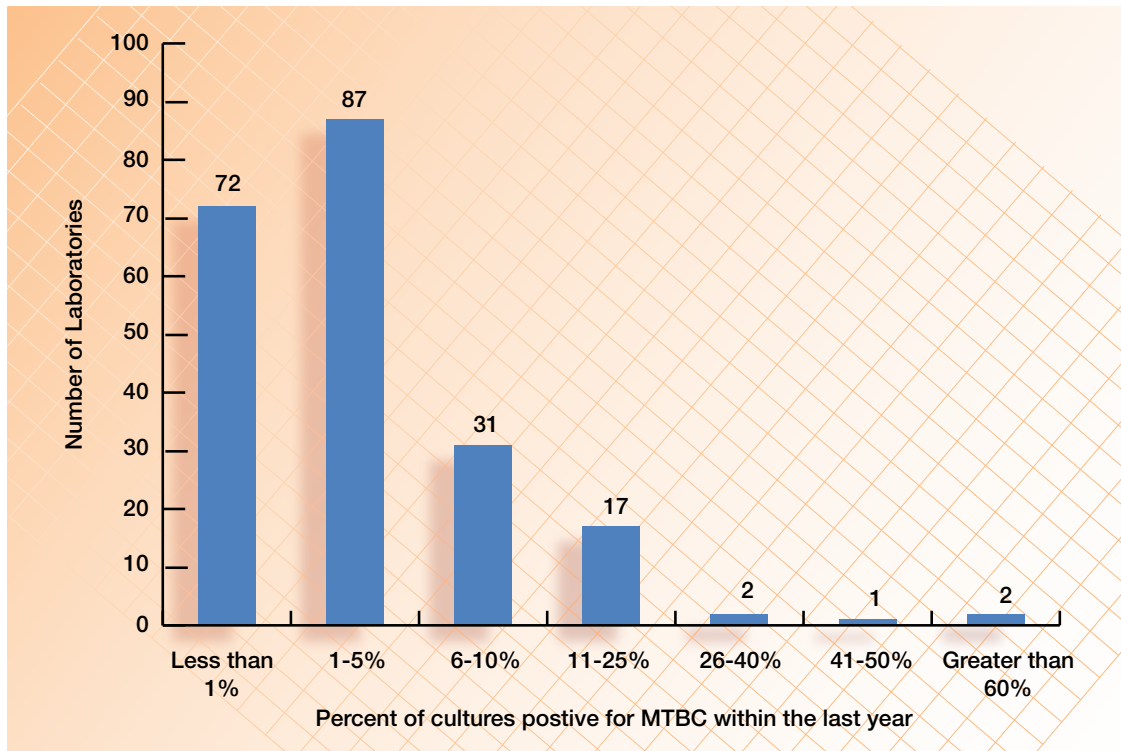


Figure 7: Culture Positivity for NTM (n=212)

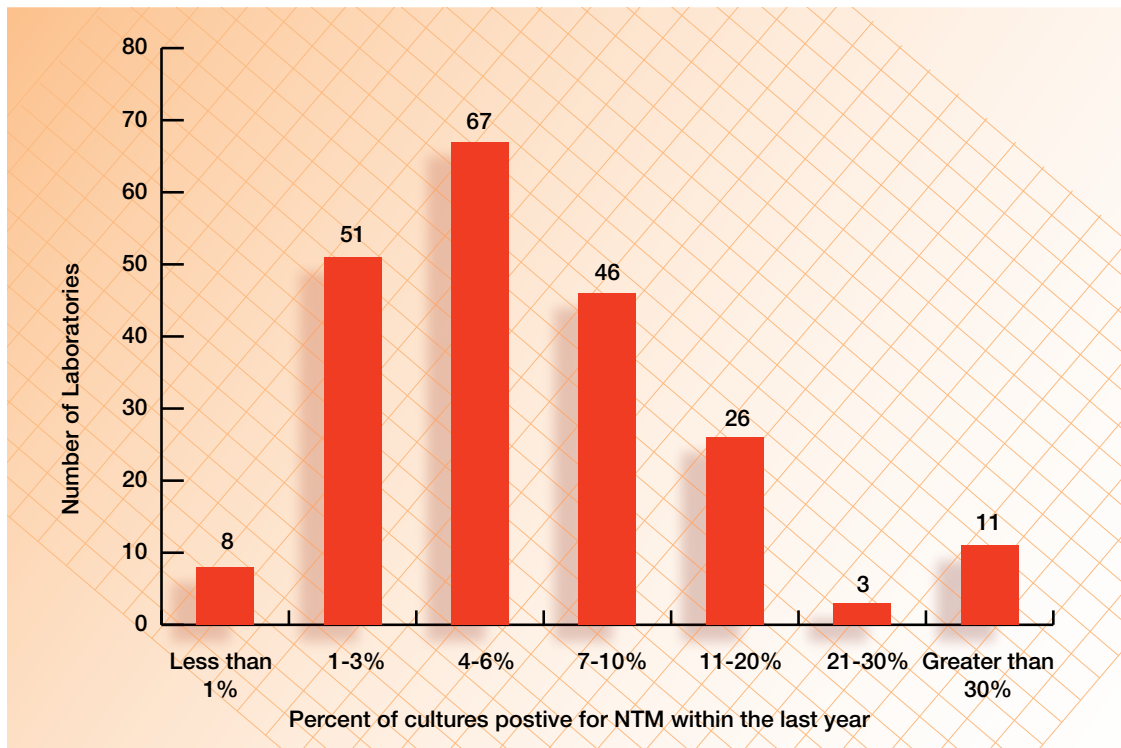


Figure 8: Primary Method for First-line Drug Susceptibility Testing (n=91)

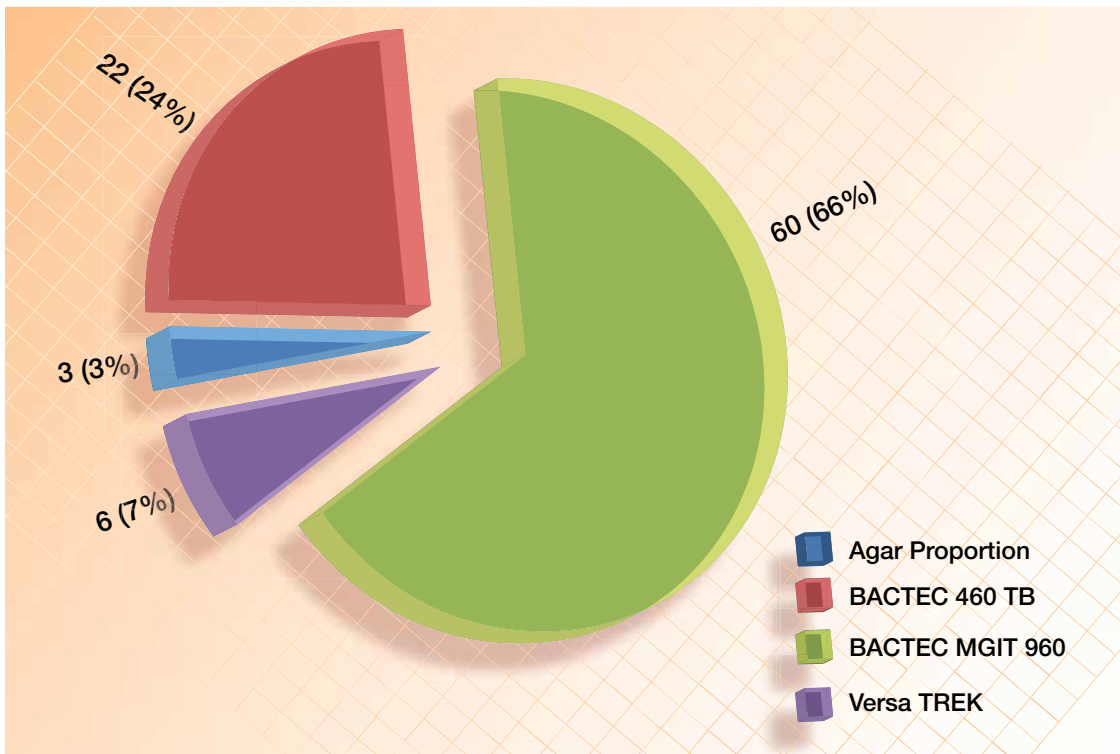


Figure 9: Average Volume of First-line DST Per Month (n=91)

