

Welcome to the National TB Laboratory Services Survey co-sponsored by the Association of Public Health Laboratories and the Centers for Disease Control and Prevention (CDC). This survey is being distributed to public health, clinical and commercial laboratories with the primary goal of characterizing the TB testing capabilities and capacities of US diagnostic laboratories. Ultimately the results of this survey will be used to identify opportunities to strengthen TB systems nationally and in local jurisdictions.

The survey consists of 115 questions divided into 11 different categories. Respondents will be routed based on the level of TB services they provide, therefore very few laboratories will be directed to all 115 questions.

We ask that you complete this survey by _____. All laboratories that complete the survey will receive a summary of the aggregate data. Please direct any subject matter questions to APHL Manager of HIV, Hepatitis, STD and TB Programs, Kelly Wroblewski at kelly.wroblewski@aphl.org. If you have technical issues with the electronic survey tool please contact APHL's Research Specialist, Doug McNamara at doug.mcnamara@aphl.org.

Thank you in advance for your assistance in making this survey a success.

Question Sections:

- Demographics
- Testing Methodologies and Volume
- Referral Strategies
- Specimen Collection, Handling and Transport
- Turn-Around-Times
- Reporting Practices
- Laboratory Staff and Training
- Safety Practices
- Proficiency Testing and Quality Assurance
- Public Health and Epidemiology
- Future Plans

Public reporting burden of this collection of information is estimated to average of 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0840).

Demographics (Questions 1-6)

Q1. Which laboratory type best describes your facility?

SELECT ONE ANSWER ONLY.

- Hospital-based clinical laboratory
- Non-hospital based clinical laboratory
- Commercial laboratory
- Department-of-Defense Laboratory
- State Public Health Laboratory
- Local (City or county) Public Health Laboratory

Q2. Is your facility part of a hospital/ health-care network?

SELECT ONE ANSWER ONLY.

- Yes
- No

Q3. What is the approximate number of beds in your facility?

WRITE IN ANSWER WITHIN THE RANGE 0 – 20000

Q4. How many days per week is your AFB Laboratory open for operation?

WRITE IN ANSWER WITHIN THE RANGE 1 – 7

Q5. How many hours per operating day is your AFB Laboratory open for operation?

SELECT ONE ANSWER ONLY.

- 24 hours
- 10-12 hours
- 8-9 hours
- Other, (Please write in)

Q6. Please select the accreditations that your laboratory holds?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Clinical Laboratory Improvement Act (CLIA)
- College of American Pathologists (CAP)
- Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)
- Other, (Please write in)

Testing Methodologies and Volume (Questions 7-45)

Q7. Does your laboratory perform or refer the following AFB services:

(Indicate the response for the primary practice in each category.)

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | The service is performed in-house | Specimens are referred to another laboratory for this service | This service is not available in-house or by referral |
|---|-----------------------------------|---|---|
| Acid-Fast Smear Microscopy | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Direct Detection (NAAT, PCR, direct HPLC, etc.) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| AFB Culture | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Mycobacterium tuberculosis complex Identification | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Culture Based DST for <i>M. tuberculosis</i> isolates for first-line drugs | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Culture Based DST for <i>M. tuberculosis</i> isolates for second-line drugs | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Interferon Gamma Release Assay (IGRA) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |

Q8. How many days per week do you routinely perform AFB smears?

SELECT ONE ANSWER ONLY.

- 7 days a week 1
- 6 days a week 2
- 5 days a week 3
- 4 days a week 4
- 3 days a week 5
- Only as needed/requested 6

Q9. Approximately, how many smears per week does your laboratory process?

SELECT ONE ANSWER ONLY.

- Less than 5 1
- 6-14 2
- 15-25 3
- 26-50 4
- 51-100 5
- More than 100 6

Q10. Does your laboratory perform direct smear microscopy (smear on unprocessed respiratory specimens)?

SELECT ONE ANSWER ONLY.

- Yes, we always perform direct smear microscopy 1
- We occasionally perform direct smear microscopy 2
- We never perform direct smear microscopy 3

Q11. What primary staining method is used for acid-fast smear microscopy of clinical specimens?

SELECT ONE ANSWER ONLY.

- Fluorochrome-Auramine O 1
- Fluorochrome-Auramine/Rhodamine 2
- Kinyoun 3
- Ziehl-Neelsen 4
- Other 5

Q12. In your laboratory, approximately what percentage of AFB smears processed within the last year were positive for acid fast bacilli?

SELECT ONE ANSWER ONLY.

- | | | |
|---------------|-------|----------------------------|
| Less than 1% | | <input type="checkbox"/> 1 |
| 1-5 % | | <input type="checkbox"/> 2 |
| 6-10 % | | <input type="checkbox"/> 3 |
| 11-25 % | | <input type="checkbox"/> 4 |
| 26-40 % | | <input type="checkbox"/> 5 |
| 41-50 % | | <input type="checkbox"/> 6 |
| 51-60% | | <input type="checkbox"/> 7 |
| More than 60% | | <input type="checkbox"/> 8 |

Q13. In your laboratory which of the following specimens types are received for Direct Detection of *Mycobacterium tuberculosis* Complex (e.g. NAAT, PCR, direct HPLC)?

(*Check all that apply.*)

SELECT ALL ANSWERS THAT APPLY.

- | | | |
|--|-------|----------------------------|
| Smear positive respiratory specimens routinely | | <input type="checkbox"/> 1 |
| Smear positive respiratory specimens by request only | | <input type="checkbox"/> 2 |
| Smear negative respiratory specimens routinely | | <input type="checkbox"/> 3 |
| Smear negative respiratory specimens by request only | | <input type="checkbox"/> 4 |
| Smear positive non-respiratory specimens | | <input type="checkbox"/> 5 |
| Smear negative non-respiratory specimens | | <input type="checkbox"/> 6 |

Q14. What is the primary direct detection method performed by your laboratory?

SELECT ONE ANSWER ONLY.

- | | | |
|---|-------|-----------------------------|
| Gen-Probe Amplified MTD | | <input type="checkbox"/> 1 |
| Roche Amplicor MTB | | <input type="checkbox"/> 2 |
| Cepheid® GeneXpert MTB/RIF assay | | <input type="checkbox"/> 3 |
| Innogenetics® INNOLiPA Mycobacteria assay | | <input type="checkbox"/> 4 |
| Hain® GenoType® assays | | <input type="checkbox"/> 5 |
| Autogenomics Infiniti MDR-TB assay | | <input type="checkbox"/> 6 |
| Akronni TruArray MDR-TB test | | <input type="checkbox"/> 7 |
| Direct HPLC | | <input type="checkbox"/> 8 |
| Laboratory developed real-time PCR | | <input type="checkbox"/> 9 |
| Laboratory developed conventional PCR | | <input type="checkbox"/> 10 |
| Other | | <input type="checkbox"/> 11 |

Q15. What is the average monthly specimen volume of Direct Detection tests performed by your laboratory?

SELECT ONE ANSWER ONLY.

