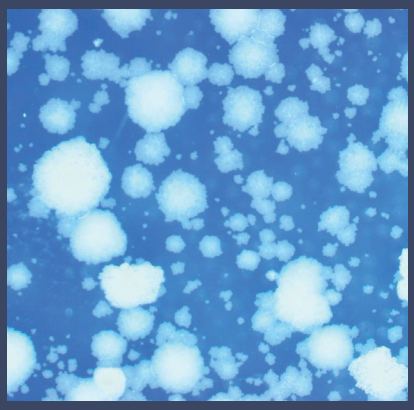

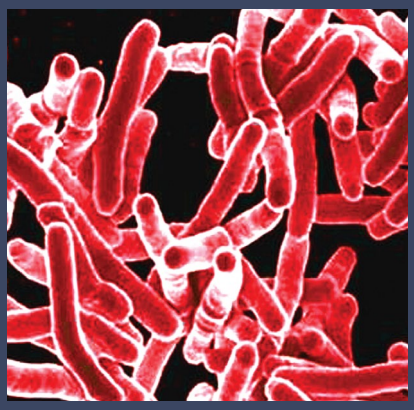

TUBERCULOSIS LABORATORY AGGREGATE REPORT

SIXTH EDITION

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

2021

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For accessibility, a full explanation of figures can be found in Appendix A: Explanation of Figures for Accessibility on page 24.

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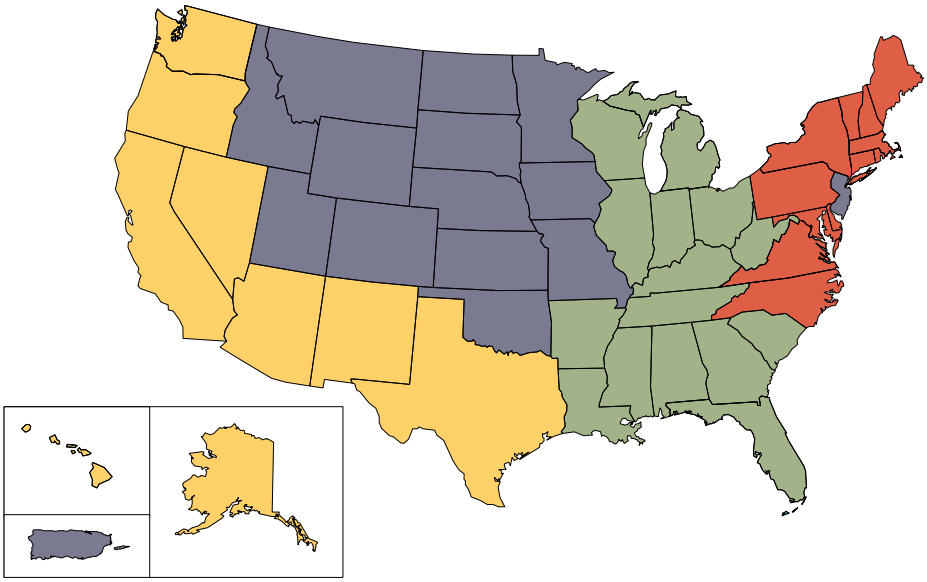
LABORATORY CAPACITY TEAM CONTACT DETAILS



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INTRODUCTION

As part of the CDC Tuberculosis (TB) Elimination and Laboratory Cooperative Agreement (CoAg), 58 supported state, local and territorial public health laboratories (PHLs) submit an Annual Performance Report (APR). The primary focus of the CoAg is laboratory strengthening. In each APR, PHLs self-report their TB testing methods and algorithms performed, progress or barriers encountered for the three focus areas defined as part of the CoAg, and laboratory workload volume and turnaround time (TAT) performance data. Data are compiled and presented in this report, the *Tuberculosis Laboratory Aggregate Report: Sixth Edition*.

The purpose of this report is for PHLs to assess progress towards meeting national TB testing benchmarks and for peer comparison with other PHLs with similar specimen or testing volume, using similar methods, or in a similar geographical location. Laboratories should monitor and evaluate TB workload volume and TAT indicators with a goal of improving performance by setting realistic, incremental laboratory-specific goals. Additionally, laboratory practices should be assessed to identify, address, and evaluate quality improvements.

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

EXECUTIVE SUMMARY

Data in this *TB Laboratory Aggregate Report: Sixth Edition* include a comparison of aggregate workload volume data, nucleic acid amplification test (NAAT) trends, and workload performance TAT data for calendar years 2017, 2018, and 2019. Also included in this report is the most recent information received (2020) regarding PHLs TB testing methods, of which, little change was observed since the previous edition.

PHLs self-reported workload volume and TAT benchmark data suggest:

- Decreases in number of clinical specimens processed, number of patients culture positive for *Mycobacterium tuberculosis* complex (MTBC), reference isolates received, growth-based drug susceptibility testing (DST) performed, and isolates received for genotyping referral.
- Increases in NAAT positivity, molecular DST performed on MTBC isolates, and interferon-gamma release assays (IGRA).
- Differences in culture positivity rates and NAAT TAT among PHLs.
- Improved National TAT Averages in 2019 for specimen receipt, AFB smear result, identification (ID), and DST. Moreover, the number of PHLs meeting or exceeding the National Average increased for specimen receipt and DST.

LCT encourages laboratorians to review the details of each section in this report 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 Elimination and Laboratory 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 and Laboratory 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.

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®: A commercial line probe assay by Fujirebio that identifies MTBC and can detect mutations associated with rifampin resistance.

LCT: Laboratory Capacity Team

LPA: Line probe assay

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® for direct detection of MTBC in clinical specimens.

MTBDR*plus*: A commercial line probe assay by Bruker 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.

National PHL Drug Susceptibility Testing Reference Center for *Mycobacterium tuberculosis*: National DST Reference Center for MTBC

PHLs: 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 used to aid in diagnosis of TB infection.

TAT: Turnaround time

TB: Tuberculosis

Trek Sensititre® MYCOTB: A commercial broth microdilution plate by ThermoScientific for determination of minimum inhibitory concentration (MIC) 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® MTB/RIF: A commercial molecular assay by Cepheid, Inc. for direct detection of MTBC and mutations associated with rifampin resistance.

WGS: Whole genome sequencing

TECHNICAL NOTES

1. Unless otherwise specified, the source of all data and information for the tables and figures in this report originates from APRs submitted to CDC by U.S. PHLs that receive TB Elimination and Laboratory Strengthening CoAg funding.
2. For Figure 3 and Table 4, PHLs were asked to describe their NAAT algorithms for inclusion in the analysis.
3. For Figures 8–13, data regarding test methods were interpreted as accurately as possible from APR narratives.

LABORATORY WORKLOAD

Table 1. National Workload Data from 58 PHLs, 2017–2019.