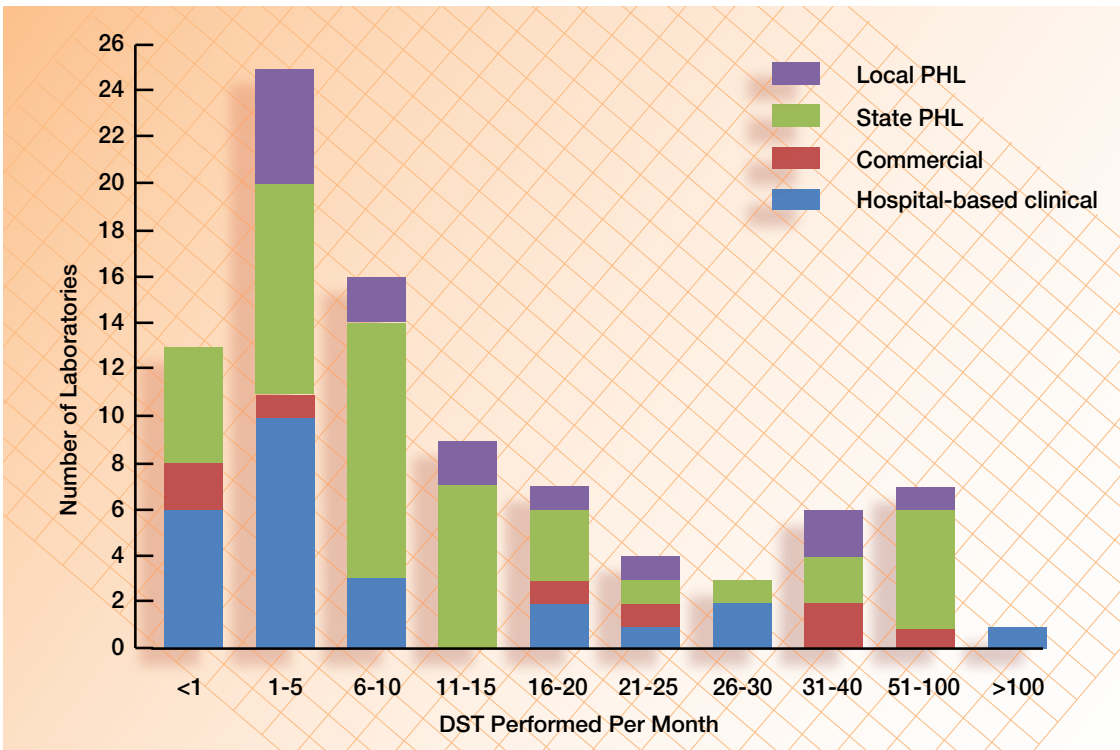


Table 4

Availability of mol-DR for MTBC	NO. OF LABORATORIES BY TYPE					Total (%)
	Hospital-based Clinical	Commercial	State Public Health	Local Public Health	Other	
Performed In-house	3	0	5	2	0	10 (1.8)
Clinical specimens referred	83	3	2	2	1	91 (16.4)
Culture isolates referred	96	6	15	7	5	129 (23.2)
Both clinical specimens and isolates referred	135	7	19	7	3	171 (30.8)
No availability of this service	128	7	9	5	6	155 (27.9)
Total	445	23	50	23	15	556

Figure 10: Reference Services by Laboratory Type

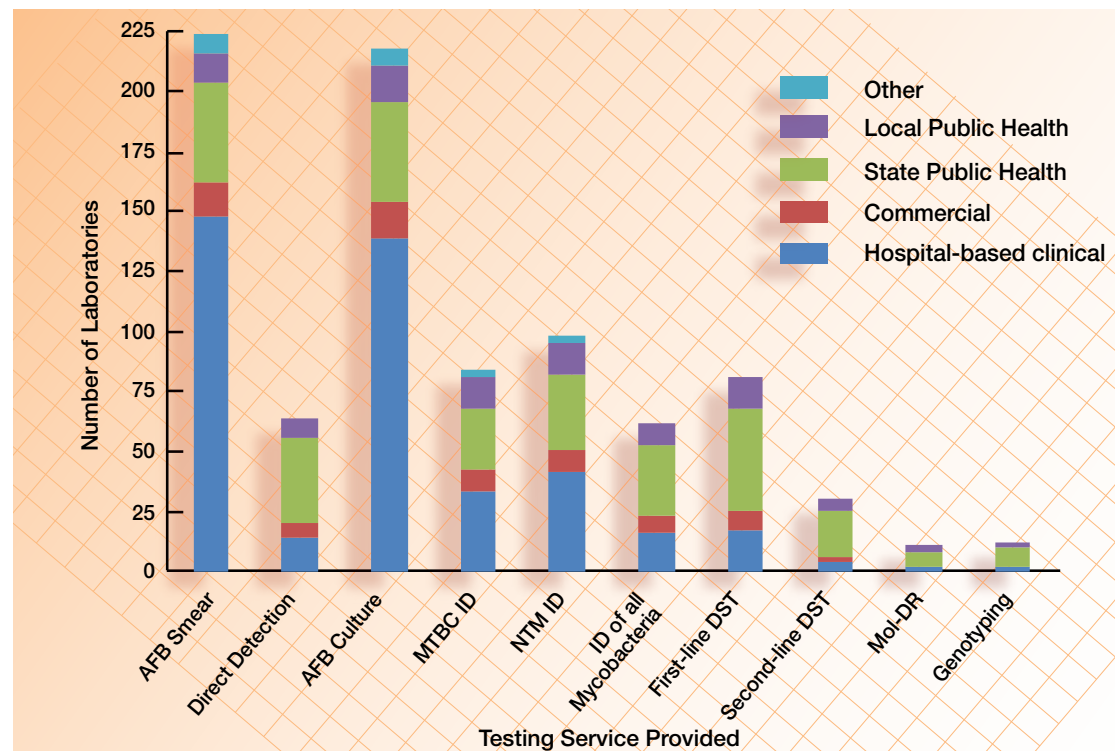


Table 5

Testing Service	NO. OF LABORATORIES BY TYPE REFERRING FOR SERVICES					Total (%)
	Hospital-based Clinical	Commercial	State Public Health	Local Public Health	Other	
AFB Culture	100	0	1	0	3	104 (17.9)
MTBC Identification	342	4	1	4	11	362 (62.4)
First-line DST	431	15	7	9	15	477 (82.2)
Second-line DST	453	21	31	21	15	541 (93.3)
Direct Detection	418	17	13	13	15	476 (82.1)
IGRA	314	10	7	7	7	345 (59.5)

Figure 11: Laboratories with $\geq 80\%$ of AFB Smear Results Reported within 24 Hours of Specimen Receipt (n=329)