- | | | |
|---------------|-------|----------------------------|
| 1-5 | | <input type="checkbox"/> 1 |
| 6-10 | | <input type="checkbox"/> 2 |
| 11-15 | | <input type="checkbox"/> 3 |
| 16-25 | | <input type="checkbox"/> 4 |
| 26-50 | | <input type="checkbox"/> 5 |
| 51-75 | | <input type="checkbox"/> 6 |
| 76-100 | | <input type="checkbox"/> 7 |
| More than 100 | | <input type="checkbox"/> 8 |

Q16. Under what circumstances does your laboratory test for nucleic acid amplification inhibitors?

(*Choose the best answer.*)

SELECT ONE ANSWER ONLY.

- | | | |
|---|-------|----------------------------|
| Routinely for smear positives that are negative by NAAT. | | <input type="checkbox"/> 1 |
| Routinely on all NAAT negative specimens. | | <input type="checkbox"/> 2 |
| Routinely on all specimens. | | <input type="checkbox"/> 3 |
| Inhibitors are tested for periodically as a Quality Assurance Measure | | <input type="checkbox"/> 4 |
| Inhibitors are tested by special request only | | <input type="checkbox"/> 5 |
| My laboratory never tests for inhibitors | | <input type="checkbox"/> 6 |
| Assay utilized has amplification control included | | <input type="checkbox"/> 7 |

Q17. Which broth-based culture system is primarily used in your laboratory for the isolation of mycobacteria from respiratory specimens?

SELECT ONE ANSWER ONLY.

- | | |
|--|----------------------------|
| Bactec 460TB (radiometric) | <input type="checkbox"/> 1 |
| Versa TREK | <input type="checkbox"/> 2 |
| MB/BacT-Alert | <input type="checkbox"/> 3 |
| BACTEC MGIT- 960 | <input type="checkbox"/> 4 |
| Manual MGIT | <input type="checkbox"/> 5 |
| SeptiChek | <input type="checkbox"/> 6 |
| Manual 7H9 broth | <input type="checkbox"/> 7 |
| Other | <input type="checkbox"/> 8 |
| None. Broth-based culture is not used in my laboratory. | <input type="checkbox"/> 9 |

Q18. Under what circumstances do you use solid media for primary culturing of AFB from clinical respiratory specimens?

SELECT ONE ANSWER ONLY.

- | | |
|-------------------------------------|----------------------------|
| Always (almost always) | <input type="checkbox"/> 1 |
| Smear positive specimens only | <input type="checkbox"/> 2 |
| Only in special circumstances | <input type="checkbox"/> 3 |
| Not routinely (almost never) | <input type="checkbox"/> 4 |

Q19. What is the average number of specimens per week that are set up for culture of AFB in your laboratory?

(Please do not include AFB blood cultures)

SELECT ONE ANSWER ONLY.

- | | |
|---------------------|-----------------------------|
| Less than 5 | <input type="checkbox"/> 1 |
| 5-9 | <input type="checkbox"/> 2 |
| 10-15 | <input type="checkbox"/> 3 |
| 16-20 | <input type="checkbox"/> 4 |
| 21-30 | <input type="checkbox"/> 5 |
| 31-40 | <input type="checkbox"/> 6 |
| 41-100 | <input type="checkbox"/> 7 |
| 101-250 | <input type="checkbox"/> 8 |
| 251-500 | <input type="checkbox"/> 9 |
| More than 500 | <input type="checkbox"/> 10 |

Q20. What is the primary method used to identify isolates of *Mycobacterium tuberculosis* complex in your laboratory?

SELECT ONE ANSWER ONLY.

- | | |
|--|-----------------------------|
| Biochemicals | <input type="checkbox"/> 1 |
| HPLC | <input type="checkbox"/> 2 |
| Gen-Probe® - The AccuProbe® System: Mycobacterial Identification | <input type="checkbox"/> 3 |
| Genetic sequencing | <input type="checkbox"/> 4 |
| Laboratory developed real-time PCR assay | <input type="checkbox"/> 5 |
| PRA (PCR/RFLP) | <input type="checkbox"/> 6 |
| HAIN® GenoType Mtb assays | <input type="checkbox"/> 7 |
| AutoGenomics - INFINITI® Analyzer | <input type="checkbox"/> 8 |
| Akonni - TruDiagnosis Systems | <input type="checkbox"/> 9 |
| Bactec 460 NAP test | <input type="checkbox"/> 10 |
| Innogenetics® InnoLipa Mycobacteria | <input type="checkbox"/> 11 |
| Laboratory developed conventional PCR | <input type="checkbox"/> 12 |
| Other | <input type="checkbox"/> 13 |

Q21. What other secondary or confirmatory methods are used for identification of *Mycobacterium tuberculosis* complex in your laboratory?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|--|-----------------------------|
| Biochemicals | <input type="checkbox"/> 1 |
| HPLC | <input type="checkbox"/> 2 |
| Gen-Probe® - The AccuProbe® System: Mycobacterial Identification | <input type="checkbox"/> 3 |
| Genetic sequencing | <input type="checkbox"/> 4 |
| Laboratory developed real-time PCR assay | <input type="checkbox"/> 5 |
| PRA (PCR/RFLP) | <input type="checkbox"/> 6 |
| HAIN® GenoType Mtb assays | <input type="checkbox"/> 7 |
| AutoGenomics - INFINITI® Analyzer | <input type="checkbox"/> 8 |
| Akronni - TruDiagnosis Systems | <input type="checkbox"/> 9 |
| Bactec 460 NAP test | <input type="checkbox"/> 10 |
| Innogenetics® InnoLipa Mycobacteria | <input type="checkbox"/> 11 |
| Laboratory developed conventional PCR | <input type="checkbox"/> 12 |
| Referral to outside laboratory | <input type="checkbox"/> 13 |
| None, other confirmatory methods are not used in my laboratory. | <input type="checkbox"/> 14 |

Q22. Please indicate the selection that most closely fits the culture identification algorithm in your laboratory.

SELECT ONE ANSWER ONLY.

- | | |
|--|----------------------------|
| We only identify growth as acid-fast bacilli present | <input type="checkbox"/> 1 |
| We identify as acid-fast bacilli, and differentiate <i>M. tuberculosis</i> complex from nontuberculosis mycobacteria (NTM). | <input type="checkbox"/> 2 |
| We identify <i>M. tuberculosis</i> complex, and some common NTM (eg. <i>M. kansasii</i> , <i>M. avium</i> , etc.) whenever possible. | <input type="checkbox"/> 3 |
| We identify <i>M. tuberculosis</i> complex, and most NTM. | <input type="checkbox"/> 4 |
| We identify <i>M. tuberculosis</i> complex, NTM, and have the capability to identify <i>M. bovis</i> and <i>M. bovis</i> BCG within the <i>M. tuberculosis</i> complex. | <input type="checkbox"/> 5 |

Q23. In your laboratory, are culture identification procedures (e.g., Accuprobe, HPLC, etc.) typically:

SELECT ONE ANSWER ONLY.

- | | |
|--|----------------------------|
| Batched | <input type="checkbox"/> 1 |
| Batched but also performed as soon as possible on special request | <input type="checkbox"/> 2 |
| Started as soon as possible after a positive AFB culture is detected | <input type="checkbox"/> 3 |

Q24. On average, how many days per week are *Mycobacterium* identification tests conducted?

SELECT ONE ANSWER ONLY.