Workload Variable	Total Number 2017	Total Number 2018	Total Number 2019	Three Year Change Number (% change)
Clinical specimens[a] processed for smear and culture	201,374 (124–18,357)	193,534 (108–18,258)	186,849 (105–17,458)	-14,525 (-7.2)
Patients for whom a specimen was processed	86,700 (79–9,939	79,490 (48–9,675)	77,208 (51–9,687)	-9,492 (-10.9)
Patients culture positive for MTBC	4,017 (0–741)	4,102 (0–801)	3,298 (0–926)	-719 (-17.9)
MTBC culture positive patients that were NAAT positive	1,957 (0–261)	1,990 (0–313)	2,023 (0–282)	66 (3.4)
MTBC culture positive patients that were NAAT positive reported in 48 hours	1,591[d] (0–261)	1,973[d] (0–313)	1,668 (0–267)	-300 (-15.2)
Patients for whom a clinical specimen was tested by NAAT or other rapid test[b]	20,203 (0–5,134)	18,738 (0–4,552)	19,124 (0–4,105)	-1,079 (-5.3)
Patients for whom a clinical specimen was NAAT positive for MTBC[b]	2,540 (0–307)	2,484 (0–431)	2,632 (0–356)	92 (3.6)
Patients for whom a reference isolate was submitted to rule out or confirm ID of MTBC	16,105 (0–2,480)	14,314 (0–2,397)	13,324 (0–2,279)	-2,781 (-17.3)
Patients for whom a reference isolate was identified as MTBC	3,378 (0–723)	3,356 (0–603)	2,700 (0–559)	-678 (-20.1)
Patients for whom growth-based DST was performed/referred	5,672 (1–849)	5,732 (2–968)	5,437 (1–1,037)	-235 (-4.1)
Patients for whom an in-house molecular DST was performed[c]	Not available	6,732 (0–643)	5,425 (0-640)	-1,307 (-19.4)[e]
Patients for whom an in-house molecular DST of a specimen was performed[c]	Not available	5,027 (0–643)	4,245 (0–485)	-782 (-15.6)[e]
Patients for whom an in-house molecular DST of an isolate was performed	Not available	1,484 (0–629)	1,517 (0–552)	33 (2.2)e
Patients for whom an MTBC isolate was referred for genotyping	7,853 (0–1,637)	7,354 (2–1,765)	7,349 (1–1766)	-504 (-6.4)
IGRAs performed in-house	108,829 (0–29,743)	109,153 (0-32,300)	116,707 (0–35,307)	7,878 (7.2)

[a] Processed and cultured, not including isolates referred from other laboratories,

[b] Included sediments received only for NAAT,

[c] Could include data for patients tested by methods that include both NAAT and molecular DST (e.g., Xpert® MTB/RIF) for whom test results were ultimately negative for MTBC,

[d] Data were omitted if value provided was greater than the number provided for culture positive patients positive by NAAT,

[e] Two-year change

Note—MTBC: *Mycobacterium tuberculosis*, NAAT: nucleic acid amplification test, DST: drug susceptibility testing, IGRA: Interferon gamma release assay

Summary of workload variable changes for 2017–2019:

- From 2017 to 2019, there was a 7.2% decrease in clinical specimens processed and a 10.9% decrease in patients for whom a specimen was submitted to PHLs. As a result of these decreases, most workload variables were reduced over the same timeframe.

- Decreases were also observed across the three-year period among number of patients for whom a reference isolate was submitted and number of patients with a reference isolate identified as MTBC.
- Percent of culture positive patients that were NAAT positive increased from 48% in 2018 to 61% in 2019.
- Number of IGRAs performed from 2017 to 2019 increased 7.2% reflecting continued expansion of testing.

Table 2. Mean and Range for Key Workload Indicators, Stratified by Number of Clinical Specimens Processed, 2019.

Workload Variable	1–1,000 Clinical Specimens Processed by Each PHL (14 [24.1%])[a]	1,001–2,000 Clinical Specimens Processed by Each PHL (14 [24.1%])[a]	2,001–4,000 Clinical Specimens Processed by Each PHL (17 [29.3%])[a]	4,001–8,000 Clinical Specimens Processed by Each PHL (9 [15.5%])[a]	>8,000 Clinical Specimens Processed by Each PHL (4 [6.9%])[a]	National Average
Clinical specimens processed for smear and culture	548 (105–903)	1,517 (1,020–1,941)	2,924 (2,080–3,958)	5,439 (4,284–7,464)	14,819 (8,535–17,458)	3,222
Patients for whom a specimen was processed	241 (51–631)	618 (160–1,164)	1,304 (466–2,199)	2,229 (749–3,546)	5,739 (2,563–9,687)	1,331
Patients culture positive for MTBC	21 (1–123)	36 (0–92)	40 (4–88)	87 (28–147)	414 (93–926)	68
MTBC culture positive patients that were NAAT positive	14 (0–119)	19 (0–41)	23 (3–56)	49 (19–101)	182 (42–313)	35
MTBC culture positive patients that were NAAT positive reported in 48 hours	13 (0–119)	16 (0–34)	18 (1–55)	42 (19–88)	146 (30–267)	29
Patients for whom a clinical specimen was tested by NAAT or other rapid test	110 (0–490)	182 (35–374)	169 (40–453)	425 (151–1,022)	2,084 (683–4,105)	330
Patients for whom a clinical specimen was NAAT positive for MTBC	32 (0–242)	28 (0–62)	29 (3–106)	54 (19–101)	201 (52–356)	45
Patients for whom a reference isolate was submitted to rule out or confirm ID of MTBC	158 (0–1,095)	162[b] (0–409)	124 (0–415)	351 (51–906)	934 (63–2,279)	234
Patients for whom a reference isolate was identified as MTBC	55 (0–559)	27[b] (0–109)	33 (0–191)	57 (21–99)	123 (0–1,037)	47
Patients for whom growth-based DST was performed/referred	31 (1–152)	68 (2–141)	63 (6–224)	121 (53–204)	475 (81–1,037)	94

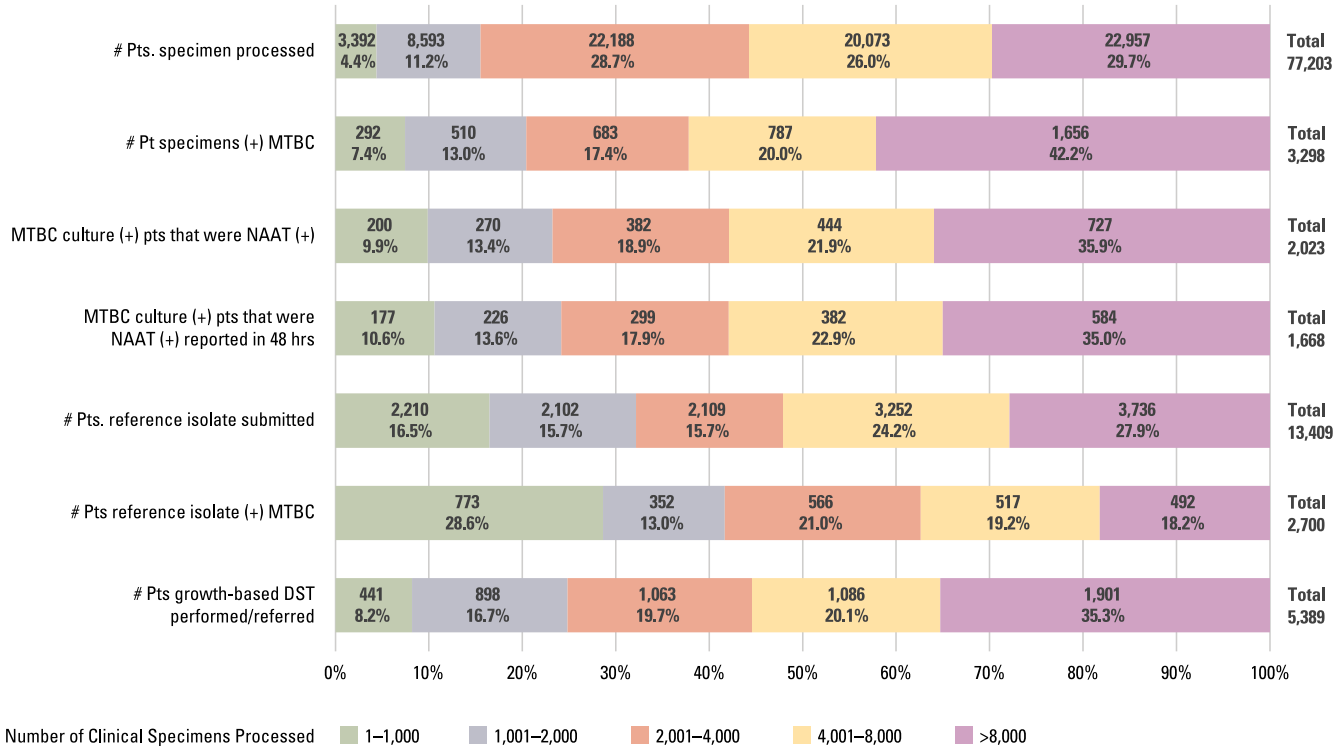
[a] (Number of PHLs [% of total]),

[b] Data available for only 13 PHLs.

