

# Tuberculosis Laboratory Aggregate Report

Fifth Edition





# 2019



**Centers for Disease Control and Prevention** National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

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2019 Tuberculosis Laboratory Aggregate Report—Fifth Edition

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For accessibility, a full explanation of figures can be found in <u>Appendix A: Explanation of Figures for</u> <u>Accessibility on page 16</u>.

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### Introduction

The Laboratory Capacity Team (LCT) in the Laboratory Branch (LB) of the Division of Tuberculosis Elimination (DTBE) at the U.S. Centers for Disease Control and Prevention (CDC) provides oversight for the laboratory component of the CDC Tuberculosis (TB) Elimination and Laboratory Strengthening Cooperative Agreement (CoAg). Each year, 58 state and local public health laboratories (PHL) submit an Annual Performance Report (APR) with self-reported laboratory workload and turnaround time (TAT) data, testing algorithms, an organizational chart, and responses to three required TB laboratory elements of the CoAg. The data are compiled into a practical report for PHL to use as a tool for benchmark assessments and peer comparisons.

As part of a robust quality assurance program, laboratories should monitor workload volume and TAT indicators. By assessing these indicators internally over time, laboratories can track performance progress and set realistic laboratory-specific goals. This report provides a resource for external comparison against peer data. Use of national averages and trends data from this report should be used to document your laboratory's accomplishments or to provide evidence to substantiate change (e.g., methodologies, protocols, or need for additional resources) to improve TAT indicators.

Please contact your LCT consultant with any questions regarding data requirements for the CDC TB CoAg or your laboratory's specific data. In addition, any recommendations concerning the report and its content are always welcomed and appreciated.

### **Executive Summary**

Data in this *TB Laboratory Aggregate Report—Fifth Edition* include a comparison of aggregate workload data and nucleic acid amplification test (NAAT) trends for calendar years 2015, 2016, and 2017. TAT data for 2017 and current public health laboratory TB testing methods are also included in this report.

CoAg PHL self-reported workload and TAT benchmark data suggest:

- Decrease in the number of clinical specimens received and number of patients for whom a specimen was submitted from 2015 to 2017, but an increase of 3.9% for the number of patients positive for *Mycobacterium tuberculosis* complex (MTBC) by culture.
- At the PHL, only 44% of patients with MTBC positive cultures had a positive NAAT performed within 48 hours.
- CoAg PHL utilize a variety of NAAT algorithms with the most common described as testing of new acid fast bacilli (AFB) smear positive specimens and when requested, those that are AFB smear negative.
- 2017 national averages for each of the four TAT indicators remain below national targets. However, more laboratories met or exceeded the national target compared to 2015 for AFB smear, identification (ID), and drug susceptibility testing (DST), indicating improved TAT performance.
- Since 2016, 4 additional laboratories implemented IGRA testing and 9 laboratories changed the NAAT method performed.

LCT encourages laboratorians to review the details of each section for more in-depth assessments and comparisons.

### **Acronyms and Abbreviations**

AFB: Acid-fast bacilli

**AP:** Agar proportion

**APR:** Annual Performance Report for the CDC TB Cooperative Agreement

**BACTEC MGIT™:** Mycobacterium Growth Indicator Tube. A commercial non-radiometric broth-based mycobacterial culture system by Becton Dickinson and Co.

CoAg: CDC TB Elimination Cooperative Agreement

**CDC:** U.S. Centers for Disease Control and Prevention

**DST:** Drug susceptibility testing. Inoculation of bacteria in/on media containing a particular drug for determination of susceptibility or resistance based on growth.

HHS: U.S. Department of Health and Human Services

HP 2020: Healthy People 2020

**HPLC:** High Performance Liquid Chromatography. Analytical technique for the identification of mycobacteria species based on differences in cell wall mycolic acids.

**ID:** Identification

**IGRA:** Interferon-Gamma Release Assay. Whole-blood test used to measure a person's immune reactivity to MTBC.

**INNO-LiPA®:** Commercial line probe assays by Fujirebio that identifies MTBC and can detect mutations associated with rifampin resistance.