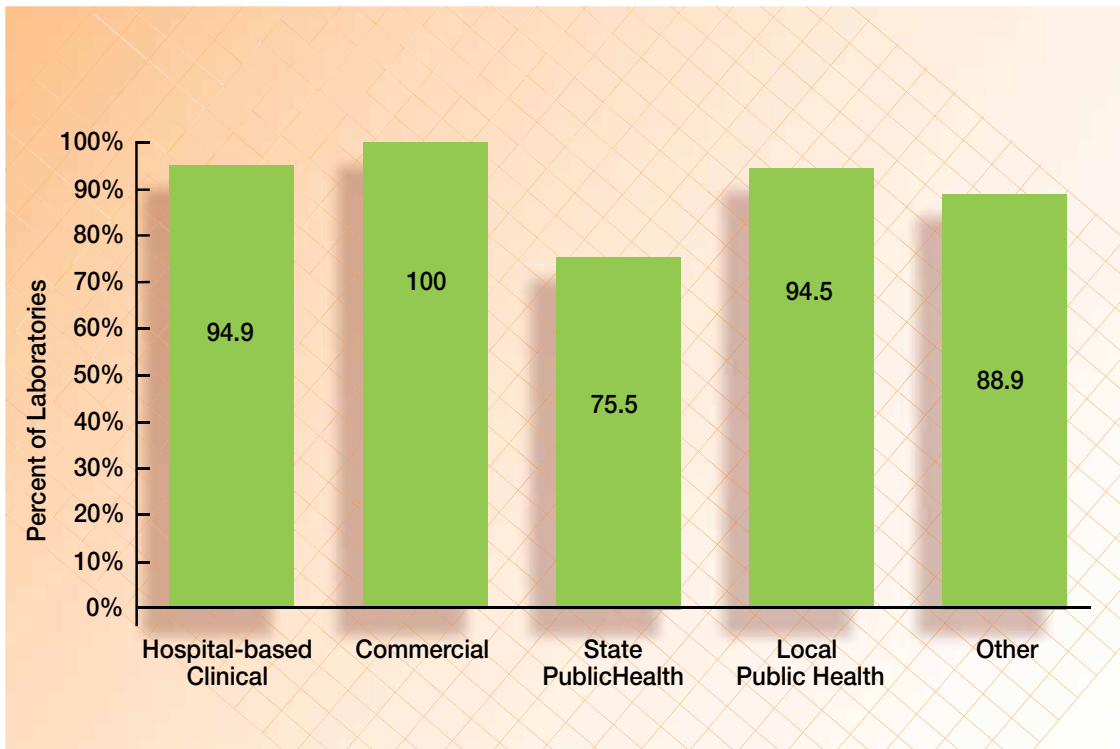
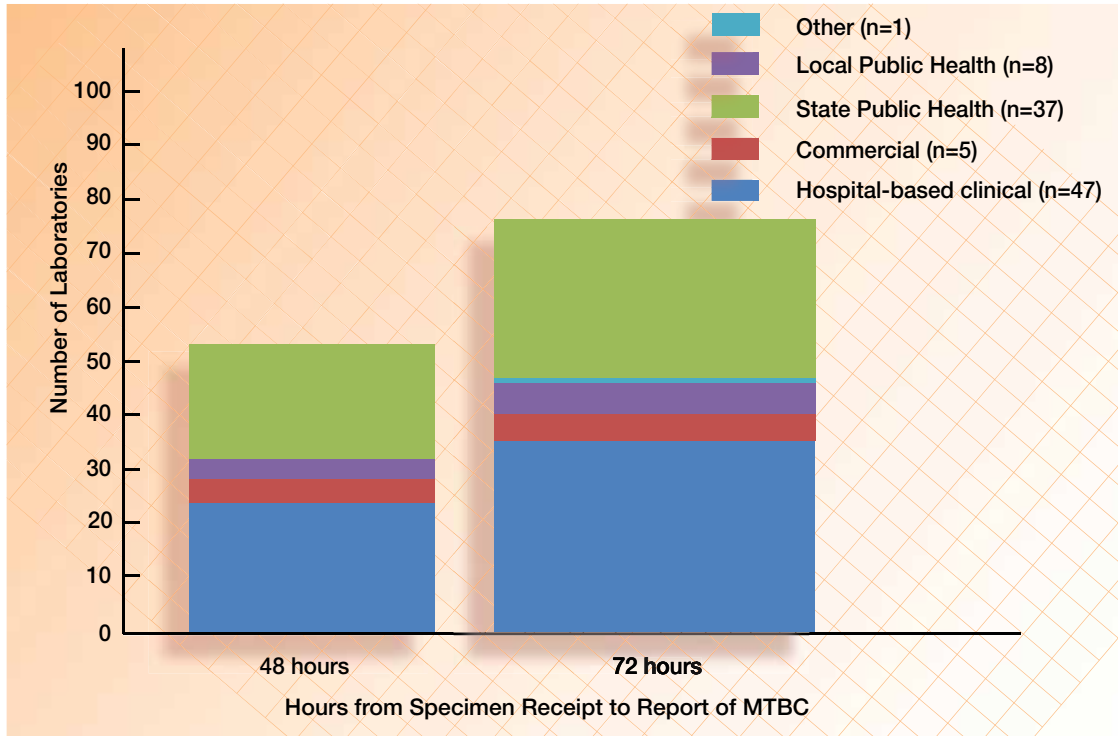
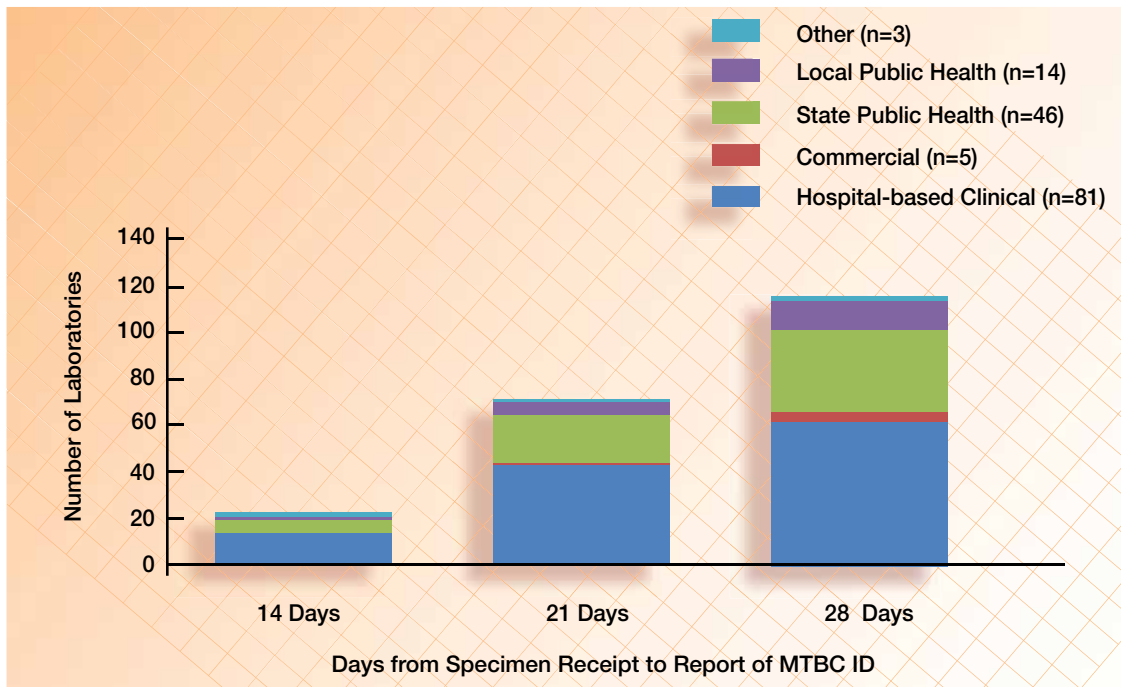


Figure 12: Laboratories with $\geq 80\%$ of MTBC Direct Detection Results Reported within 48 and 72 hours of Specimen DVM of (n=98)*



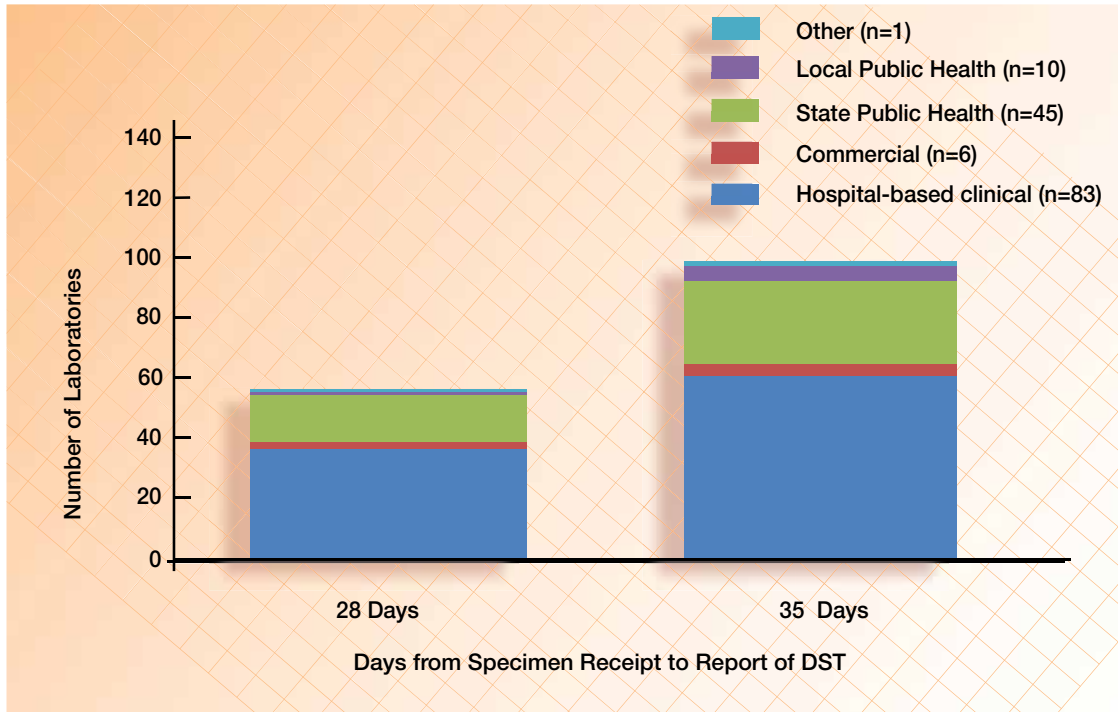
*includes TAT for in-house and referred testing

Figure 13: Laboratories with $\geq 80\%$ of MTBC ID within 14, 21 and 28 days of Specimen Receipt (n=149)*



*includes TAT for in-house and referred testing

Figure 14: Laboratories with $\geq 80\%$ of First-line DST within 28 and 35 Days of Specimen Receipt (n=145)*



*includes TAT for in-house and referred testing

Figure 15: Maximum Specimen Transport Time Allowed (n=561)