- | | |
|--------------------------------|----------------------------|
| 5-7 days | <input type="checkbox"/> 1 |
| 4 days | <input type="checkbox"/> 2 |
| 3 days | <input type="checkbox"/> 3 |
| 2 days | <input type="checkbox"/> 4 |
| 1 day | <input type="checkbox"/> 5 |
| Less than 1 day per week | <input type="checkbox"/> 6 |

Q25. In your laboratory, approximately what percentage of mycobacterial cultures processed within the last year were positive for *M. tuberculosis* complex?

(Please do not include AFB blood cultures.)

SELECT ONE ANSWER ONLY.

- | | |
|---------------------|----------------------------|
| Less than 1% | <input type="checkbox"/> 1 |
| 1-5 % | <input type="checkbox"/> 2 |
| 6-10 % | <input type="checkbox"/> 3 |
| 11-25 % | <input type="checkbox"/> 4 |
| 26-40 % | <input type="checkbox"/> 5 |
| 41-50 % | <input type="checkbox"/> 6 |
| 51-60% | <input type="checkbox"/> 7 |
| More than 60% | <input type="checkbox"/> 8 |

Q26. In your laboratory, approximately what percentage of mycobacterial cultures processed within the last year were positive for NTM?

(Please do not include AFB blood cultures.)

SELECT ONE ANSWER ONLY.

- | | | |
|---------------|-------|----------------------------|
| Less than 1% | | <input type="checkbox"/> 1 |
| 1-3 % | | <input type="checkbox"/> 2 |
| 4-6 % | | <input type="checkbox"/> 3 |
| 7-10 % | | <input type="checkbox"/> 4 |
| 11-20 % | | <input type="checkbox"/> 5 |
| 21-30 % | | <input type="checkbox"/> 6 |
| More than 30% | | <input type="checkbox"/> 7 |

Q27. What type of Drug Susceptibility Testing (DST) does your laboratory perform?

SELECT ONE ANSWER ONLY.

- | | | |
|---|-------|----------------------------|
| Direct (from smear positive clinical specimen) only | | <input type="checkbox"/> 1 |
| Indirect (from positive culture) only | | <input type="checkbox"/> 2 |
| Direct and Indirect | | <input type="checkbox"/> 3 |

Q28. In the last year, what was the average number of *M. tuberculosis* isolates set up for first-line drug susceptibility testing each month?

SELECT ONE ANSWER ONLY.

- | | | |
|---------------|-------|-----------------------------|
| Less than 1 | | <input type="checkbox"/> 1 |
| 1-5 | | <input type="checkbox"/> 2 |
| 6-10 | | <input type="checkbox"/> 3 |
| 11-15 | | <input type="checkbox"/> 4 |
| 16-20 | | <input type="checkbox"/> 5 |
| 21-25 | | <input type="checkbox"/> 6 |
| 26-30 | | <input type="checkbox"/> 7 |
| 31-40 | | <input type="checkbox"/> 8 |
| 41-50 | | <input type="checkbox"/> 9 |
| 51-100 | | <input type="checkbox"/> 10 |
| More than 100 | | <input type="checkbox"/> 11 |

Q29. What methods does your laboratory use for first-line drug susceptibility testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | | |
|------------------|-------|----------------------------|
| Agar proportion | | <input type="checkbox"/> 1 |
| BACTEC 460 TB | | <input type="checkbox"/> 2 |
| BACTEC MGIT 960 | | <input type="checkbox"/> 3 |
| Manual MGIT | | <input type="checkbox"/> 4 |
| Versa TREK | | <input type="checkbox"/> 5 |
| Etest | | <input type="checkbox"/> 6 |
| Molecular Method | | <input type="checkbox"/> 7 |
| Other | | <input type="checkbox"/> 8 |

Q30. Which is the primary method for first-line drug susceptibility testing?

SELECT ONE ANSWER ONLY.

- | | | |
|------------------|-------|----------------------------|
| Agar proportion | | <input type="checkbox"/> 1 |
| BACTEC 460 TB | | <input type="checkbox"/> 2 |
| BACTEC MGIT 960 | | <input type="checkbox"/> 3 |
| Manual MGIT | | <input type="checkbox"/> 4 |
| Versa TREK | | <input type="checkbox"/> 5 |
| Etest | | <input type="checkbox"/> 6 |
| Molecular Method | | <input type="checkbox"/> 7 |
| Other | | <input type="checkbox"/> 8 |

Q31. Which drugs are included in your first-line drug susceptibility panel?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

dst_q5

- | | |
|---------------------|-----------------------------|
| Isoniazid | <input type="checkbox"/> 1 |
| Rifampin | <input type="checkbox"/> 2 |
| Pyrazinamide | <input type="checkbox"/> 3 |
| Ethambutol | <input type="checkbox"/> 4 |
| Streptomycin | <input type="checkbox"/> 5 |
| Ciprofloxacin | <input type="checkbox"/> 6 |
| Ofloxacin | <input type="checkbox"/> 7 |
| Moxifloxacin | <input type="checkbox"/> 8 |
| Levofloxacin | <input type="checkbox"/> 9 |
| Other | <input type="checkbox"/> 10 |

Q32. How does your laboratory confirm first-line drug resistance?

SELECT ONE ANSWER ONLY.

- | | |
|---|----------------------------|
| Refer to another laboratory | <input type="checkbox"/> 1 |
| Confirm in-house by repeating the original method | <input type="checkbox"/> 2 |
| Confirm in-house using a different method | <input type="checkbox"/> 3 |
| Confirm in-house and refer to another laboratory | <input type="checkbox"/> 4 |
| Our laboratory does not confirm resistance | <input type="checkbox"/> 5 |
| Unsure | <input type="checkbox"/> 6 |

Q33. In your laboratory, when resistance to first-line drugs is detected, typically how soon is the isolate tested (in-house or referred) for susceptibility to second-line drugs?

SELECT ONE ANSWER ONLY.

- | | |
|--|----------------------------|
| Concurrently with first-line testing when a high clinical suspicion for resistance exists | <input type="checkbox"/> 1 |
| As soon as first-line drug resistance is initially detected | <input type="checkbox"/> 2 |
| As soon as first-line drug resistance is confirmed through additional testing | <input type="checkbox"/> 3 |
| Other | <input type="checkbox"/> 4 |

Q34. Which of these hypothetical first-line drug susceptibility results would prompt testing (in-house or referred) to second-line drugs?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|---|----------------------------|
| Isolate resistant to rifampin only | <input type="checkbox"/> 1 |
| Isolate resistant to both rifampin and isoniazid | <input type="checkbox"/> 2 |
| Isolate resistant to rifampin and another first-line drug (not isoniazid) | <input type="checkbox"/> 3 |
| Isolate resistant to any two first-line drugs | <input type="checkbox"/> 4 |
| By request only | <input type="checkbox"/> 5 |
| Second-line testing always performed concurrently with first-line panel | <input type="checkbox"/> 6 |
| Unsure | <input type="checkbox"/> 7 |

Q35. What methods does your laboratory use for second-line drug susceptibility testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|------------------------|----------------------------|
| Agar proportion | <input type="checkbox"/> 1 |
| BACTEC 460 TB | <input type="checkbox"/> 2 |
| BACTEC MGIT 960 | <input type="checkbox"/> 3 |
| Manual MGIT | <input type="checkbox"/> 4 |
| Versa TREK | <input type="checkbox"/> 5 |
| Etest | <input type="checkbox"/> 6 |
| Molecular method | <input type="checkbox"/> 7 |
| Other | <input type="checkbox"/> 8 |

Q36. What method does your laboratory primarily use for second-line drug susceptibility testing?