LCT: Laboratory Capacity Team

LIMS: Laboratory Information Management System

**Maldi-TOF:** Matrix-assisted Laser Desorption Ionization Time of Flight. A mass-spectrometry based assay for bacterial identification based on time of flight of proteins and peptides.

MTBC: Mycobacterium tuberculosis complex

**MTD®:** Amplified Mycobacterium tuberculosis Direct Test. A commercial molecular assay by Hologic<sup>®</sup> for direct detection of MTBC in clinical specimens. **MTBDR***plus***:** Commercial line probe assay by Bruker (previously by HAIN LifeScience) that detects mutations associated with both rifampin and isoniazid resistance.

**NAAT:** Nucleic acid amplification test. In this report, generic terminology for molecular methods used for direct detection of MTBC in clinical specimens.

PHL: Public health laboratories

**PRA:** PCR restriction analysis. Analysis of amplified DNA fragments produced by the cleaving of DNA by restriction enzymes.

**Quantiferon®:** A commercial IGRA blood test by QIAGEN that is used to aid in diagnosis of TB infection.

TAT: Turnaround time

**TB:** Tuberculosis

**Trek Sensititre® MYCOTB:** A commercial microtiter plate by ThermoScientific for minimum inhibitory concentration (MIC) testing of 12 antituberculosis drugs, simultaneously.

**T-SPOT®.***TB***:** A commercial IGRA blood test by Oxford ImmunoTec used to aid in diagnosis of TB infection.

**Xpert<sup>™</sup> MTB/RIF:** A commercial molecular assay by Cepheid, Inc. for direct detection of MTBC and mutations associated with rifampin resistance.

### **Technical Notes**

- Unless otherwise specified, the source of all data and information for the tables and figures in this report originates from APR submitted to CDC by U.S. PHL that receive TB Elimination and Laboratory Strengthening CoAg funding.
- 2. For Figure 3, PHL were asked to describe their NAAT algorithm for inclusion in the analysis.
- For Figure 5, data for regions were based on defined HHS Regions with the addition of a City/County group.
- 4. For Figures 6–10, data for test methods were interpreted as accurately as possible from project narratives of CoAg APR.

### Laboratory Workload

#### Table 1. National Workload Data Among 58 PHL, 2015–2017.

Workload Variable	Total Number 2015	Total Number 2016	Total Number 2017	Three Year Change Number (% change)
Clinical specimens <sup>a</sup> received	207,018 (251–21,071)	210,508 (157–21,018)	201,374 (124–18,357)	-5,644 (-2.7)
Patients for whom a specimen was submitted	92,169 (130–10,017)	93,383 (100–9,407)	86,700 (79–9,939)	-5,469 (-5.9)
Patients culture positive for MTBC	3,868 (2–663)	3,826 (0–706)	4,017 (0–741)	149 (3.9)
Patients culture positive for MTBC that were NAAT positive	2125 (0–301)	1981 (0–295)	1957 (0–261)	-168 (-7.9)
Patients tested by NAAT or other rapid test <sup>b</sup>	20,053 (0–5,101)	20,027 (0–5,256)	20,203 (0–5,134)	150 (0.7)
Patients NAAT positive for MTBC <sup>b</sup>	3,244 (1–485)	2,760 (0–384)	2,540 (0–307)	-704 (-21.7)
Patients for whom a reference isolate was submitted <sup>c</sup>	15,766 (0–2,313)	15,757 (0–2,547)	16,105 (0–2,480)	339 (2.2)
Patients with a reference isolate identified as MTBC	3,307 (0–592)	3,263 (0–740)	3,378 (0–723)	71 (2.1)
Patients for whom DST was performed	6,006 (2–834)	5,877 (1–863)	5,672 (1–849)	-334 (-5.6)
IGRA performed	91,519 (0–23,709)	107,065 (0–28,803)	108,829 (0–29,743)	17,310 (18.9)