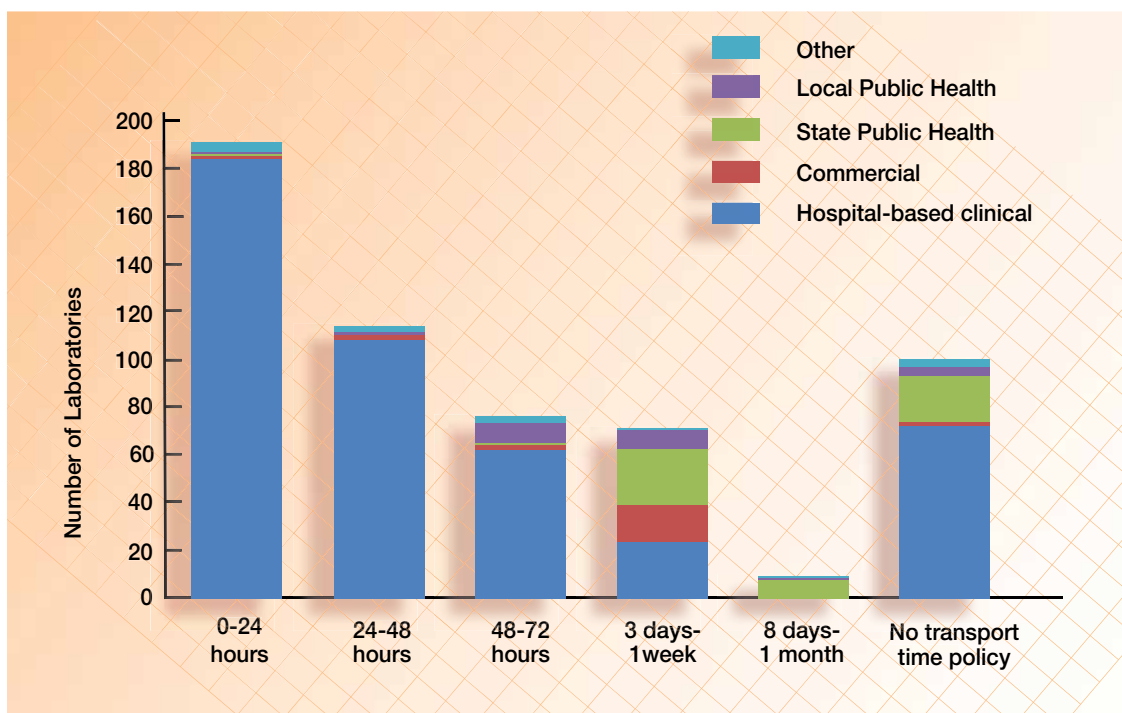


Figure 16: Barriers to Timely Transport of Specimens (n=310)

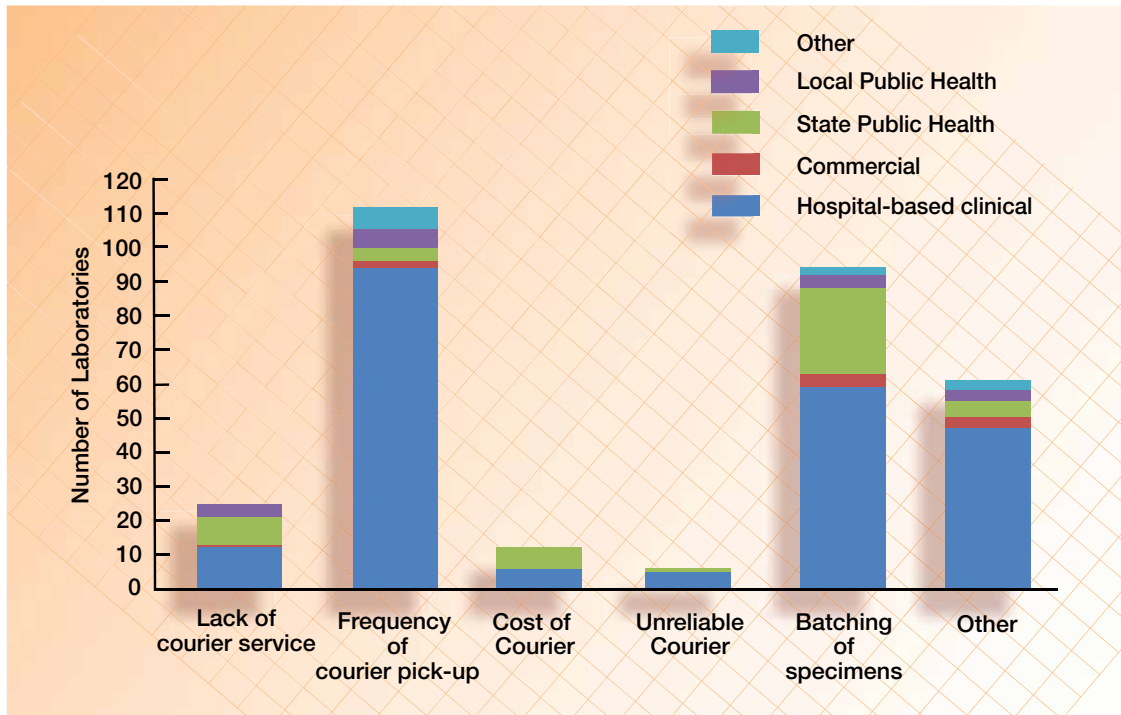


Figure 17: State Requirement for Submission of MTBC Isolate to Public Health Laboratory (n=548)

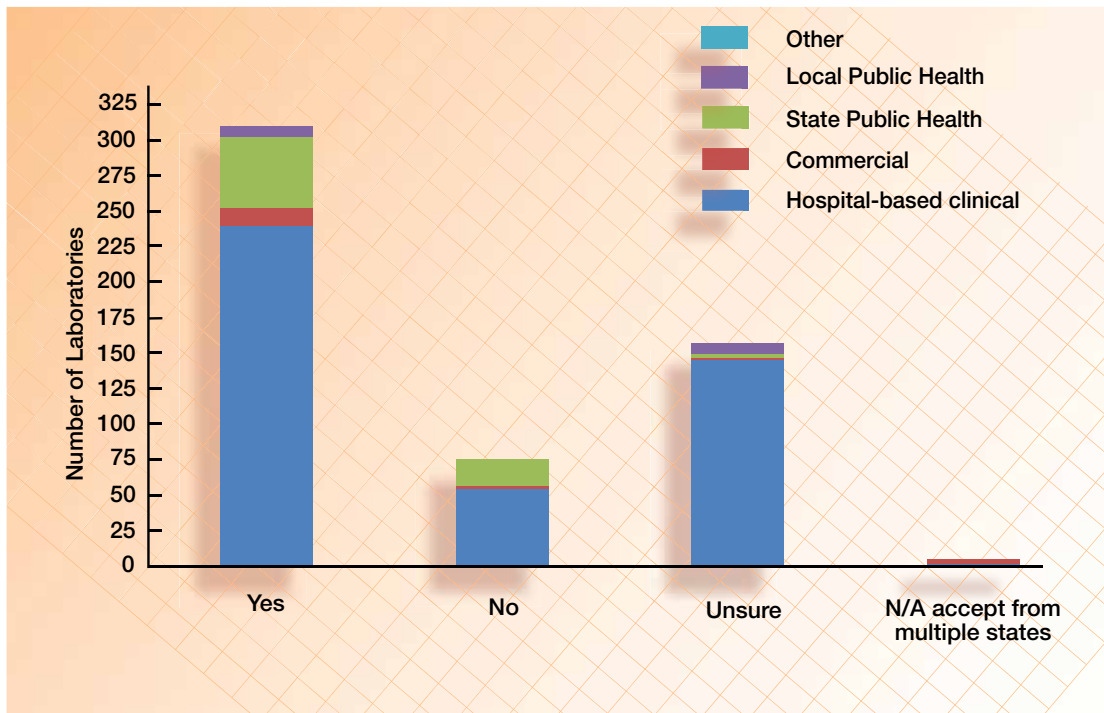


Figure 18: Laboratory Capability for Electronic Reporting (n=557)