SELECT ONE ANSWER ONLY.

- | | |
|------------------------|----------------------------|
| Agar proportion | <input type="checkbox"/> 1 |
| BACTEC 460 TB | <input type="checkbox"/> 2 |
| BACTEC MGIT 960 | <input type="checkbox"/> 3 |
| Manual MGIT | <input type="checkbox"/> 4 |
| Versa TREK | <input type="checkbox"/> 5 |
| Etest | <input type="checkbox"/> 6 |
| Molecular method | <input type="checkbox"/> 7 |
| Other | <input type="checkbox"/> 8 |

Q37. Which drugs are included in your second-line drug susceptibility panel?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|--------------------------------|-----------------------------|
| High Level isoniazid | <input type="checkbox"/> 1 |
| High level ethambutol | <input type="checkbox"/> 2 |
| Streptomycin | <input type="checkbox"/> 3 |
| Ciprofloxacin | <input type="checkbox"/> 4 |
| Ofloxacin | <input type="checkbox"/> 5 |
| Moxifloxacin | <input type="checkbox"/> 6 |
| Levofloxacin | <input type="checkbox"/> 7 |
| Rifabutin | <input type="checkbox"/> 8 |
| Capreomycin | <input type="checkbox"/> 9 |
| Kanamycin | <input type="checkbox"/> 10 |
| Amikacin | <input type="checkbox"/> 11 |
| Ethionamide | <input type="checkbox"/> 12 |
| Para-aminosalicylic acid | <input type="checkbox"/> 13 |
| Cycloserine | <input type="checkbox"/> 14 |
| Clofazamine | <input type="checkbox"/> 15 |
| Linezolid | <input type="checkbox"/> 16 |
| Imipenem | <input type="checkbox"/> 17 |
| Other | <input type="checkbox"/> 18 |

Q38. How does your laboratory confirm second-line drug resistance?

SELECT ONE ANSWER ONLY.

- | | |
|---|----------------------------|
| Refer to another laboratory | <input type="checkbox"/> 1 |
| Confirm in-house by repeating the original method | <input type="checkbox"/> 2 |
| Confirm in-house using a different method | <input type="checkbox"/> 3 |
| Confirm in-house and refer to another laboratory | <input type="checkbox"/> 4 |
| Our laboratory does not confirm second line drug resistance | <input type="checkbox"/> 5 |

Q39. Which type of IGRA does your laboratory perform?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|---|----------------------------|
| QuantiFERON-TB Gold (Celestis) | <input type="checkbox"/> 1 |
| QuantiFERON-TB Gold In-Tube (Cellestis) | <input type="checkbox"/> 2 |
| T-SPOT.TB (Oxford Immunotec) | <input type="checkbox"/> 3 |
| Unsure | <input type="checkbox"/> 4 |

Q40. Does your laboratory report numerical values for IGRA results?

SELECT ONE ANSWER ONLY.

- | | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |

Q41. Does your laboratory perform testing for the molecular detection of mutations associated with drug resistance (mol-DR) for *M. tuberculosis* complex?

SELECT ONE ANSWER ONLY.

- | | |
|---|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No, clinical specimens are referred for mol-DR | <input type="checkbox"/> 2 |
| No, culture isolates are referred for mol-DR | <input type="checkbox"/> 3 |
| No, clinical specimens and culture isolates are referred for mol-DR | <input type="checkbox"/> 4 |
| No, mol-DR is not available in-house or through referral | <input type="checkbox"/> 5 |

Q42. Which assay does your laboratory perform for mol-DR?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|--|----------------------------|
| Conventional DNA sequencing | <input type="checkbox"/> 1 |
| Pyrosequencing | <input type="checkbox"/> 2 |
| Cepheid® GeneXpert MTB/RIF Assay | <input type="checkbox"/> 3 |
| Innogenetics® INNO-LiPA Rif.TB | <input type="checkbox"/> 4 |
| Hain® GenoType MTBDRplus | <input type="checkbox"/> 5 |
| Autogenomics Infiniti MDR-TB assay | <input type="checkbox"/> 6 |
| Akronni TruArray MDR-TB test | <input type="checkbox"/> 7 |
| Laboratory developed real-time PCR | <input type="checkbox"/> 8 |
| Other | <input type="checkbox"/> 9 |

Q43. Does your laboratory perform mol-DR on the following?

SELECT ONE ANSWER ONLY.

- Direct Specimens, but not isolates 1
Isolates, but not direct specimens 2
Both direct specimens and isolates 3

Q44. What is the average monthly testing volume (specimens and/or isolates) for mol-DR in your laboratory?

SELECT ONE ANSWER ONLY.

- Less than 1 1
1-5 2
6-10 3
11-15 4
16-20 5
21-25 6
26-30 7
31-40 8
41-50 9
51-100 10
More than 100 11

Q45. For which of the following gene mutations associated with resistance to antituberculosis drugs is molecular testing performed (in-house or referred testing)?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- rpoB* 1
inhA 2
katG 3
embB 4
pncA 5
gyrA 6
tlyA 7
rrs 8
eis 9
Other 10
Unsure 11

Referral Strategies (Question 46-57)

Q46. Does your laboratory routinely refer any of the following to another laboratory for AFB testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Yes, send specimens 1
Yes, send positive culture 2
Yes, send isolates 3
No 4

Q47. To which laboratory(ies) do you refer AFB specimens, cultures and/or isolates?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Regional or National Commercial Reference Laboratory 1
Clinical (Hospital) Laboratory Within our State 2
Clinical (Hospital) Laboratory Outside of our State 3
State Public Health Laboratory within our state 4
City or County Public Health Laboratory within our jurisdiction 5
Other State Public Health Laboratory (outside of our state) 6
US Centers for Disease Control and Prevention 7

Q48. You indicated that you refer specimens and/or isolates to a referral laboratory. Approximately what is the distance between your primary referral laboratory and your laboratory?

SELECT ONE ANSWER ONLY.

- Less than 10 miles 1
11-25 miles 2
26-60 miles 3
More than 60 miles 4

Q49. For which AFB testing or services does your laboratory refer specimens or isolates to your state or local public health laboratory (PHL)?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Do not refer to the state or local PHL 1
Refer unprocessed patient specimens for smear and culture 2
Perform smears in house and refer specimens for culture 3
Process specimens, inoculate media and refer for incubation 4
Refer positive cultures for identification 5
Refer NTM isolates only for identification 6
Refer isolates for first-line drug susceptibility testing 7
Refer isolates for second-line drug susceptibility testing 8
Refer specimens for NAAT or other molecular detection 9
Refer specimens/isolates for molecular detection of mutations associated with drug resistance 10
Refer isolates to the state or local PHL to comply with state law/requirements or on request 11
Refer specimens for IGRA 12
Refer isolates of *Mycobacteria tuberculosis* for genotyping 13

Q50. You indicated that you do not refer specimens or isolates to your state or local PHL. Why not?

(Select up to 3 choices.)

SELECT ALL ANSWERS THAT APPLY.