<sup>a</sup> Processed and cultured, not including isolates referred from other laboratories,

<sup>b</sup> Includes sediments received only for NAAT

<sup>c</sup> Received to rule out or confirm the ID of MTBC

Summary of workload variable changes for 2015–2017:

- Number of patients culture positive for MTBC increased by 3.9% over the three-year period, however, patients culture positive for MTBC that were NAAT positive decreased by 7.9%.
- Patients tested by NAAT or another rapid test remained relatively unchanged from 2015 through 2017, increasing only 0.7%.
- Patients for whom a DST was performed decreased each year for a total decrease of 5.6%.
- Number of IGRA performed to detect TB infection increased 18.9% from 2015 to 2017. During this time period, four additional laboratories began performing IGRA. Of note was the large range in volumes among PHL performing IGRA.



## Figure 1. Distribution of Public Health Laboratory Testing Volumes Measured by Total Number of Clinical Specimens Received, 2015 and 2017.

\*These jurisdictions referred all TB testing to another laboratory.

Note: DC=Washington, D.C., PHI=Philadelphia, SAN=San Diego, SFO=San Francisco, HOU=Houston, NYC=New York City, LAX=Los Angeles. All others are U.S. Postal Service abbreviations.

The distribution of TB testing volumes, as measured by clinical specimens received, is variable and has changed from 2015<sup>1</sup> to 2017. Twenty-one laboratories changed volume ranges in the three-year time frame; these transitions are observed among PHL receiving less than 8,000 clinical specimens.

Public health mycobacteriology laboratories across the United States may function differently (e.g., diagnostic versus primarily reference) based on their populations served and the availability of mycobacteriology testing at other laboratories in their jurisdiction. Although clinical specimens typically account for the majority of the workload, some PHL may serve primarily as reference laboratories in which isolates and inoculated media are received for identification and subsequent testing<sup>2</sup>. A full picture of workload data requires an understanding of the nature of the work for both diagnostic and reference testing by a public health laboratory.

### **Trends in Nucleic Acid Amplification Testing**



#### Figure 2. Trends in NAAT, 2015–2017.

Note: Laboratories were excluded from the analysis if data were missing for any of the three indicators or if the number of patients with MTBC positive culture with a positive NAAT reported within 48 hours (Healthy People 2020) was greater than either of the other two workload indicators.

Summary of Trends in NAAT from 2015–2017:

- The Healthy People 2020 goal is to detect MTBC by NAAT for 77% of patients with culture-confirmed TB within 48 hours. In CoAg funded PHL, only 44% (2017) of patients with MTBC positive cultures had a positive NAAT within 48 hours.
- The number of patients with MTBC positive culture increased, however, the number of patients with MTBC positive culture initially detected by NAAT decreased from 2015 to 2017.



#### Figure 3. NAAT Algorithm, 2018.

PHL clarified their current NAAT algorithms based on information provided in the APR. In 2018, seven NAAT algorithms were used for rapid detection of MTBC among the 58 PHL funded through the TB CoAg.

- Testing of specimens from new AFB smear-positive patients and when requested, those that are AFB smear-negative, was the most frequent NAAT algorithm in place; however, this algorithm was subdivided by the number of specimens per patient that are routinely tested. Thirty-three (57%) PHL perform NAAT routinely on the first smear-positive specimen per patient only, while two (3%) laboratories automatically perform NAAT on >1 smear-positive specimen per patient.
- Thirteen (22%) laboratories specified that NAAT was only performed when testing was requested by the TB program or healthcare provider.

PHL are encouraged to assess their NAAT algorithm in conjunction with laboratory-specific data from workload indicators presented in Figure 2. Laboratories could examine results for patients with MTBC positive cultures that did not receive a NAAT or those that were not tested within 48 hours as a means of evaluating their algorithm. PHL should collaborate with their TB program to adjust NAAT algorithms, if necessary, to capture additional MTBC positive culture cases within 48 hours of specimen receipt. It should be noted that NAAT is not solely performed in PHL; clinical laboratories may be performing NAAT initially thereby capturing a portion of patients with MTBC positive cultures. In these cases, PHL might not repeat NAAT. Analysis of laboratory-specific data and discussions with the TB program will help to discern the number of patients this applies to and whether an adjustment to the NAAT algorithm would capture missed TB patients.