Note—MTBC: *Mycobacterium tuberculosis*, NAAT: nucleic acid amplification test, DST: drug susceptibility testing

U.S. TB PHLs receive different numbers of clinical specimens which may influence laboratory workflow. For easier laboratory testing volume comparison, the 58 CoAg PHLs were divided into 5 groups based on number of clinical specimens processed and key workload indicators presented. Mean and range for key workload indicators are displayed.

Figure 1. Total Workload Volume and Proportion of Total for Selected Indicators, Stratified by Number of Clinical Specimens Processed, 2019.

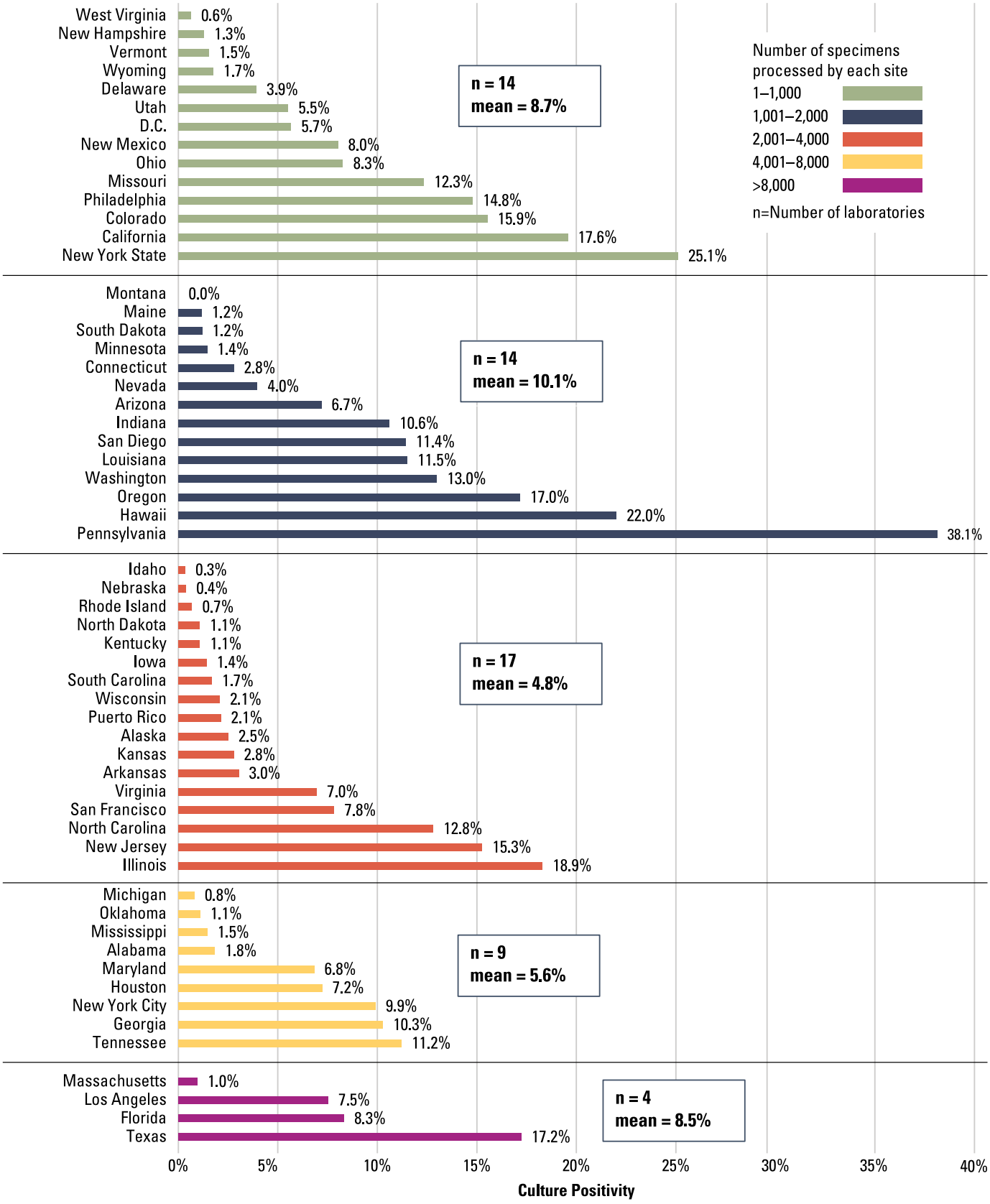


Note—Pt: patient, MTBC: *Mycobacterium tuberculosis*, NAAT: nucleic acid amplification test, DST: drug susceptibility testing

Above, for 2019, the proportion of testing contributed for each of five workload volume groups (identified in Table 2 based on number of clinical specimens processed) for seven selected workload indicators are shown. Of note, although the laboratories are subdivided into five categories by the total number of clinical specimens processed, the seven selected workload indicators are reported by PHLs on a per patient basis (i.e., each patient was considered uniquely even though more than one specimen or isolate may have been tested).

- High-volume PHLs (>8,000 clinical specimens) reported higher numbers for most workload variables compared to other PHLs when stratified by number of clinical specimens processed.
- PHLs processing 2,001–4,000, 4,001–8,000, and >8,000 clinical specimens contributed similar proportions of the total number of patient specimens processed across PHLs at 28.7%, 26.0%, and 29.7%, respectively. Thus, PHLs processing ≥2,001 clinical specimens in 2019 processed 84.4% of all clinical specimens received by PHLs.
- PHLs that processed between 1–1,000 clinical specimens contributed the largest proportion (28.6%) of patient reference isolates positive for MTBC.
- High-volume PHLs (>8,000 clinical specimens) contributed the largest proportion (42.2%) of patient specimens positive for MTBC by culture; yet these PHLs accounted for the second smallest percentage (18.2%) of patients with reference isolates positive for TB reflecting the potential differences in how PHLs may function within their jurisdiction.
- Lower volume PHLs (1–1,000, 1,001–2,000, and 2,001–4,000 clinical specimens) received similar volumes of patient reference isolates at 16.6%, 15.8%, and 15.8% respectively; collectively contributing half of all reference isolates received to rule out TB.
- While high-volume PHLs (>8,000 clinical specimens) perform the majority of growth-based DST (35%), PHLs in volume groups 2,001–4,000 and 4,001–8,000 perform similar proportions of overall DST at approximately 20%.

Figure 2. Culture Positivity Stratified by Number of Specimens Processed, 2019.