- Turn-around-time issues 1
Customer service issues 2
Cost of services 3
Communication issues 4
Billing (business practices)? 5
Specimen shipping/transport 6
Monday – Friday work schedule 7
Menu of services does not include DST 8
Menu of services does not include NAAT or Direct Detection 9
Results are not reliable 10
PHL does not accept specimens 11
Our laboratory has contractual obligations with a different referral laboratory 12
Availability of electronic accessioning/reporting 13
Other 14

Q51. Does your laboratory monitor the turnaround time of your referral laboratory(s)?

SELECT ONE ANSWER ONLY.

- Yes 1
No, never 2

Q52. Are you generally satisfied with the turnaround times produced by your referral laboratory from specimen receipt to reporting of . . .

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Yes | No | Not Applicable |
|--|----------------------------|----------------------------|----------------------------|
| AFB Smear Results (24hours)? ... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Identification of <i>M. tuberculosis</i> complex (21 days)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| Drug Susceptibility Testing Results for M. tb complex (28 days)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |

Q53. Does your referral laboratory notify the following entities with the following results?

(Check all that apply.)

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Smear Positive form AFB | Culture positive for AFB | Positive Mtb Identification | Drug resistance detected | Unsure |
|---|----------------------------|----------------------------|-----------------------------|----------------------------|----------------------------|
| Clinical Care Provider | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Original Submitting Laboratory..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| State or Local Health Department (TB Control) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

Q54. In addition to your laboratory, who receives reports (either written or electronic) from your referral laboratory?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Ordering Clinical Care Provider (physician, clinic, etc) 1
 Original submitting laboratory 2
 State or Local Health Department (TB control) 3
 State, County or City Public Health Laboratory 4
 Unsure 5
 No other entity receives reports from our referral laboratory 6

Q55. Does your laboratory receive referred specimens or isolates for any AFB testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Yes, receive specimens 1
 Yes, receive isolates 2
 Yes, receive positive culture 3
 No 4

Q56. What Mycobacteriology reference services do you provide for other laboratories in house?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Smear 1
 Direct Detection (e.g NAAT) to identify *Mycobacterium tuberculosis* complex 2
Mycobacterium culture 3
 Identification of *Mycobacterium tuberculosis* complex only 4
 Identification of frequently encountered NTMs. 5
 Identification of all *Mycobacterium* spp. 6
 Confirmation of *Mycobacterium* identification 7
 First-line drug susceptibility testing 8
 Second-line drug susceptibility testing 9
 Confirmation of Drug Resistance 10
 Molecular testing for mutations associated with drug resistance 11
 Genotyping 12
 Other 13

Q57. From whom does your laboratory primarily receive specimens, cultures, and/or isolates?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Public health clinics 1
 In state hospitals 2
 Out of state hospitals 3
 Physician offices 4
 Public health laboratories 5
 Indian health services 6
 Commercial laboratories 7
 Corrections (Jails and prisons) 8
 Military hospitals 9
 VA hospitals 10
 Refugee health services 11
 International settings 12
 Immigration Services 13
 Other 14

Specimen Collection, Handling and Transport (Questions 58-60)

Q58. In what format(s) is your laboratory's manual of services (information on available tests, specimen collection and handling) available to your clients?

SELECT ONE ANSWER ONLY.

- Electronically only 1
Hard Copy only 2
Both electronically and in hard copy 3
We do not provide a manual of services to our clients 4

Q59. What is the maximum transport time that your laboratory allows before a specimen will be rejected (date of collection to date of receipt)?

SELECT ONE ANSWER ONLY.

- 0 - 24 hours 1
24 -47 hours 2
48 -71 hours 3
3 days -1 week 4
8 days -1 month 5
Our laboratory does not have a rejection policy for maximum transport time 6

Q60. What is the single biggest obstacle to the timely transport of specimens to your laboratory?

SELECT ONE ANSWER ONLY.

- We have no obstacles 1
Lack of courier/ carrier service 2
Frequency of courier/ carrier service (e.g. courier/ carrier picks up specimens at infrequent intervals) 3
Cost of courier/ carrier service 4
Unreliable courier/ carrier service (e.g. courier/ carrier does not always show up when scheduled) 5
Batching of specimens prior to transport (e.g. test requestors batch multiple specimens before sending them to the laboratory) 6
Other 7

Turn-around-Times (Questions 61-67)

Q61. Does your laboratory monitor turn-around-times for:

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Specimen collection to receipt 1
Specimen receipt to reporting of AFB smear results 2
Specimen receipt to reporting of Direct Detection Results 3
Specimen receipt to reporting of *M. tuberculosis* complex identification results from culture 4
Specimen receipt to reporting of *M. tuberculosis* complex drug susceptibility results 5
We do not routinely monitor turn-around times 6

Q62. What percentage of clinical specimens does your laboratory receive for Mycobacteriology testing within 1 calendar day of specimen collection?

SELECT ONE ANSWER ONLY.

- 0-9% 1
10-19% 2
20-29% 3
30-39% 4
40-49% 5
50-59% 6
60-69% 7
70-79% 8
80-89% 9
90-100% 10

Q63. What percentage of clinical specimens for Mycobacteriology testing are received 3 or more days after collection?

SELECT ONE ANSWER ONLY.

| | |
|---------------|-----------------------------|
| 0-9% | <input type="checkbox"/> 1 |
| 10-19% | <input type="checkbox"/> 2 |
| 20-29% | <input type="checkbox"/> 3 |
| 30-39% | <input type="checkbox"/> 4 |
| 40-49% | <input type="checkbox"/> 5 |
| 50-59% | <input type="checkbox"/> 6 |
| 60-69% | <input type="checkbox"/> 7 |
| 70-79% | <input type="checkbox"/> 8 |
| 80-89% | <input type="checkbox"/> 9 |
| 90-100% | <input type="checkbox"/> 10 |

Q64. In your laboratory, what percentage of AFB smear microscopy results are reported to the provider within 24 hours of specimen receipt?

SELECT ONE ANSWER ONLY.

| | |
|---------------|-----------------------------|
| 0-9% | <input type="checkbox"/> 1 |
| 10-19% | <input type="checkbox"/> 2 |
| 20-29% | <input type="checkbox"/> 3 |
| 30-39% | <input type="checkbox"/> 4 |
| 40-49% | <input type="checkbox"/> 5 |
| 50-59% | <input type="checkbox"/> 6 |
| 60-69% | <input type="checkbox"/> 7 |
| 70-79% | <input type="checkbox"/> 8 |
| 80-89% | <input type="checkbox"/> 9 |
| 90-100% | <input type="checkbox"/> 10 |

Q65. In your laboratory, what percentage of *M. tuberculosis* complex Direct Detection results are reported to the provider within. . .

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | 0-9% | 10-19% | 20-29% | 30-39% | 40-49% | 50-59% | 60-69% | 70-79% | 80-89% | 90-100% |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 48 hours of specimen receipt? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |
| 72 hours of specimen receipt (response should include % reported within 48 hours (i.e., cumulative))?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |

Q66. What percent of *M. tuberculosis* complex does your laboratory identify from culture of clinical specimens (e.g., sputum) within. . .