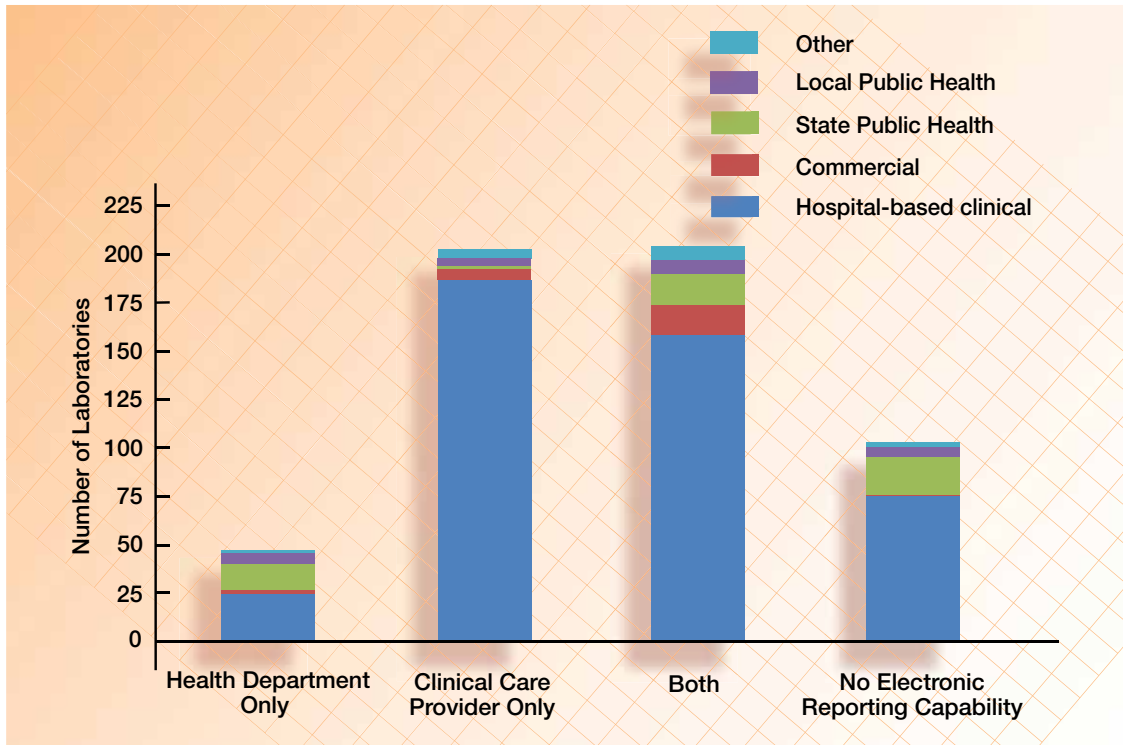


Figure 19: Experienced Staff Shortages for Mycobacteriology within the Last Year

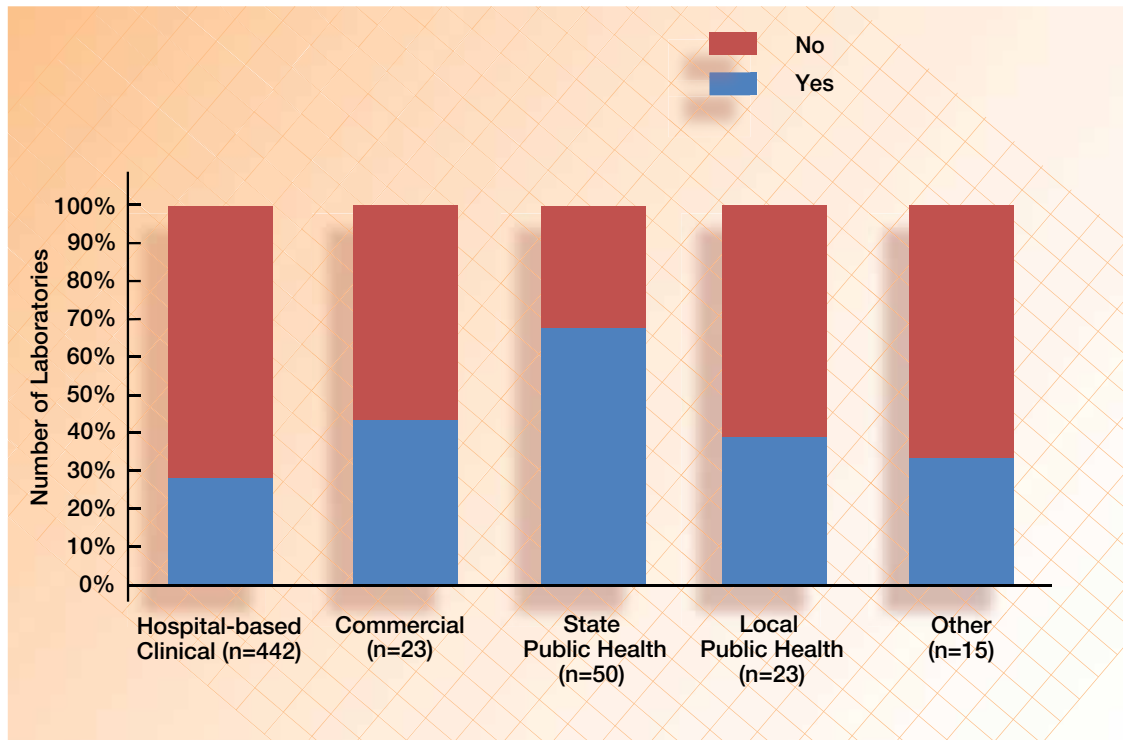


Figure 20: Have Staff Shortages Resulted in a Decrease in Services or an Increase in Turnaround Times¹

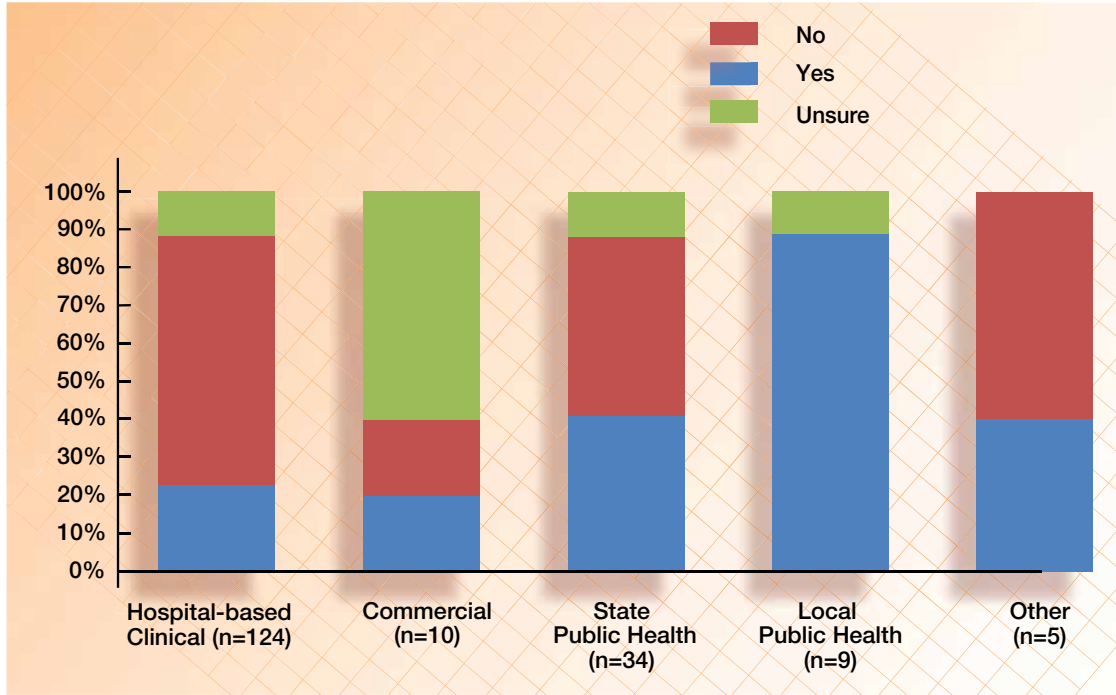


Figure 21: Experienced Obstacles Recruiting Qualified Staff for ? kUaTSUWfa'aYk Testing