### **Turnaround Times**

#### Table 2. TAT Indicators, 2017.

TAT Measurement	Specimen receipt within 1 day of collection	AFB smear result within 1 day of receipt	ID of MTBC within 21 days of receipt*	DST within 17 days of ID of MTBC
National Target: (% of specimens that should meet the benchmark)	67%	92%	74%	69%
Number of laboratories meeting or exceeding national target	12	33	30	26
National Average (reported % of specimens meeting the benchmark)	49%	89%	72%	57%
Number of laboratories at or above national average	28	35	33	32

\*Number of laboratories = 56 (2 laboratories had no MTBC identified)

#### Figure 4. TAT, 2017.



In 2017, the national average for the four TAT indicators remained below the national targets. PHL improved TAT performance for AFB smear, ID, and DST when measured by the number of PHL that met or exceeded the national targets (Table 2) compared to 2015. The number of PHL in 2015 that met or exceeded the national targets were n=31 for AFB smear, n=25 for ID, and n=20 for DST.<sup>1</sup> Specimen receipt remained the same for both years with 12 PHL who met or exceeded the national TAT target within 1 day and continues to be a challenge for state PHL.

Regarding the 2017 TAT data, there does not appear to be a consistent trend for PHL among any of the four volume ranges of clinical specimens received and the four TAT indicators.

- All PHL had similar metrics for specimen receipt within 1 day, except PHL with specimen volume of 2,001–5,000, which received more specimens within 1 day at 53%.
- Larger volume laboratories achieved higher average percentages meeting TAT benchmarks for AFB smear within 1 day and ID within 21 days.
- Laboratories receiving 5,001–8,000 clinical specimens per year had a greater percentage of DST reported within 17 days of ID than all other PHL.

#### **Testing Algorithms and Improvement of TAT**

Each year in CoAg APR, recipients describe how their laboratory has improved efficiency and quality assurance through use of laboratory-specific data. Changes in the laboratory to improve TAT have included:

- Assessing specimen receipt TAT data by submitter for focused education/intervention
- Improving specimen processing efficiency by reviewing staffing, laboratory hours, arrival times of specimens, equipment availability, use of commercial kits, contamination rates, and policies
- Reviewing specimen submission guidelines and providing annual refreshers for TB Control Program and submitters
- Evaluating alternative AFB smear fixation procedures
- Increasing frequency of specific tests performed each week
- Implementing new testing methods or algorithms (e.g., Maldi-TOF, Xpert<sup>™</sup> MTB/RIF, real-time PCR, sequencing)
- Cross-training of staff
- Implementing new LIMS and report queries
- Establishing isolate shipment policies to the National DST Reference Center<sup>3</sup>

#### **Public Health Laboratory Barriers to Meeting TAT**

PHL across the U.S. experience challenges when striving to meet recommended TAT. These include:

- Resources (staffing and funding)
- Hours of operation (closed on weekends and holidays)
- Lack of courier service
- Specimen batching from patients and submitters
- Delayed specimen shipments
- LIMS limitations

#### Figure 5. TAT for Specimen Receipt by Health and Human Services (HHS) Region\*, 2017.



#### \*States organized by HHS Region with the addition of a City/County group

Rapid specimen delivery continues to be a challenge for PHL. Specimen receipt TAT, presented by HHS region in Figure 5, indicates there are differences based on geographical regions, however, many HHS regions have wide ranges in TAT suggesting variability between sites within each region. The smaller geographical size of cities and thus prompt courier services likely contribute to City/County PHL receiving more specimens within 1 day. Laboratories can use Figure 5 to compare their specimen receipt TAT performance to others within their HHS region and to other regions that may have similar size states, populations, or geography.