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | 0-9% | 10-19% | 20-29% | 30-39% | 40-49% | 50-59% | 60-69% | 70-79% | 80-89% | 90-100% |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 14 days of specimen receipt? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |
| 21 days of specimen receipt (response should include % identified within 14 days (i.e., cumulative))?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |
| 28 days of specimen receipt (response should include % identified within 21 days (i.e., cumulative))?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |

Q67. What percent of *M. tuberculosis* complex first-line drug susceptibility testing results does your laboratory report from clinical specimens (e.g., sputum) within. . .

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | 0-9% | 10-19% | 20-29% | 30-39% | 40-49% | 50-59% | 60-69% | 70-79% | 80-89% | 90-100% |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 28 days of specimen receipt? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |
| 35 days of specimen receipt (response should include % reported within 28 days (i.e., cumulative))?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 |

Reporting Practices (Questions 68-72)

68. Does your laboratory have the capability to report results electronically to the:

SELECT ONE ANSWER ONLY.

- State or Local Public Health Department only 1
Clinical Care Provider only 2
Both to State or Local Public Health Department and to Clinical Care Provider 3
Laboratory does not have electronic reporting capability 4

Q69. To whom do you report positive test results for AFB smear, Direct Detection and/or culture?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Health care provider 1
State or Local Health Department (TB Controller) 2
Infection Control 3
Submitting Laboratory 4
Nursing Floor 5

Q70. Which of the following are considered “critical values” (i.e. For which values do you expedite notification) in your laboratory?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Positive AFB smear 1
Positive TB culture 2
Direct Detection positive for *M. tuberculosis* complex 3
Drug resistant TB 4
Multi-drug resistant TB 5
None 6

Q71. What is the primary way your laboratory reports critical values (expedited notification) to the state or local public health department and the clinician?

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Phone | Fax | Email | Electronically through Laboratory Information Management System – reports delivered automatically | Postal mail – LIMS reports delivered via mail | Postal mail – report generated by hand not through LIMS | Web-based reporting tool | We never report results to this entity | |
|---|----------------------------|----------------------------|----------------------------|---|---|---|----------------------------|--|---|
| State or Local Public Health Department | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | |
| Test requestor | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | r |

Q72. Do you notify the submitter when drug resistance is suspected by preliminary test results (e.g. the initial DST results suggest Rifampin resistance and confirmatory test results are underway)?

SELECT ONE ANSWER ONLY.

- Yes as soon as resistance is suspected. 1
No, not until resistance is confirmed. 2

Laboratory Staff and Training (Question 73-85)

Q73. Does your Mycobacteriology staff consist of the following:

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Yes | No |
|---|----------------------------|----------------------------|
| Staff that work in Mycobacteriology only..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Staff that work in Mycobacteriology and other areas of Microbiology | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| Staff that work in areas of the laboratory other than Microbiology that are cross- trained to perform AFB processing..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

Q74. How many Full-Time Equivalents (FTEs) are in each of the following staffing categories in your laboratory?

WRITE IN ANSWER WITHIN THE RANGE 0 - 255

Q74. How many Full-Time Equivalents (FTEs) are in each of the following staffing categories in your laboratory?

| | |
|---|----------------------|
| Staff that work in Mycobacteriology only | <input type="text"/> |
| Staff that work in Mycobacteriology and other areas of Microbiology | <input type="text"/> |
| Staff that are cross-trained to perform AFB processing or testing | <input type="text"/> |

Q75. What is the average number of years of professional, diagnostic Mycobacteriology experience of the current staff in your laboratory?

SELECT ONE ANSWER ONLY.

| | |
|--------------------------|----------------------------|
| Less than 1 year | <input type="checkbox"/> 1 |
| 1-5 years | <input type="checkbox"/> 2 |
| 6-10 years | <input type="checkbox"/> 3 |
| 11-20 years | <input type="checkbox"/> 4 |
| More than 20 years | <input type="checkbox"/> 5 |

Q76. Have you experienced staff shortages for Mycobacteriology within the last 12 months?

SELECT ONE ANSWER ONLY.

| | |
|-----------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |

Q77. Have those shortages resulted in a decrease in AFB services or an increase in turnaround times?

SELECT ONE ANSWER ONLY.

| | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |

Q78. Has your laboratory experienced any obstacles in recruiting qualified staff to perform Mycobacteriology testing?

SELECT ONE ANSWER ONLY.

| | |
|-----------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |

Q79. What are the biggest obstacles in recruiting qualified staff to perform Mycobacteriology testing?

(Select up to 3 choices.)

SELECT ALL ANSWERS THAT APPLY.

- Individuals in the applicant pool lack professional experience 1
Individuals in the applicant pool lack certification 2
Inability of your institution to offer competitive salary 3
Individuals in the applicant pool are resistant to working with Mycobacteria 4
Shortage of Medical Technologists or Clinical Laboratory Scientists 5
Individuals in the applicant pool are resistant to working the needed shifts (2nd shift, 3rd shift, weekends) 6
State licensing requirements 7
Difficulty in hiring process 8
Hiring freeze 9
Other please specify (Please write in) 10

Q80. Has your laboratory experienced any obstacles in retaining qualified staff to perform Mycobacteriology testing?

SELECT ONE ANSWER ONLY.

- Yes 1
No 2

Q81. What are the biggest obstacles in retaining qualified staff in your laboratory to perform Mycobacteriology testing?

(Select up to 3 choices.)

SELECT ALL ANSWERS THAT APPLY.

- Inability to offer competitive salary 1
Existing staff resistant to working with TB 2
Retirement of experienced Mycobacteriology staff 3
Ergonomic issues 4
Occupational Health Issues 5
Individuals in the applicant pool are resistant to working the needed shifts (2nd shift, 3rd shift, weekends) 6
Lack of advancement opportunities 7
Other (Please write in) 8

Q82. Choose which type of diagnostic Mycobacteriology training method your laboratory would be most interested in participating.

SELECT ONE ANSWER ONLY.

- Teleconference 1
Webinar 2
Correspondence course 3
On-site training in your laboratory 4
Workshop at an off-site location 5
Wet laboratory 6
Videotaped lectures 7
Lectures on CD-Rom 8
Self study (paper or web-based) 9

Q83. What training topics are most relevant to those performing Mycobacteriology testing in your laboratory?

(Select up to 3 choices.)

SELECT ALL ANSWERS THAT APPLY.

- Biosafety 1
AFB smears 2
Direct Detection of Mycobacteria 3
AFB Culture 4
AFB Identification 5
Drug Susceptibility Testing for Mycobacteria 6
Interferon Gamma Release Assays 7
Molecular Diagnostics 8
QA/ QMS/ laboratory management 9
TB public health issues/ epidemiology 10
Other please specify (Please write in) 11

Q84. Did you provide Mycobacteriology training for other laboratories within the last year?
SELECT ONE ANSWER ONLY.

Yes 1
No 2

Q85. Do you receive Mycobacteriology training from your State Public Health Laboratory?
SELECT ONE ANSWER ONLY.

Yes 1
No, training was offered but not attended 2
No, not aware of training opportunities 3
Unsure 4

Safety Practices (Question 86 -92)

Q86. Has your laboratory performed a safety risk assessment at each stage of testing for mycobacteria (from specimen receipt to reporting)?

SELECT ONE ANSWER ONLY.