Culture positivity in 2019 for the 58 PHLs is presented as the same five groups, stratified by number of clinical specimens processed, as in Table 2 and Figure 1. MTBC culture positivity (percent of individual patients' clinical specimens that were positive for MTBC in culture) ranged from 0.0% to 38.1% among all sites. Each group had a wide range of culture positivity with the exception of PHLs that processed between 4,001–8,000 clinical specimens. Among all groups, PHLs processing less than 2,000 specimens (n = 28) had a mean culture positivity of 9.4%; nearly twice as high as PHLs processing greater than 2,000 specimens (n = 30) with a mean culture positivity of 5.5%.

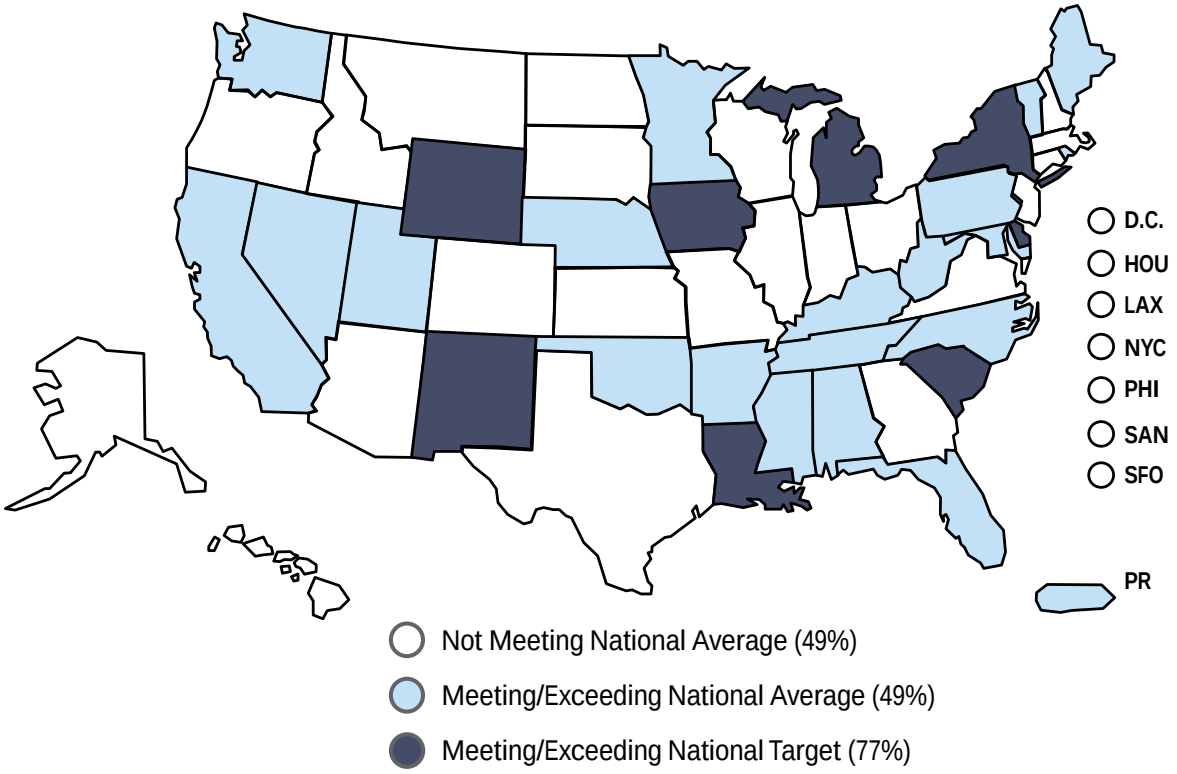
The wide range of culture positivity may be explained by several differences. In some areas, the state or local PHL may be the sole facility processing AFB specimens and, therefore, may see a lower percent of cultures positive for MTBC due to receipt of a larger number of specimens from individuals being tested for TB. In other areas, the PHL may function primarily in a reference laboratory capacity by receiving follow-up specimens after diagnosis and therefore, might encounter a relatively higher MTBC culture positivity. Other factors that may influence MTBC culture positivity include the nature of the patient population served by the PHL, differences in clinicians' test ordering, or local incidence of nontuberculous mycobacterial (NTM) disease.

It is important for individual laboratories to determine baseline MTBC culture positivity and monitor this percentage routinely to detect fluctuations. Significant incremental deviations in this indicator could indicate potential laboratory issues such as false-positive cultures or an increase in the number of cases. In both instances, communication should occur with the jurisdictional TB Program.

M. tuberculosis on 7H10/7H11 agar. *Picture courtesy of APHL*

TRENDS IN NUCLEIC ACID AMPLIFICATION TESTING

Figure 3. Map of PHLs Meeting or Exceeding NAAT TAT Performance Targets, 2019.



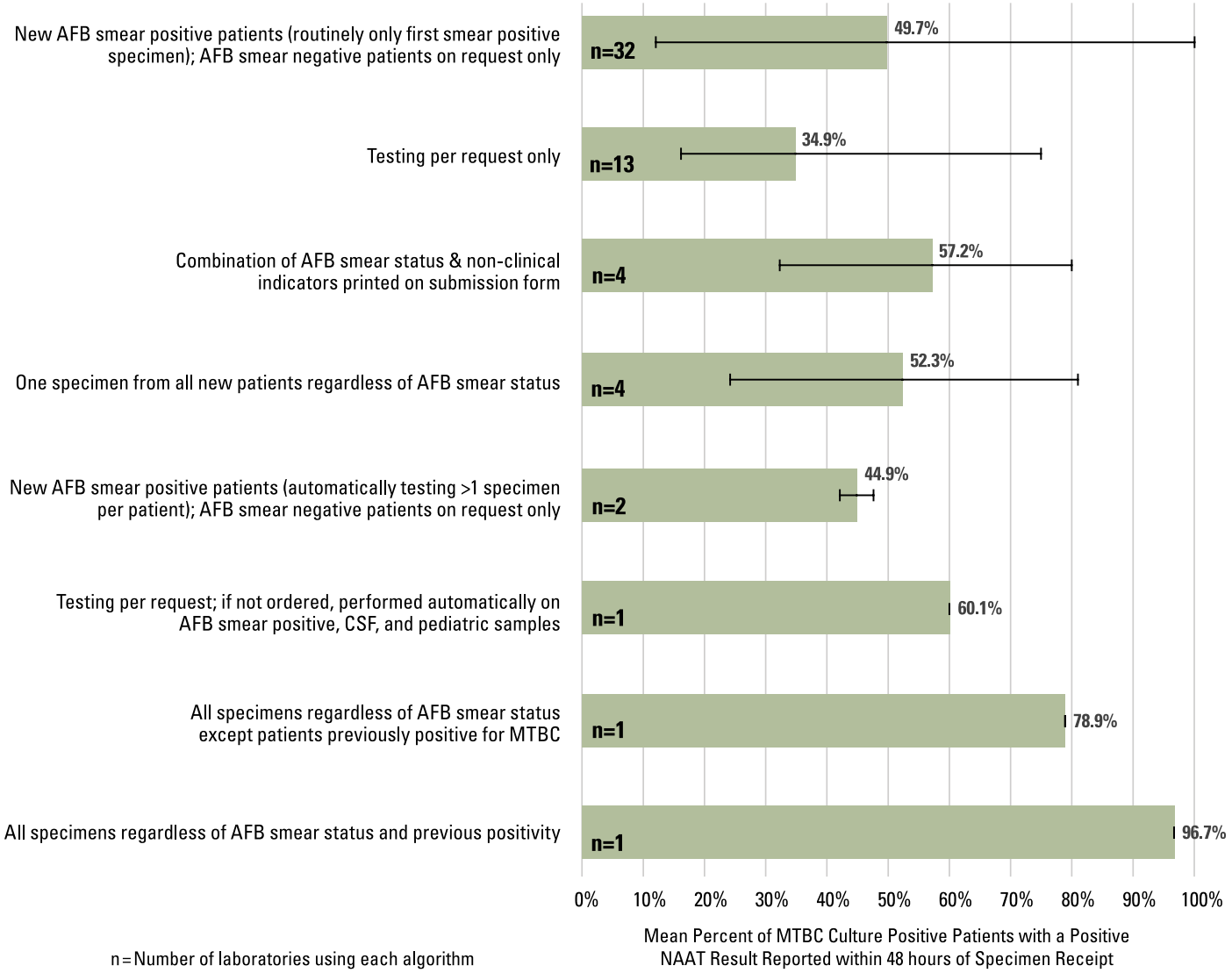
NAAT TAT assesses the effectiveness of a laboratory's testing algorithm by measuring the percentage of patients later confirmed as MTBC culture-positive that had a positive NAAT reported within 48 hours of specimen receipt. National Average is calculated across 58 PHLs as total number of NAAT positive patients that were later MTBC culture positive with NAAT results reported within 48 hours of specimen receipt divided by total number of MTBC culture positive patients. The National Target for NAAT is defined as ≥77% of MTBC cases that are later culture confirmed diagnosed using NAAT within 2 days of specimen receipt. PHLs that met or exceeded the National Average of 49% and National Target of 77% of patients with specimens with a positive NAAT result within this timeframe are presented in the Figure 3 map.