### **Methods in Public Health Laboratories**

Methods performed by PHL supported, in part, by the TB CoAg for NAAT, ID, DST, molecular testing for detection of drug resistance, and IGRA, are displayed in Figures 6–10. For each figure, the total number of PHL equals 58, with the exception of molecular testing for detection of drug resistance which has a total of 7 PHL and IGRA with 30 PHL. As new technology emerges and laboratories adjust testing algorithms, methods performed will continue to evolve.

#### Figure 6. NAAT Methods, 2018.



Direct detection of MTBC in clinical specimens by NAAT provides the earliest opportunity for treatment and intervention. In 2018, Cepheid Xpert<sup>™</sup> MTB/RIF and laboratory-developed real-time PCR assays accounted for 88% of NAAT methods performed.

#### Figure 7. Primary ID Methods, 2018.



Although many PHL utilize more than one ID method within their testing algorithm, the primary ID method described from APR is included for all 58 laboratories.

#### Figure 8. First-line Growth-based DST Methods, 2018.



The majority of PHL continue to perform first-line DST via the BACTEC MGIT<sup>™</sup> system. Fourteen laboratories, performing less than 50 DST per year, have utilized the APHL/CDC National TB DST Reference Center<sup>3</sup> for susceptibility testing; additionally, 4 laboratories have established individual DST referral practices with another laboratory.



#### Figure 9. Molecular Testing for Detection of Drug Resistance, 2018.

\* Performed on culture growth

#### Table 3. Sites Performing Molecular Testing for Detection of Drug Resistance by Method, 2018.

Method	Public Health Laboratory
Targeted Sequencing	CA, FL, IN, MO, NY
Cepheid Xpert™ MTB/RIF	IL, SAN
Whole Genome Sequencing	NY
Bruker MTBDR <i>plus</i> Line Probe Assay	FL

#### Figure 10. IGRA Methods, 2018.



#### Table 4. Sites Performing IGRA by Method, 2018.

Method	Public Health Laboratory
Oxford Immunotec T-SPOT <sup>®</sup> .TB	AR, LA
Qiagen QuantiFERON® in Mycobacteriology Laboratory	DE, HOU, KS, ME, MD, MT, NV, TN
Qiagen QuantiFERON <sup>®</sup> in other section of PHL	CT, FL, GA, IA, LAX, MS, NE, NJ, NM, ND, OR, PA, SAN, SFO, SC, SD, TX, UT, VT, WY

Thirty of the 58 funded PHL reported use of IGRA testing; 4 laboratories implemented IGRA testing since 2016.

### References

- 1. CDC. 2017. <u>Tuberculosis Laboratory Aggregate Report</u>: Fourth Edition. U.S. Department of Health and Human Services, CDC, Atlanta, Georgia.
- 2. Livingston KA, Lobato MN, Sosa LE, Budnick GE, Bernardo J. 2011. Mycobacterium tuberculosis testing practices in hospital, commercial and state laboratories in the New England states. *Int J Tuberc Lung Dis* 15:1218–22, i.
- 3. APHL. National Public Health Laboratory Drug Susceptibility Testing Reference Center. Silver Springs, MD. 2015.

### Resources

APHL TB Web page <a href="https://www.aphl.org/programs/infectious\_disease/tuberculosis/Pages/default.aspx">https://www.aphl.org/programs/infectious\_disease/tuberculosis/Pages/default.aspx</a>

CDC TB Website <a href="http://www.cdc.gov/tb/">http://www.cdc.gov/tb/</a>

CDC Molecular Detection of Drug Resistance (MDDR) Service <u>http://www.cdc.gov/tb/topic/laboratory/</u> <u>default.htm</u>

CDC Model Performance Evaluation Program http://www.cdc.gov/tb/topic/laboratory/mpep/

Guide to the Application of Genotyping to Tuberculosis Prevention and Control <u>http://www.cdc.gov/tb/</u>programs/genotyping/manual.htm

TB Notes Newsletter http://www.cdc.gov/tb/publications/newsletters/default.htm

FIND TB Education and Training Resources http://www.findtbresources.org/

### **Journal Articles of Interest**

#### **Laboratory Practices**

Theron G, Venter R, Smith L, Esmail A, Randall P, Sood V, Oelfese S, Calligaro G, Warren R, Dheda K. 2018. False-Positive Xpert MTB/RIF Results in Retested Patients with Previous Tuberculosis: Frequency, Profile, and Prospective Clinical Outcomes. *J Clin Microbiol* 56.