Yes 1
No 2
Unsure 3

Q87. Does your laboratory require the following for new employees performing Mycobacteriology testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

A one-step Mantoux tuberculin skin test (TST) 1
A two-step Mantoux tuberculin skin test (TST) or an interferon gamma release assay (IGRA) 2
A medical evaluation, including a chest radiograph, if the TST or IGRA is positive 3
A medical evaluation as part of a respiratory fit testing program 4
None of the Above 5

Q88. Does your laboratory require the following for all employees performing Mycobacteriology testing?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

At least annual tuberculin skin test (TST) or IGRA on tuberculin negative employees 1
A medical evaluation if the TST or IGRA converts to positive or if symptoms of tuberculosis are exhibited 2
Medical evaluation, follow-up, and counseling for any known exposure event or TST/IGRA conversion 3
Maintenance of a permanent record of skin testing or IGRA results 4
A periodic (at least annual) symptom review for individuals with a history of latent TB infection (LTBI) or prior tuberculosis 5
Annual fit testing if N-95 or N-100 respirators are used 6
None of the Above 7

Q89. Which of the following types of respiratory protection, if any, are worn by laboratory staff performing Mycobacteriology testing and how frequently is each type of respiratory protection used?

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Routinely Used by Most Staff | Occasionally Used (in the case of spills or other special circumstances) | Never Used | Unsure |
|---|------------------------------|--|----------------------------|----------------------------|
| Surgical Mask..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| N-95 respirator with fit testing | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| N-95 respirator without fit testing..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| Powered Air Purifying Respirators (PAPR)..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |

Q90. What is the BioSafety Level (BSL) of practices in your laboratory used for Mycobacteriology testing?

(Use the chart presented below as reference to answer this question.)

SELECT ONE ANSWER ONLY.

BSL1 1
BSL 2 2
BSL 3 3
Unsure 4

Q91. What is the BSL of primary barriers (i.e. safety equipment) in your laboratory used for Mycobacteriology testing?

(Use the chart presented below as reference to answer this question.)

SELECT ONE ANSWER ONLY.

| | |
|--------------|----------------------------|
| BSL1 | <input type="checkbox"/> 1 |
| BSL 2 | <input type="checkbox"/> 2 |
| BSL 3 | <input type="checkbox"/> 3 |
| Unsure | <input type="checkbox"/> 4 |

Q92. What is the BSL of secondary barriers (i.e. facilities) in your laboratory used for Mycobacteriology testing?

(Use the chart presented below as reference to answer this question.)

SELECT ONE ANSWER ONLY.

| | |
|--------------|----------------------------|
| BSL1 | <input type="checkbox"/> 1 |
| BSL 2 | <input type="checkbox"/> 2 |
| BSL 3 | <input type="checkbox"/> 3 |
| Unsure | <input type="checkbox"/> 4 |

Proficiency Testing and Quality Assurance (Questions 93-97)

Q93. Which external Mycobacteriology proficiency testing categories do you participate in?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

| | |
|---|----------------------------|
| Acid fast stain | <input type="checkbox"/> 1 |
| Mycobacteriology Culture | <input type="checkbox"/> 2 |
| Mycobacteriology Identification | <input type="checkbox"/> 3 |
| Mycobacteriology Drug Susceptibility Testing | <input type="checkbox"/> 4 |
| Mycobacteriology Nucleic Acid Amplification Testing | <input type="checkbox"/> 5 |
| Other | <input type="checkbox"/> 6 |

Q94. Are you aware of the CDC Model Performance Evaluation Program (MPEP) program?

SELECT ONE ANSWER ONLY.

| | |
|-----------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |

Q95. What improvements, if any, can be made in Mycobacteriology Proficiency Testing programs?

SELECT ALL ANSWERS THAT APPLY.

| | |
|---|----------------------------|
| My PT program meets my needs as it currently exists | <input type="checkbox"/> 1 |
| Make the challenges more difficult | <input type="checkbox"/> 2 |
| Decrease the cost of proficiency testing programs | <input type="checkbox"/> 3 |
| Increase the frequency of challenges | <input type="checkbox"/> 4 |
| Decrease the frequency of challenges | <input type="checkbox"/> 5 |
| Improve the specimen quality leading to more consistent results | <input type="checkbox"/> 6 |
| Increase the reporting options | <input type="checkbox"/> 7 |
| Make the challenges less time consuming | <input type="checkbox"/> 8 |
| Offer more assay or analyte options | <input type="checkbox"/> 9 |

Q96. How are the results of proficiency tests used in your laboratory?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

| | |
|--|----------------------------|
| Compare your laboratory's performance with other laboratories | <input type="checkbox"/> 1 |
| Assess the performance of individual laboratorians | <input type="checkbox"/> 2 |
| Review and revise training and CE activities based on PT results | <input type="checkbox"/> 3 |
| Review and revise laboratory procedures/processes | <input type="checkbox"/> 4 |
| To comply with CLIA/CMS requirements | <input type="checkbox"/> 5 |

Q97. Which of the following policies does your laboratory have in place?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Review and record the number of specimens rejected and the reason for rejections 1
- Monitoring the resistance patterns of *M. tuberculosis* complex isolated in your laboratory 2
- Inoculate a negative control with each batch of cultures that are inoculated 3
- Monitor contamination rates by specimen 4
- Monitor contamination rates by individual media 5
- Confirm or ensure confirmation of drug resistance 6
- Maintain reference strains of Mycobacteria spp adequate for your QC procedures 7
- Limit the number of specimens submitted per patient 8
- To prevent cross contamination and false positives 9
- To detect cross contamination and false positives 10

Public Health and Epidemiology (Questions 98-110)

Q98. Does your state provide/ fund a no or low cost courier system to transport AFB specimens or isolates to your state or local PHL?

SELECT ONE ANSWER ONLY.

- Yes 1
- Yes, but with limited coverage 2
- No 3
- Unsure 4

Q99. Under what circumstances does your laboratory communicate with other clinical, commercial, or other (non public health) laboratories regarding Mycobacteriology?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Reporting Laboratory Results 1
- Providing guidance for submission of specimens to or from your laboratory 2
- Providing guidance for interpretation of laboratory results 3
- Exchanging patient information 4
- Formal training/ education sessions about laboratory methodologies 5
- Unsure 6

Q100. 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?

SELECT ONE ANSWER ONLY.

- Yes 1
- No 2
- Unsure 3
- N/A—we accept specimens from multiple states 4

Q101. Please rate your satisfaction with your State or Local Public Health TB Laboratory for the following measures:

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Very Unsatisfied | Unsatisfied | Neither Satisfied nor Dissatisfied | Satisfied | Very Satisfied |
|-----------------------------|----------------------------|----------------------------|------------------------------------|----------------------------|----------------------------|
| Timeliness of results..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Expertise of Staff | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Cost of Services..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Accessibility..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Menu of Services..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Reliability of Results..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

Q102. Please rate your satisfaction with the US Centers for Disease Control and Prevention's TB Laboratory for the following measures:

SELECT ONE ANSWER ON EACH LINE ACROSS.

| | Very Unsatisfied | Unsatisfied | Neither Satisfied nor Dissatisfied | Satisfied | Very Satisfied |
|-----------------------------|----------------------------|----------------------------|------------------------------------|----------------------------|----------------------------|
| Timeliness of results | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Expertise of Staff | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Accessibility | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Menu of Services | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| Reliability of Results..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

Q103. Under what circumstances does your laboratory communicate with the state or local Public Health Department (TB Control Program)?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Reporting Positive Laboratory Results 1
Providing guidance for interpretation of or problems with laboratory results 2
Case and/ or Cohort Reviews 3
Consultation concerning TB genotyping results 4
To facilitate testing requests 5
Research collaboration 6
Unsure 7
We do not communicate with the TB Control Program 8

Q104. Under what circumstances does your laboratory communicate with the state or local Public Health Department (TB Control Program)?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Reporting Positive Laboratory Results 1
Providing guidance for interpretation with laboratory results 2
Case and/ or Cohort Reviews 3
Consultation concerning TB genotyping results 4
Formal training/ education sessions about laboratory tests 5
Budgetary issues 6
Grants and cooperative agreements 7
To facilitate testing requests 8
Research collaboration 9
Unsure 10

Q105. How would you characterize your relationship with the jurisdictional TB Control Program?