- 21 (36%) sites met or exceeded the National Average of 49%
- 8 (14%) sites met or exceeded the National Target of 77%

Table 3. NAAT Method by PHL, 2019.

NAAT Method	Sites
Xpert® MTB/RIF	AL, AK, AZ, AR, CO, CT, GA, HOU, ID, IL, IA, KS, KY, LA, MD, MA, MS, MT, NE, NV, NH, NYC, ND, OK, OR, PR, SAN, SFO, SC, SD, TN, TX, UT, VT, VA, WV
Real-time PCR Laboratory Developed Test	DE, FL, IN, LAX, ME, MI, MN, NM, NY, NC, OH, PA, RI, WA, WI
Referred to Another Laboratory	DC, NJ, PHI, WY
MTD®	HI, MO
Pyrosequencing	CA

Figure 4. Percent of MTBC Culture Positive Patients with a Positive NAAT Result Reported within 48 hours of Specimen Receipt, Stratified by NAAT Algorithm, 2019



PHLs use a variety of algorithms to determine which specimens routinely receive NAAT. Although multiple laboratories use the same algorithm, differences in NAAT TAT were observed (range bars). PHLs are encouraged to assess their NAAT algorithm in conjunction with laboratory-specific data. Laboratories could examine results for patients with MTBC positive cultures that did not receive a NAAT or those patients not tested within 48 hours as a means of evaluating the algorithm. Analysis of laboratory-specific data and discussions with TB Programs will help determine whether an adjustment to the NAAT algorithm is necessary. Note: NAAT data presented in this report are limited to those reported by PHLs and as such, does not represent all NAAT performed. Clinical and commercial laboratories may initially perform NAAT.

Table 4. NAAT Algorithm by PHL, 2019.

NAAT Method	Sites
New AFB smear positive patients (routinely only first smear positive specimen); AFB smear negative patients on request only	AL, AK, AZ, CO, DC, GA, IL, IA, KY, MD, MI, MN, MS, MO, MT, NV, NH, NYC, NC, ND, OK, PA, PR, SAN, SC, TN, TX, UT, VT, VA, WI, WY
Testing per request only	HI, HOU, ID, KS, LAX, ME, NE, NJ, PHI, RI, SFO, SD, WA
Combination of AFB smear status & non-clinical indicators printed on submission form	CA, DE, MA, WV
One specimen from all new patients regardless of AFB smear status	AR, LA, OH, OR
New AFB smear positive patients (automatically testing >1 specimen per patient); AFB smear negative patients on request only	IN, CT
Testing per request; if not ordered, performed automatically on AFB smear positive, CSF and pediatric samples	FL
All specimens regardless of AFB smear status except patients previously positive for MTBC	NM
All specimens regardless of AFB smear status and previous positivity	NY

TURNAROUND TIMES

Table 5. TAT Indicators, 2017–2019.

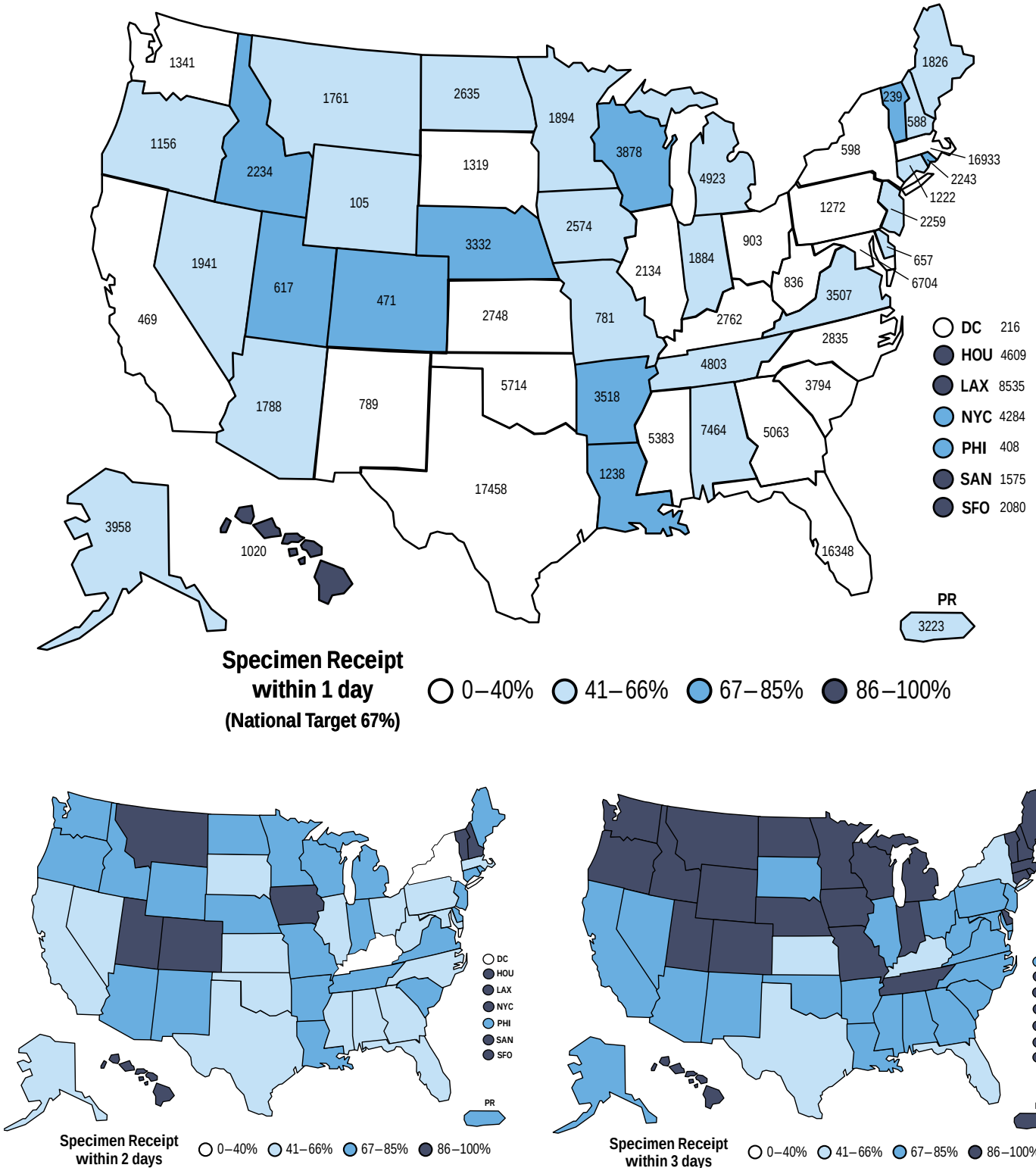
TAT Measurement	Specimen receipt within 1 day of collection	AFB smear result within 1 day of receipt	ID of MTBC within 21 days of receipt*	DST within 17 days of ID of MTBC*
National Target[3]: (% of specimens that should meet the benchmark)	**67%**	**92%**	**74%**	**69%**
Number of laboratories meeting or exceeding National Target (2017 to 2019)	12 to 16	33 to 32	30 to 32	26 to 22
National Average (reported % of specimens meeting the benchmark) (2017 to 2019)	49% to 52%	89% to 90%	72% to 75%	57% to 59%
Number of laboratories at or above National Average (2017 to 2019)	28 to 33	35 to 34	33 to 31	32 to 35