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Forbes BA, Hall GS, Miller MB, Novak SM, Rowlinson MC, Salfinger M, Somoskovi A, Warshauer DM, Wilson ML. 2018. Practice Guidelines for Clinical Microbiology Laboratories: Mycobacteria. *Clin Microbiol Rev* 31.

#### **Drug Resistance**

Technical Report on critical concentrations for drug susceptibility testing of medicines used in the treatment of drug-resistant tuberculosis. Geneva: World Health Organization; 2018 (WHO/CDS/TB/2018.5). License: CC BY-NC-SA 3.0 IGO.

Georghiou SB, Seifert M, Catanzaro DG, Garfein RS, Rodwell TC. 2017. Increased Tuberculosis Patient Mortality Associated with Mycobacterium tuberculosis Mutations Conferring Resistance to Second-Line Antituberculous Drugs. *J Clin Microbiol* 55:1928–1937.

Miotto P, Cabibbe AM, Borroni E, Degano M, Cirillo DM. 2018. Role of Disputed Mutations in the rpoB Gene in Interpretation of Automated Liquid MGIT Culture Results for Rifampin Susceptibility Testing of Mycobacterium tuberculosis. *J Clin Microbiol* 56.

Shah NS, Grace Lin SY, Barry PM, Cheng YN, Schecter G, Desmond E. 2016. Clinical Impact on Tuberculosis Treatment Outcomes of Discordance Between Molecular and Growth-Based Assays for Rifampin Resistance, California 2003–2013. *Open Forum Infect Dis* 3:ofw150.

#### **Next Generation Sequencing**

Shea J, Halse TA, Lapierre P, Shudt M, Kohlerschmidt D, Van Roey P, Limberger R, Taylor J, Escuyer V, Musser KA. 2017. Comprehensive Whole-Genome Sequencing and Reporting of Drug Resistance Profiles on Clinical Cases of Mycobacterium tuberculosis in New York State. *J Clin Microbiol* 55:1871–1882.

Doyle RM, Burgess C, Williams R, Gorton R, Booth H, Brown J, Bryant JM, Chan J, Creer D, Holdstock J, Kunst H, Lozewicz S, Platt G, Romero EY, Speight G, Tiberi S, Abubakar I, Lipman M, McHugh TD, Breuer J. 2018. Direct Whole-Genome Sequencing of Sputum Accurately Identifies Drug-Resistant Mycobacterium tuberculosis Faster than MGIT Culture Sequencing. *J Clin Microbiol* 56.

Quan TP, Bawa Z, Foster D, Walker T, Del Ojo Elias C, Rathod P, Iqbal Z, Bradley P, Mowbray J, Walker AS, Crook DW, Wyllie DH, Peto TEA, Smith EG. 2018. Evaluation of Whole-Genome Sequencing for Mycobacterial Species Identification and Drug Susceptibility Testing in a Clinical Setting: a Large-Scale Prospective Assessment of Performance against Line Probe Assays and Phenotyping. *J Clin Microbiol* 56.

Lee RS, Pai M. 2017. Real-Time Sequencing of Mycobacterium tuberculosis: Are We There Yet? *J Clin Microbiol* 55:1249–1254.

Votintseva AA, Bradley P, Pankhurst L, Del Ojo Elias C, Loose M, Nilgiriwala K, Chatterjee A, Smith EG, Sanderson N, Walker TM, Morgan MR, Wyllie DH, Walker AS, Peto TEA, Crook DW, Iqbal Z. 2017. Same-Day Diagnostic and Surveillance Data for Tuberculosis via Whole-Genome Sequencing of Direct Respiratory Samples. J Clin Microbiol 55:1285–1298.