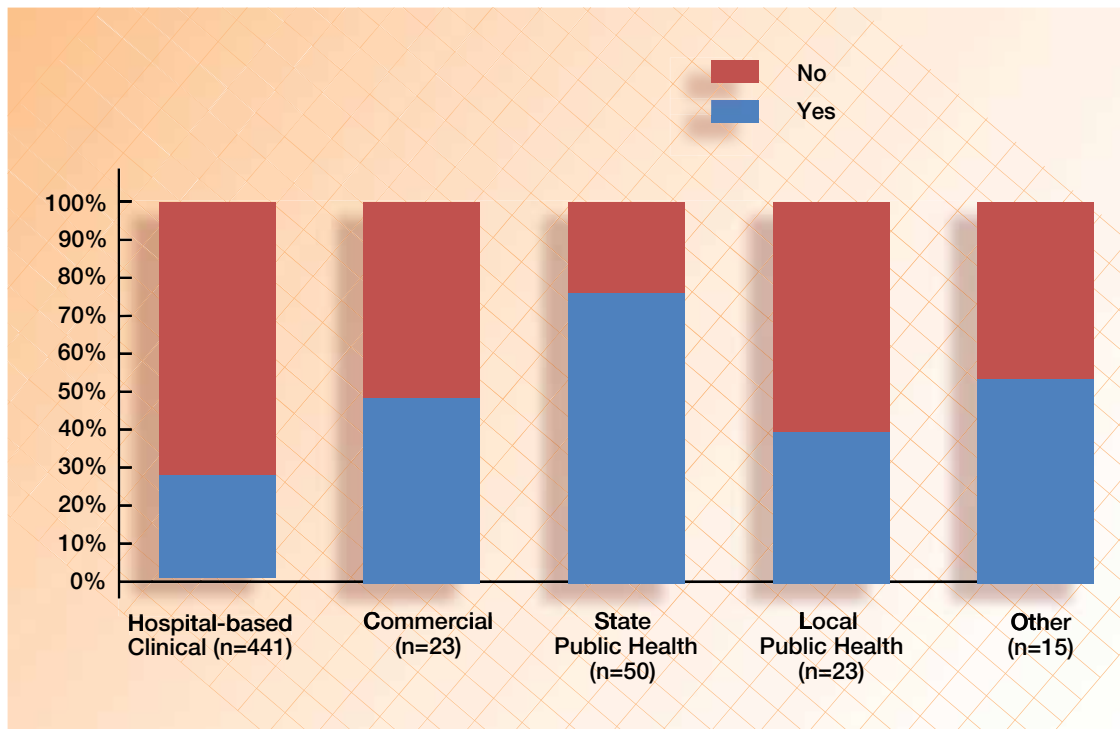
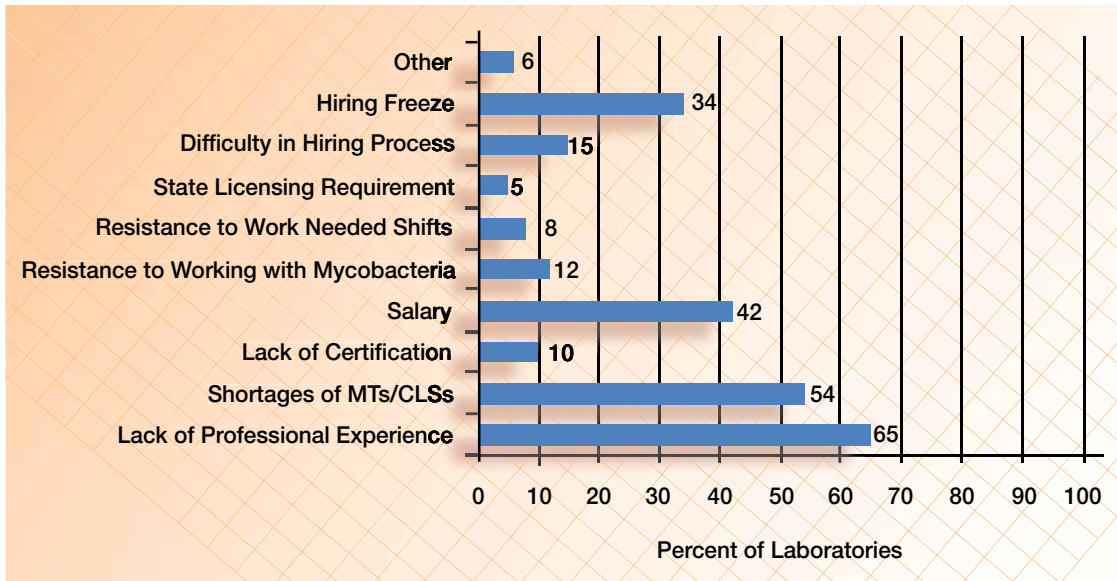


Figure 22: Obstacles to Recruiting Qualified Staff / / #* +fl



*Respondents could select up to three recruitment obstacles

Figure 23: Anticipate Change in Workload in Next Year (n=545)

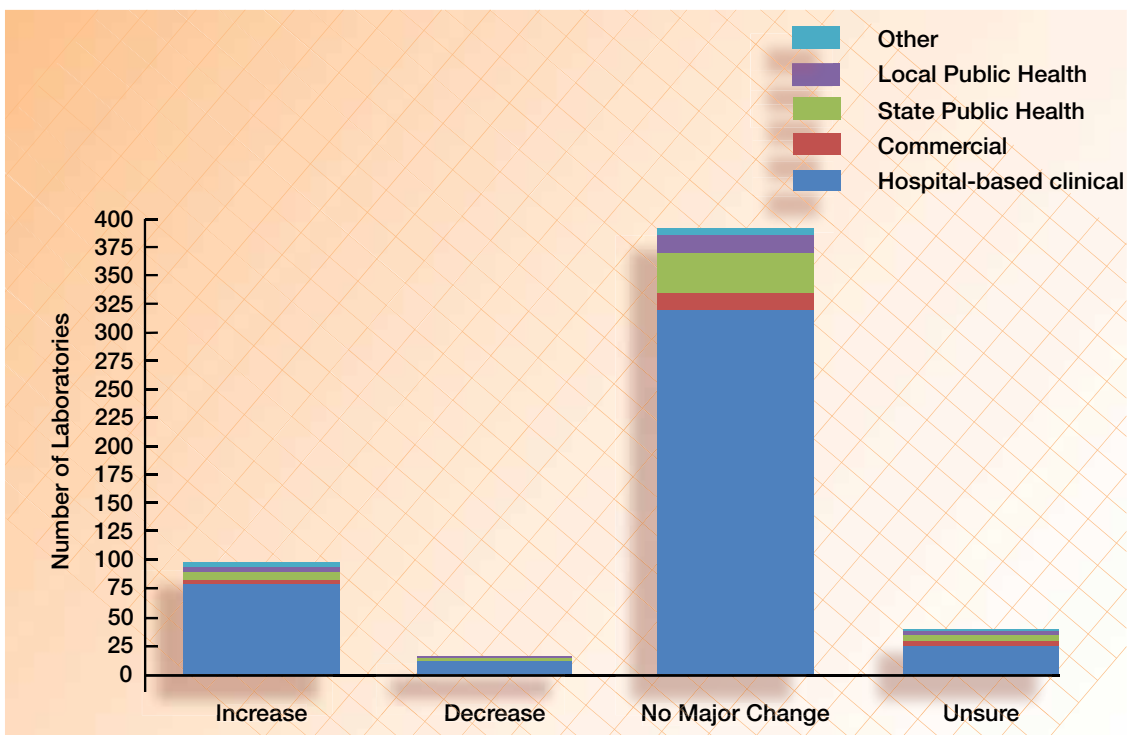


Figure 24: Service Consolidation as Reason for Change in Workload (n=114)