* Number of laboratories = 56 in 2017 and 57 in 2019. Two PHLs did not identify MTBC in 2017 and one did not in 2019; data from these PHLs were excluded from the analysis.

In 2017, National Averages for the four TAT benchmarks were below National Targets. In 2019, improvements in TAT data were observed.

- National Averages for all four TAT benchmarks improved in 2019.
- 2019 National Average of MTBC identified from culture within 21 Days of specimen receipt was 75%, exceeding the National Target by 1 percentage point.
- In 2019, PHLs improved TAT performance for specimen receipt and ID as measured by number of PHLs that met or exceeded the National Targets.
- In 2019, the number of PHLs that met or exceeded the National Average increased for specimen receipt and DST.

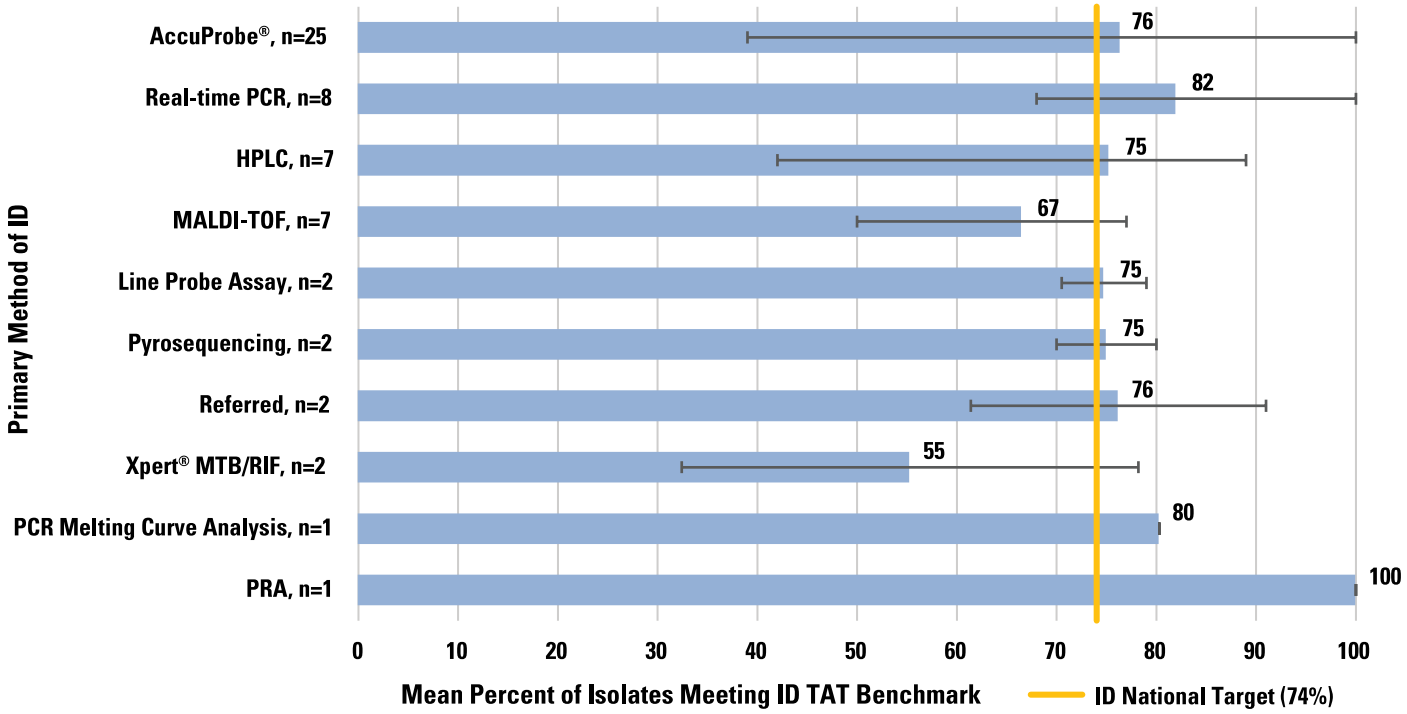
Figure 5. Maps of Percent of Specimens Received within One, Two, and Three Days from Specimen Collection, with Total Number of Specimens Received by PHL, 2019.



Specimen receipt within 1 day of collection continues to be a challenge for most PHLs. The first map shows the varying number of specimens that PHLs received and the percent of specimens received within one day of collection stratified by different ranges below and above the National Target of 67%. The variability in TAT demonstrates differences among PHLs, including how specimens are collected and transported. Local PHLs have a smaller geographic radius of submitter locations aiding faster receipt times.

- In 2019, 10 state PHLs (17%) and 6 local PHLs (10%) met or exceeded the National Target of 67% for specimen receipt within 1 day of collection.
  - These PHLs processed as few as 408 specimens and as many as 4,284 specimens.
  - 21 PHLs (36%) had a specimen receipt range of 41–66% within 1 day of collection.
    - » 8 of 21 PHLs had specimen receipt at the high end (60–66%) of the range.
- PHLs greatly improved specimen receipt TAT by day 3.
  - 53 PHLs (91%) received at least 67% of specimens by day 3.
  - 32 PHLs (55%) received more than 86% of specimen by day 3.

Figure 6. Mean Percent of MTBC Identified* from Culture within 21 Days of Specimen Receipt, by Primary ID Method, 2019.