#### **Interferon Gamma Release Assay**

Moon HW, Gaur RL, Tien SS, Spangler M, Pai M, Banaei N. 2017. Evaluation of QuantiFERON-TB Gold-Plus in Health Care Workers in a Low-Incidence Setting. *J Clin Microbiol* 55:1650–1657.

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### **Updates**

Clinical and Laboratory Standards Institute (CLSI). 2018. Laboratory Detection and Identification of Mycobacteria, 2nd ed. CLSI guideline M48. Wayne, PA.

Clinical and Laboratory Standards Institute (CLSI). 2018. Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes; 3rd ed. CLSI standard M24. Wayne, PA.

Clinical and Laboratory Standards Institute (CLSI). 2018. Performance Standards for Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes. CLSI supplement M62. Wayne, PA.

Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. *MMWR Morb Mortal Wkly Rep* 2019;68:439–443.

### **Appendix A: Explanation of Figures for Accessibility**

**LCT Contact Details** Map of the U.S. divided by LCT consultant. Each consultant is assigned a color:

- Stephanie Johnston, MS (Yellow)—Alaska, Arizona, California, Hawaii, Nevada, New Mexico, Oregon, Texas, Washington
- Robert Domaoal, PhD (Orange)—Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Pennsylvania, Rhode Island, Vermont, Virginia
- Cortney Stafford, MPH (Green)—Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Michigan, Mississippi, Ohio, South Carolina, Tennessee, West Virginia, Wisconsin
- Monica Youngblood, MPH (Blue)—Colorado, Idaho, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, New Jersey, North Dakota, Oklahoma, Puerto Rico, South Dakota, Utah, Wyoming < <a href="mailto:back">back</a>

Figure 1. The distribution of public health laboratory testing volumes measured by total number of clinical specimens received in 2015 and 2017 is displayed in a vertical bar graph. The vertical y-axis is the number of PHL ranging from 0 to 16, by increments of 2. Along the horizontal x-axis are sixteen vertical bars (eight for 2015 and eight for 2017) representing the number of clinical specimens received. From left to right: 5 laboratories in 2015 and 3 laboratories in 2017 received between 1 and 500 clinical specimens; 7 laboratories in 2015 and 11 laboratories in 2017 received between 1,001 and 2,000 clinical specimens; 11 laboratories in 2015 and 10 laboratories in 2017 received between 2,001 and 3,000 clinical specimens; 10 laboratories in 2015 and 11 laboratories in 2017 received between 3,001 and 5,000 clinical specimens; 6 laboratories in 2015 and 7 laboratories in 2017 received between 5,001 and 8,000 clinical specimens; 2 laboratories in 2015 and 2 laboratories in 2017 received between 8,001 and 15,000 clinical specimens; 3 laboratories in 2017 received between 8,001 and 15,000 clinical specimens; 4 back

**Figure 2.** Trends in NAAT for 2015–2017 are presented in a vertical bar graph. The vertical y-axis is the number of patients ranging from 0 to 4,000, by increments of 500. Along the horizontal x-axis are nine vertical bars (three each for 2015, 2016, and 2017), clustered for the following workload indicators: Number of patients with MTBC positive culture (workload indicator 2a), Number of patients with MTBC positive culture (workload indicator 2b), and Number of patients with MTBC positive culture with a positive NAAT (workload indicator 2b), and Number of patients with MTBC positive culture with a positive NAAT reported within 48 hours (Healthy People 2020).