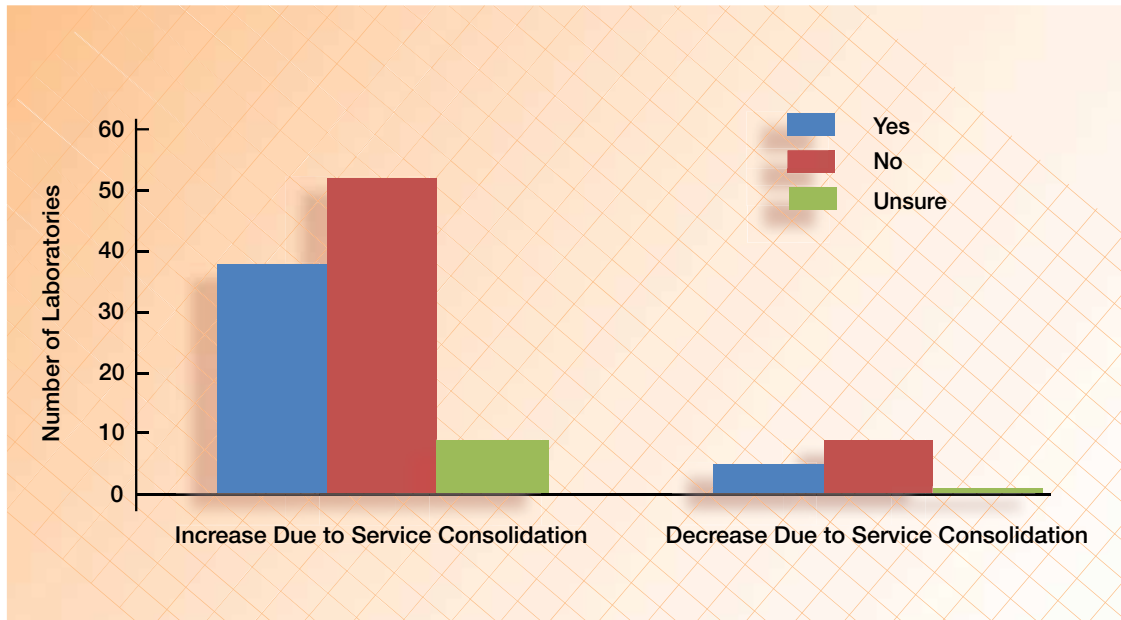


Figure 25: Plans to Add or Eliminate Mycobacteriology Laboratory Services

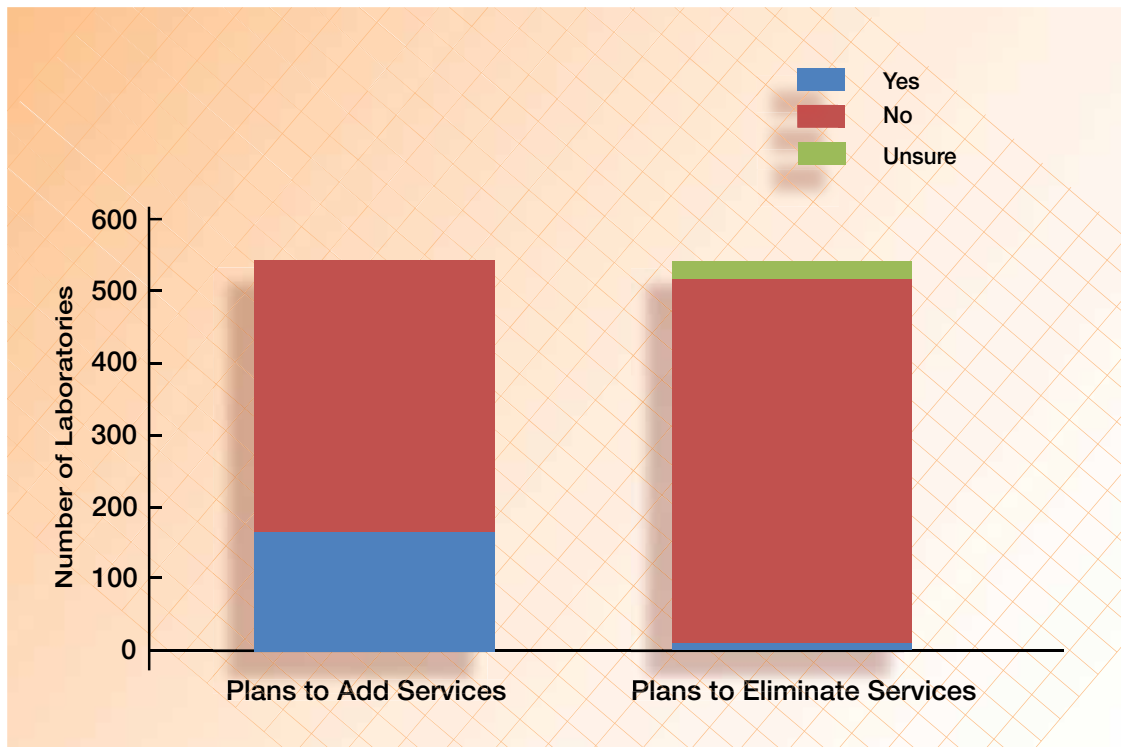
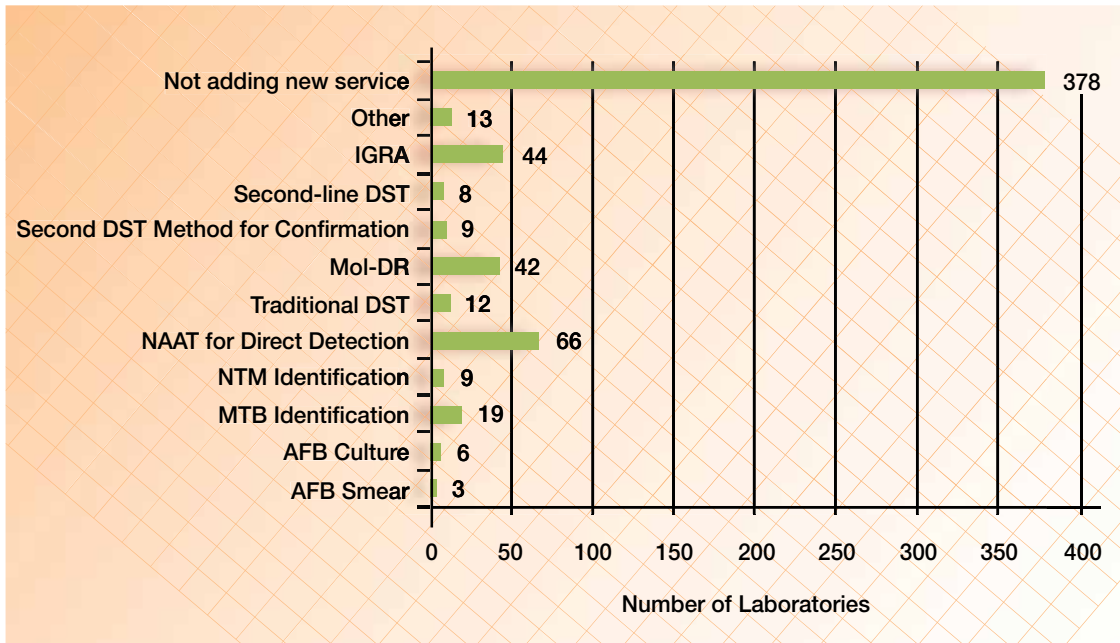
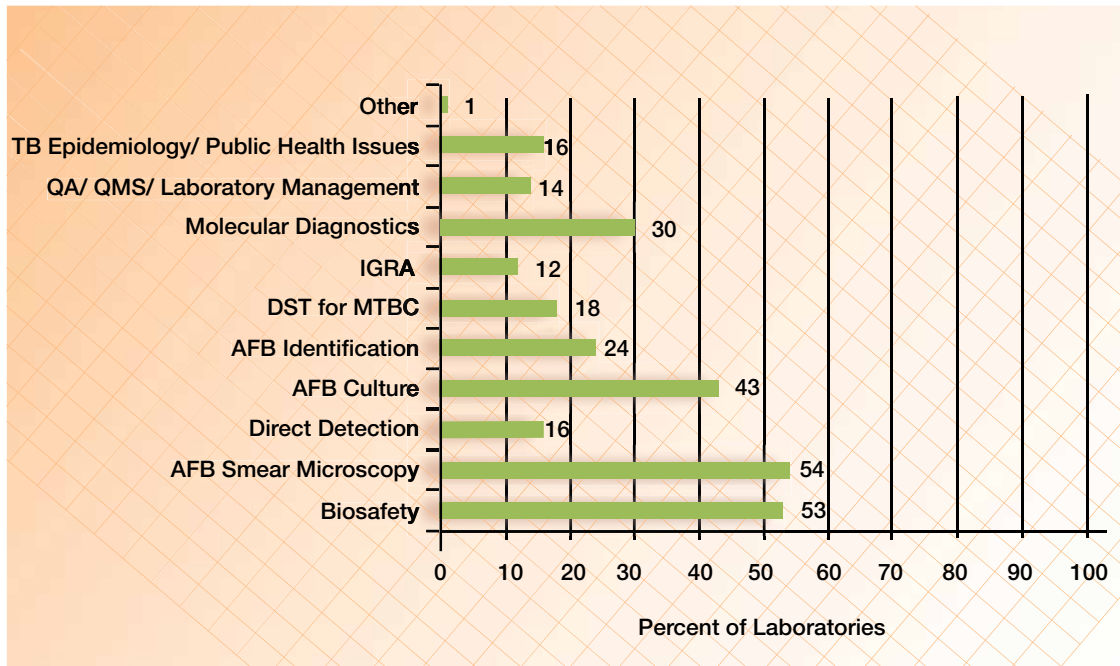


Figure 26: Additional Services Under Consideration (n=545)*



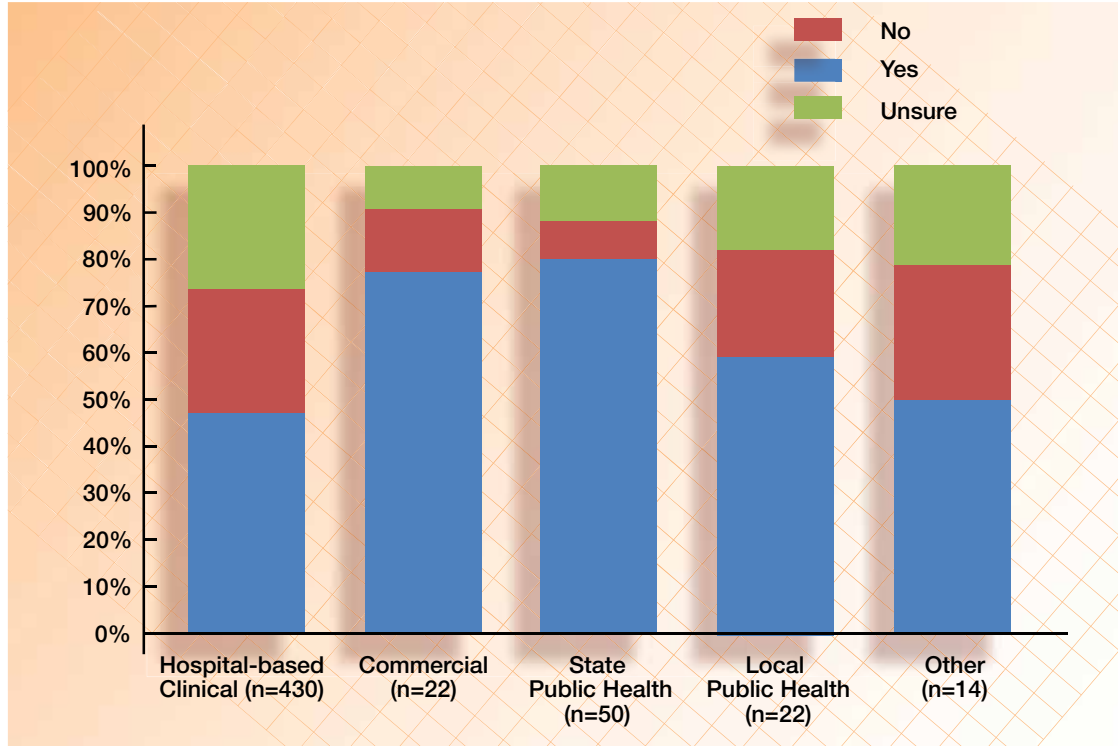
*Respondents could select multiple responses