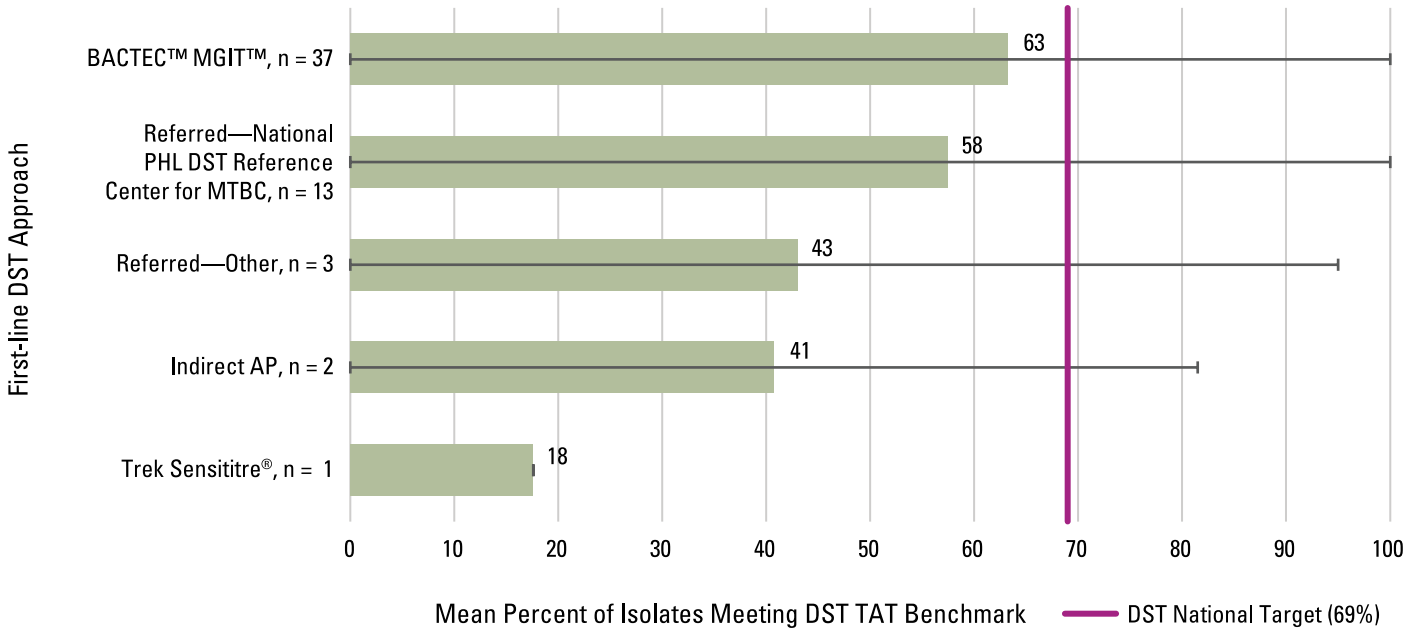


n=Number of laboratories using each method

*One laboratory did not ID MTBC in 2019 and was excluded from the analysis.

In 2019, 57 PHLs identified MTBC from diagnostic specimens. Individual PHLs' percent of MTBC identified from culture within 21 days of specimen receipt ranged from 32% to 100%. Each PHL indicated their primary method of ID; 10 different ID methods were reported. Most PHLs (n=25) performed AccuProbe® with a mean percent of MTBC identified within 21 days of specimen receipt equal to 76% and a range of 39% to 100%. The majority of primary ID methods had a mean percent of MTBC identified at or above the National Target (74%).

Figure 7. Mean Percent of Isolates with Growth-based DST Performed within 17 days of ID*, by Primary DST Approach, 2019.

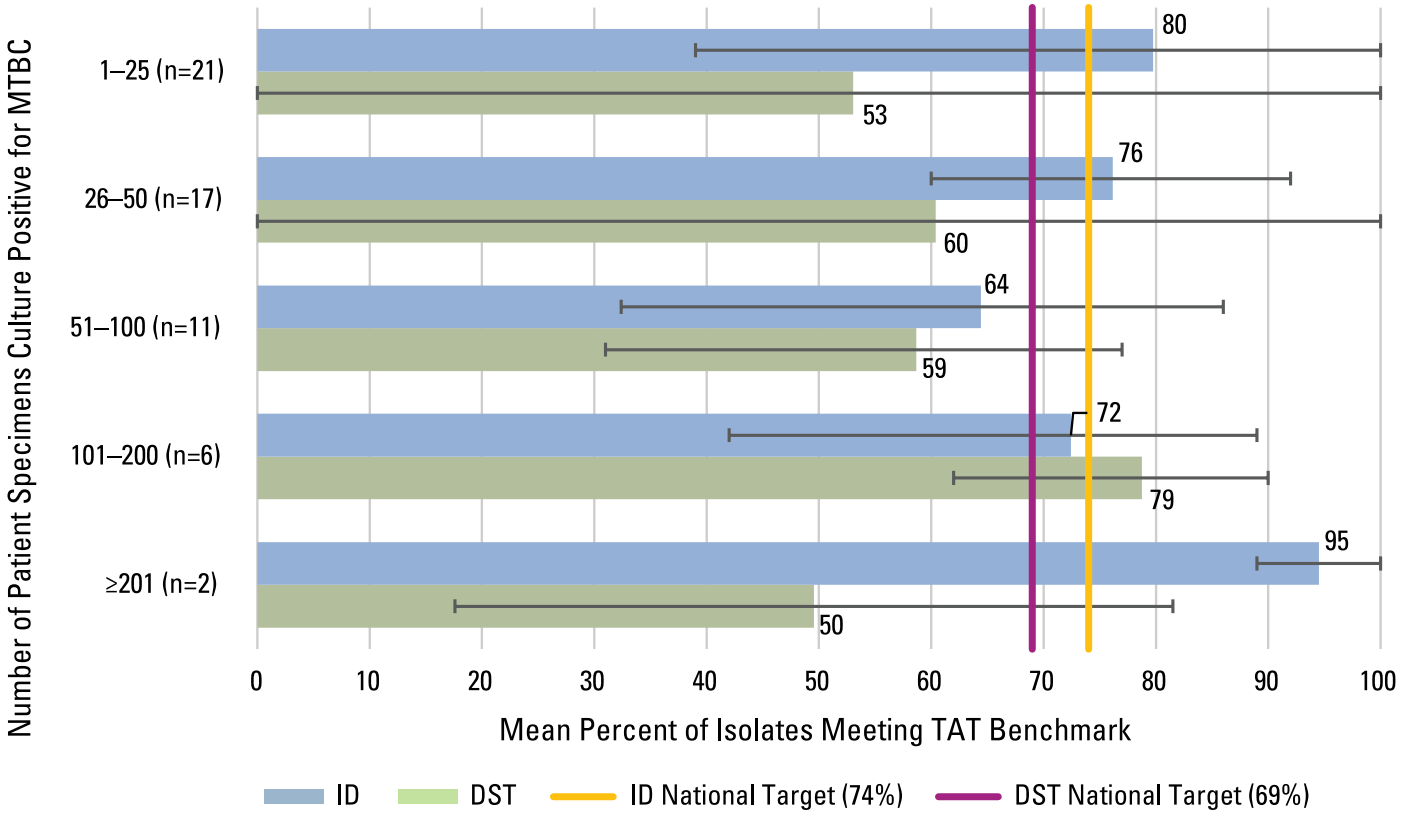


n = Number of laboratories using each approach

*One laboratory did not ID MTBC, therefore DST was not performed on an initial diagnostic specimen in 2019 and was excluded from the analysis.

All PHLs that identified MTBC from culture growth in 2019 (n=57) ensured first-line DST was performed. As shown in Figure 7, reported PHL mean percent of isolates with growth-based DST performed within 17 days of ID ranged from 0% to 100%. Each PHL indicated their first-line DST method or referral strategy; there were 6 different DST approaches among the PHLs. Each DST approach had a mean percent below the National Target (69%). The majority of PHLs (n=37, 65%) utilized BACTEC™ MGIT™ with a mean percent of isolates with growth-based DST performed within 17 days of ID of 63%. This demonstrates the need to continue to monitor and assess approaches to improve TAT of growth-based DST.

Figure 8. Mean Percent of MTBC Identified* from Culture within 21 Days of Specimen Receipt and Growth-based DST Performed within 17 days of ID, by Number of MTBC Culture Positive Patients, 2019.



*One laboratory did not ID MTBC in 2019 and is excluded from the analysis.