**Figure 3.** The NAAT algorithms used by PHL in 2018 are displayed in a horizontal bar graph. The vertical y-axis contains a list of NAAT algorithms and the horizontal x-axis contains the number of PHL ranging from 0 to 35, by increments of 5. There are 7 horizontal bars with each bar representing the number of laboratories using a particular NAAT algorithm. 'New smear positive patients (routinely only first smear positive specimen); smear negative patients on request only' is the most commonly used algorithm with 33 PHL. 'Testing by request only' is the second most commonly used algorithm with 13 PHL. **deck** 

**Figure 4.** The 2017 turnaround time data stratified by four ranges of clinical specimens received is displayed in a horizontal bar graph. The vertical y-axis contains a list of the four turnaround time indicators and the horizontal x-axis contains the percent of specimens meeting the benchmark with ranges from 0% to 100%, by increments of 20%. Along the vertical y-axis are sixteen horizontal bars (four for specimen receipt, four for smear, four for ID, and four for DST). For specimen receipt within 1 day: PHL receiving  $\leq 2,000$  clinical specimen achieved 46%, PHL receiving between 2,001 and 5,000 achieved 53%, PHL receiving between 5,001 and 8,000 achieved 48%, and PHL receiving  $\geq 8,001$  achieved 48%. For smear within 1 day: PHL receiving  $\leq 2,000$  clinical specimen achieved 85%, PHL receiving between 2,001 and 5,000 achieved 91%, PHL receiving between 5,001 and 8,000 achieved 93%, and PHL receiving  $\geq 8,001$  achieved 95%. For ID within 21 days: PHL receiving  $\leq 2,000$  clinical specimen achieved 72%, PHL receiving between 2,001 and 5,000

achieved 72%, PHL receiving between 5,001 and 8,000 achieved 77%, and PHL receiving  $\geq$ 8,001 achieved 81%. For DST within 17 days of ID: PHL receiving  $\leq$ 2,000 clinical specimen achieved 57%, PHL receiving between 2,001 and 5,000 achieved 52%, PHL receiving between 5,001 and 8,000 achieved 77%, and PHL receiving  $\geq$ 8,001 achieved 57%.  $\triangleleft$  back

**Figure 5.** The 2017 specimen receipt turnaround time comparisons by HHS Region are displayed in a horizontal bar graph. The vertical y-axis contains a list of each region and the horizontal x-axis contains the percent of specimens received ranging from 0% to 100%, by increments of 20%. Each of the eleven regions have three horizontal bars representing the average percent of specimens received within 1 day, 2 days, and 3 days and each bar includes a small thin line representing the range. < back

**Figure 6.** The NAAT methods used by PHL in 2018 are presented in a pie chart. The largest slice represents the 36 PHL that perform Cepheid Xpert MTB/RIF. The second largest slice represents the 15 PHL that perform real-time PCR testing. The next three slices represent 4 PHL that refer testing, 2 PHL that perform Hologic MTD, and 1 public health laboratory that performs pyrosequencing. < <u>back</u>

**Figure 7.** The primary ID methods used by PHL in 2018 are presented in a pie chart. The largest slice represents the 30 PHL that perform Hologic Accuprobe. The following nine slices represent: 7 PHL that perform HPLC, 6 PHL that perform real-time PCR, 5 PHL that perform Maldi-TOF, 2 PHL that perform Cepheid Xpert MTB/RIF assay, 2 PHL that perform Fujirebio INNP-LiPA, 2 PHL that refer testing, 2 PHL that perform sequencing, 1 public health laboratory that performs PRA, and 1 public health laboratory that performs PCR melting curve analysis. < back

**Figure 8.** The first-line growth-based DST methods used by PHL in 2018 are presented in a pie chart. The largest slice represents the 38 PHL that perform DST using BACTEC MGIT. The next four slices represent 14 PHL that refer testing to the DST Reference Center, 4 PHL that refer testing to another PHL, 1 public health laboratory that performs indirect agar proportion, and 1 public health laboratory that performs Thermoscientific Sensititre. < back

**Figure 10.** The IGRA methods used by PHL in 2018 are presented in a pie chart. The largest slice represents the 20 PHL that perform Qiagen QuantiFERON in another section of the PHL. The other two slices represent 8 PHL that perform Qiagen QuantiFERON in the mycobacteriology section of the PHL and 2 PHL that use Oxford Immunotec T-SPOT.*TB.*  $\triangleleft$  back