SELECT ONE ANSWER ONLY.

- Very Strong 1
Strong 2
Weak 3
Very Weak 4

Q106. Under what circumstances does your TB laboratory communicate with other clinical, commercial, and/or public health laboratories within your jurisdiction?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- Reporting Laboratory Results 1
Providing guidance for submission or referral of specimens to or from your laboratory ... 2
Providing guidance for interpretation of laboratory results 3
Formal training/ education sessions about laboratory methodologies 4
Laboratory inspection or regulatory visit 5
Research collaboration 6
Unsure 7

Q107. Which of the following CDC TB laboratory services did your laboratory utilize in the past year?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|---|----------------------------|
| Submitted isolates for the molecular detection of drug resistance | <input type="checkbox"/> 1 |
| Submitted isolates for drug susceptibility testing | <input type="checkbox"/> 2 |
| Submitted isolates for identification within the <i>M. tuberculosis</i> complex | <input type="checkbox"/> 3 |
| Contacted CDC for technical advice | <input type="checkbox"/> 4 |
| Training | <input type="checkbox"/> 5 |
| We have no knowledge of TB services offered by CDC | <input type="checkbox"/> 6 |
| None of the above | <input type="checkbox"/> 7 |

Q108. 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?

SELECT ONE ANSWER ONLY.

- | | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |

Q109. Does your state legally require laboratories to report the AFB smear positive, direct detection or isolation of *M. tuberculosis* complex for all new TB cases to Public Health Authorities?

SELECT ONE ANSWER ONLY.

- | | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |

Q110. How are TB genotyping results used in your laboratory?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|---|----------------------------|
| Not used | <input type="checkbox"/> 1 |
| Genotyping results are only received and forwarded to TB Control Program | <input type="checkbox"/> 2 |
| Used for identification of potential false positives | <input type="checkbox"/> 3 |
| Used to provide laboratory developed report and/or consultation to TB Control Program | <input type="checkbox"/> 4 |
| Used to indicate species within <i>M. tuberculosis</i> complex | <input type="checkbox"/> 5 |
| Genotyping results are not received in the laboratory | <input type="checkbox"/> 6 |
| For QA/QC purposes | <input type="checkbox"/> 7 |
| Other | <input type="checkbox"/> 8 |

Planning for the Future (Questions 111- 118)

Q111. In your laboratory, what are the biggest barriers when trying to do the following:

(Select up to 3 choices.)

SELECT ALL ANSWERS THAT APPLY PER LINE.

| | No difficulties are experienced | Time required for validation/s/verification | Complex procurement system within your organization (it's difficult to purchase new equipment) | Lack of adequate staffing (staffing shortage) | Facilities/Space Limitations | Staff skill-set does not permit | Lack of available FDA approved or cleared tests | No perceived customer need | Lack of management buy-in | Lack of available specimens for verifications/validations | Cost of implementing new service or technology |
|--|---------------------------------|---|--|---|------------------------------|---------------------------------|---|----------------------------|----------------------------|---|--|
| Add new Mycobacteriology Services not already offered..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 | <input type="checkbox"/> 11 |
| Implement new Mycobacteriology assays or technologies..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 | <input type="checkbox"/> 10 | <input type="checkbox"/> 11 |

Q112. Over the next 12 months does your laboratory plan (or anticipate) changes in the volume of testing performed in house?

SELECT ONE ANSWER ONLY.

- Anticipate an increase in workload 1
 Anticipate a decrease in workload 2
 Anticipate no major change in workload 3
 Unsure 4

Q113. You indicated that your laboratory is anticipating an increase in workload. Is this increase due to service consolidation within your network or geographic region?

SELECT ONE ANSWER ONLY.

- Yes 1
 No 2
 Unsure 3

Q114. You indicated that your laboratory is anticipating a decrease in workload. Is this decrease due to service consolidation within your network or geographic region?

SELECT ONE ANSWER ONLY.

- Yes 1
 No 2
 Unsure 3

Q115. Which of the following Mycobacteriology services is your laboratory considering adding?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|--|-----------------------------|
| AFB Smear | <input type="checkbox"/> 1 |
| AFB Culture | <input type="checkbox"/> 2 |
| <i>M. tuberculosis</i> complex identification | <input type="checkbox"/> 3 |
| NTM identification | <input type="checkbox"/> 4 |
| Nucleic Acid Amplification Testing for Direct Detection for TB | <input type="checkbox"/> 5 |
| Drug Susceptibility Testing (traditional method) | <input type="checkbox"/> 6 |
| Molecular Detection of Mutations Associated with Drug Resistance | <input type="checkbox"/> 7 |
| Interferon Gamma Release Assay (IGRA) | <input type="checkbox"/> 8 |
| Expanding identification capabilities/capacities | <input type="checkbox"/> 9 |
| Adding first-line drug susceptibility testing | <input type="checkbox"/> 10 |
| Adding a second method for confirmation of resistance for first-line drugs | <input type="checkbox"/> 11 |
| Adding second-line drug susceptibility testing | <input type="checkbox"/> 12 |
| Other | <input type="checkbox"/> 13 |
| Not considering adding new services | <input type="checkbox"/> 14 |

Q116. 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?

SELECT ONE ANSWER ONLY.

- | | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |

Q117. What services has/is your Mycobacteriology laboratory considering eliminating within the next 12 months or has your laboratory eliminated services within the last 12 months?

(Check all that apply.)

SELECT ALL ANSWERS THAT APPLY.

- | | |
|--|----------------------------|
| There are no plans to eliminate services or no services have been eliminated | <input type="checkbox"/> 1 |
| AFB smears – direct (unconcentrated) | <input type="checkbox"/> 2 |
| AFB smears - concentrated | <input type="checkbox"/> 3 |
| AFB Culture | <input type="checkbox"/> 4 |
| AFB Identification | <input type="checkbox"/> 5 |
| Identification of NTM | <input type="checkbox"/> 6 |
| Drug Susceptibility Testing for Mycobacteria | <input type="checkbox"/> 7 |
| NAAT | <input type="checkbox"/> 8 |
| Other | <input type="checkbox"/> 9 |

Q118. 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?

SELECT ONE ANSWER ONLY.

- | | |
|--------------|----------------------------|
| Yes | <input type="checkbox"/> 1 |
| No | <input type="checkbox"/> 2 |
| Unsure | <input type="checkbox"/> 3 |