Figure 27: Training Topics Most Relevant for those Performing Mycobacteriology Testing (n=552)*



*Respondents could select multiple responses

Figure 28: Laboratories With Continuity of Operations Plan for TB Laboratory Services (n=538)



SUMMARY OF MAJOR FINDINGS

- Survey responses were obtained from 45% of all US laboratories enrolled in a mycobacteriology proficiency testing program in 2009.
- Of the 580 laboratories performing AFB-smear microscopy, 82% also performed AFB culture.
- Most laboratories performing culture refer isolates for MTBC identification, first and second-line DST, and direct detection.
- 81% of laboratories use a fluorescent stain as a primary staining method for AFB-smear microscopy, consistent with CDC recommendations (1, 2).
- 39% of laboratories perform fewer than 15 AFB smears per week. The current ATS and CDC recommendation specifies preparation and examination of at least 15 specimens per week for each microscopist to maintain proficiency (1).
- 15% of laboratories perform direct detection for rapid identification of MTBC from a clinical specimen. Of these, 55% were public health laboratories. Current CDC recommendations encourage the use of nucleic acid amplification testing on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test results would alter case management or TB control activities (3).
- Of those laboratories performing AFB culture, 40% inoculate fewer than 20 AFB cultures per week. To maintain proficiency in culture and identification of MTBC, it is recommended that laboratories process a minimum of 20 specimens per week (4).
- In 75% of laboratories performing identification in-house, 5% or less of mycobacterial cultures processed within the last year were positive for MTBC.
- In 72% of laboratories performing identification in-house, 4% or more of mycobacterial cultures processed within the last year were positive for nontuberculous mycobacteria.
- 42% of laboratories performing first-line DST perform testing for five or fewer MTBC isolates per month. The current APHL recommendation is referral if performing DST for less than 50 isolates per year (5).
- 72% of laboratories reported access, primarily through referral, for the molecular detection of mutations associated with drug resistance for MTBC.

- The majority of laboratories reported that greater than 80% of AFB-smear results are reported within 24 hours of specimen receipt. However, only 54% of laboratories performing direct detection reported rapid reporting of $\geq 80\%$ of results within the recommended 48 hours of specimen receipt (3).
- Meeting the recommended turnaround times for identification of MTBC within 21 days and DST within 28 days of specimen receipt was problematic for many laboratories with only 71 of 149 (48%) reporting $\geq 80\%$ of ID within 21 days and 57 of 145 (39%) reporting $\geq 80\%$ of DST results within 28 days.
- 250 of 560 (44%) respondents indicated no obstacles to timely transport of specimens.
- 37% of laboratories have electronic reporting capability for providing results to both the health department and clinical care provider. 34% of public health laboratories have no electronic reporting capability, including 38% of State Public Health Laboratories.
- Most laboratories anticipate no major change in workload during the next year but are considering adding additional services. The three top selections for additional services under consideration include nucleic acid amplification tests for direct detection of MTBC, molecular detection of mutations associated with drug resistance, and IGRA.

RESOURCES

APHL TB Laboratory Assessment Tool

Laboratories are encouraged to incorporate the use of this tool into their current Quality Assurance practices as a means to determine the existence of areas within individual laboratories that may be in need of improvement.

<http://www.aphl.org/aphlprograms/infectious/tuberculosis/Pages/tbtool.aspx>

APHL TB Resource Page

This webpage provide access to reports, tools and guidelines developed by APHL's TB Steering Committee.

<http://www.aphl.org/aphlprograms/infectious/tuberculosis/Pages/tbresources.aspx>

GLOSSARY OF TERMS

AFB: Acid fast bacilli

Direct detection: Test performed directly from patient specimen (e.g., sputum or bronchial alveolar lavage) for the detection of *Mycobacterium tuberculosis* complex. Tests may include nucleic acid amplification or direct HPLC.

DST: Drug susceptibility test (i.e., antimicrobial susceptibility test)

HPLC: High performance liquid chromatography

ID: Identification

IGRA: Interferon gamma release assay

LDT: Laboratory developed test

Mol-DR: Molecular detection of mutations associated with drug resistance

MTBC: *Mycobacterium tuberculosis* complex

QMS: Quality management system

NTM: Nontuberculous mycobacteria

TAT: Turnaround time

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APPENDIX

Survey Questions and Corresponding Figure

- Figure 1: Which laboratory type best describes your facility?
- Figure 2: What primary staining method is used for acid-fast smear microscopy of clinical specimens?
- Figure 3: What is the primary direct detection method performed by your laboratory?
- Figure 4: Which broth-based culture system is primarily used in your laboratory for the isolation of mycobacteria from respiratory specimens?
- Figure 5: What is the primary method used to identify isolates of *Mycobacterium tuberculosis* complex in your laboratory?
- Figure 6: In your laboratory, approximately what percentage of mycobacterial cultures processed within the last year were positive for *M. tuberculosis* complex?
- Figure 7: In your laboratory, approximately what percentage of mycobacterial cultures processed within the last year were positive for NTM?
- Figure 8: What is the primary method for first-line drug susceptibility testing?
- Figure 9: In the last year, what was the average number of *M. tuberculosis* isolates set up for first-line drug susceptibility testing each month?
- Figure 10: What Mycobacteriology reference services do you provide for other laboratories in-house?
- Figure 11: In your laboratory, what percentage of AFB-smear microscopy results are reported to the provider within 24 hours of specimen receipt?
- Figure 12: In your laboratory, what percentage of *M. tuberculosis* complex direct detection results are reported to the provider within 48 hours and 72 hours of specimen receipt?
- Figure 13: What percent of *M. tuberculosis* complex does your laboratory identify from culture of clinical specimens (e.g., sputum) within 14, 21, and 28 days of specimen receipt?
- Figure 14: What percent of *M. tuberculosis* complex first-line drug susceptibility testing results does your laboratory report from clinical specimens (e.g., sputum) within 28 and 35 days of specimen receipt?
- Figure 15: What is the maximum transport time that your laboratory allows before a specimen will be rejected (date of collection to date of receipt)?
- Figure 16: What is the single biggest obstacle to the timely transport of specimens to your laboratory?
- Figure 17: Does your state legally require the submission of an isolate of *M. tuberculosis* complex from all new TB cases to your state and/or local public health laboratory?

- Figure 18: Does your laboratory have the capability to report results electronically to the state or local public health department only, clinical care provider only, both, or your laboratory does not have electronic reporting capability?
- Figure 19: Have you experienced staff shortages for Mycobacteriology within the last 12 months?
- Figure 20: Have those shortages resulted in a decrease in AFB services or an increase in turnaround times?
- Figure 21: Has your laboratory experienced any obstacles in recruiting qualified staff to perform Mycobacteriology testing?
- Figure 22: What are the biggest obstacles in recruiting qualified staff to perform Mycobacteriology testing?
- Figure 23: Over the next 12 months, does your laboratory plan (or anticipate) changes in the volume of testing performed in house?
- Figure 24: You indicated your laboratory is anticipating an increase or decrease in workload. Is this increase due to service consolidation within your network or geographic region?
- Figure 25: Does your laboratory have any plans to eliminate Mycobacteriology services within the next 12 months or has your laboratory decreased services within the last 12 months?
- Figure 26: Which of the following Mycobacteriology services is your laboratory considering adding?
- Figure 27: What training topics are most relevant to those performing Mycobacteriology testing in your laboratory?
- Figure 28: Does your laboratory have a Continuity of Operations plan to ensure the uninterrupted provision of TB laboratory services in the event of any unforeseen event that affects laboratory testing capability?

Survey Question and Corresponding Table

- Table 1: Does your laboratory perform or refer for the following AFB services: AFB-smear microscopy, direct detection, AFB culture, MTBC identification, first-line DST, second-line DST, and IGRA?
- Table 2: Approximately how many smears per week does your laboratory process?
- Table 3: What is the average number or specimens per week that are set up for culture of AFB in your laboratory?
- Table 4: Does your laboratory perform testing for the molecular detection of mutations associated with drug resistance (mol-DR) for *M. tuberculosis* complex?
- Table 5: Does your laboratory perform or refer for the following AFB services: AFB-smear microscopy, direct detection, AFB culture, MTBC identification, first-line DST, second-line DST, and IGRA?

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