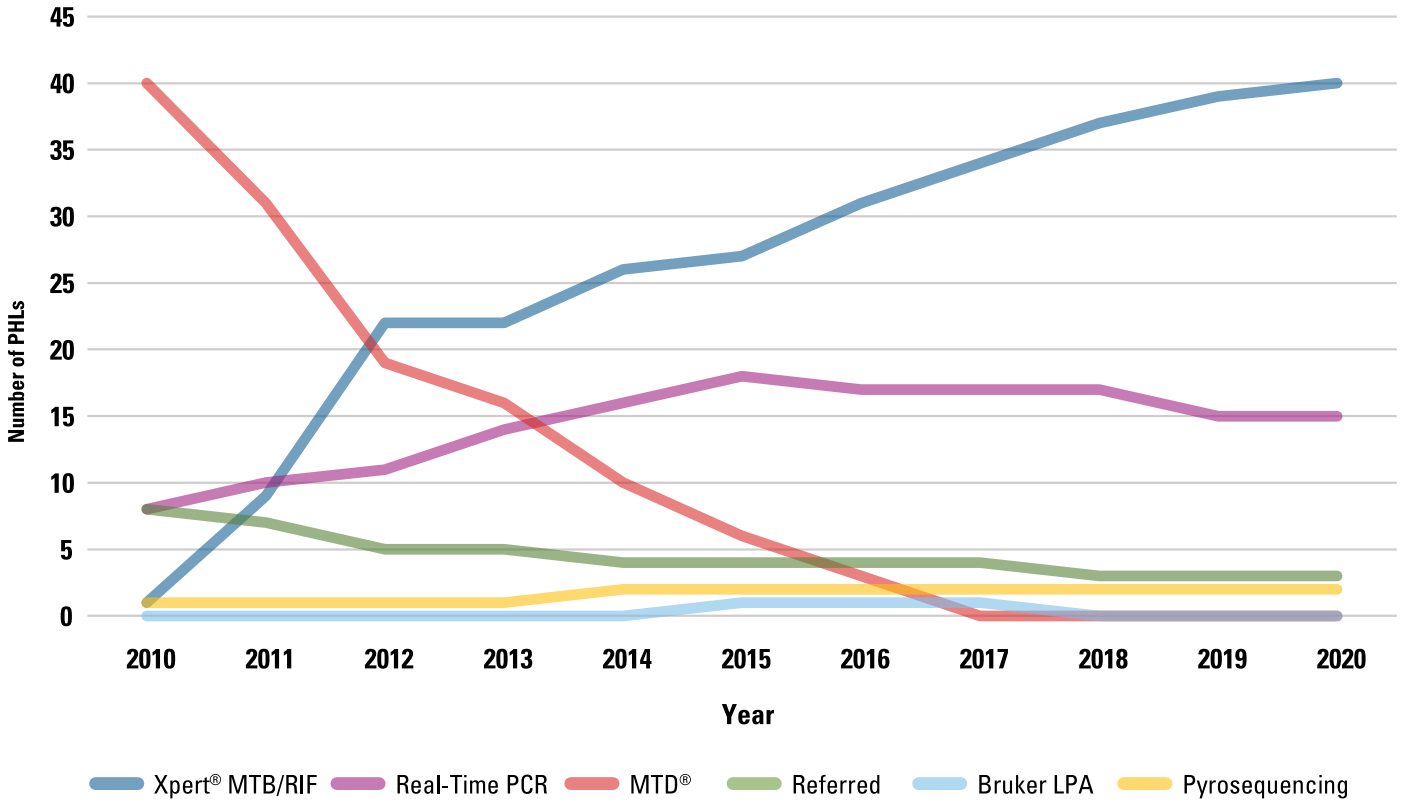
In Figure 8, PHLs were grouped based on the number of patients that were culture positive for MTBC ranging from 1–926. The mean percent of isolates meeting recommended TATs for ID reported within 21 days from specimen receipt and first-line DST results reported within 17 days of ID were evaluated for each PHL group. Three of the five groups, including the lowest and highest stratifications based on number of culture positive patients, had a mean percent of isolates with MTBC identified from culture within 21 days that met or exceeded the National Target. However, only one group (101–200) had a mean percent of isolates with DST performed within 17 days of ID that met or exceeded the National Target.

Many PHLs (n=21, 37%) identified 25 or fewer patients that were culture positive for MTBC. For this group, the mean of the percent of isolates with ID reported within 21 days was 1 percentage point above the National Target, with a range of 39% to 100%; however, the mean percent of isolates across PHLs in this group with DST performed within 17 days of ID was below the National Target with a wide range (0%–100%).

METHODS IN PUBLIC HEALTH LABORATORIES

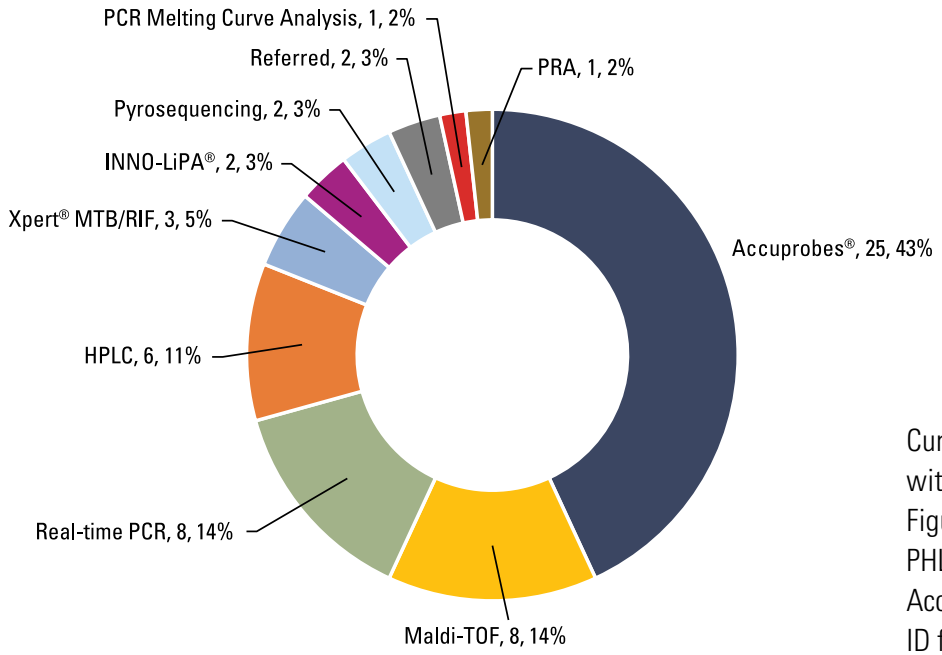
Methods performed or accessed through referral by PHLs supported, in part, by the TB CoAg for NAAT, ID, DST, molecular testing for detection of drug resistance, and IGRA are displayed in Figures 9–14. As new technology emerges and laboratories adjust testing algorithms, methods performed will continue to evolve.

Figure 9. Changes in PHL NAAT Methods/Referral, 2010–2020 (n=60).



NAAT methods have changed throughout the past 10 years. NAAT continues to provide the earliest opportunity for rapid detection of MTBC for initiation of treatment and public health intervention. Data is reported for 58 CoAg PHLs, however, two laboratories performed two NAAT methods depending on specimen type and test order request (n=60). Cepheid Xpert® MTB/RIF was widely used by PHLs (40/60, 67%) followed by laboratory developed real-time PCR assays (15/60, 25%). Together, these two methods accounted for 92% of NAAT methods performed by PHLs in 2020. Additionally, laboratories referred testing (3/60, 5%) and performed pyrosequencing (2/60, 3%); for 2020, CoAg PHLs reported that Bruker LPA and MTD® are no longer performed as NAAT methods.

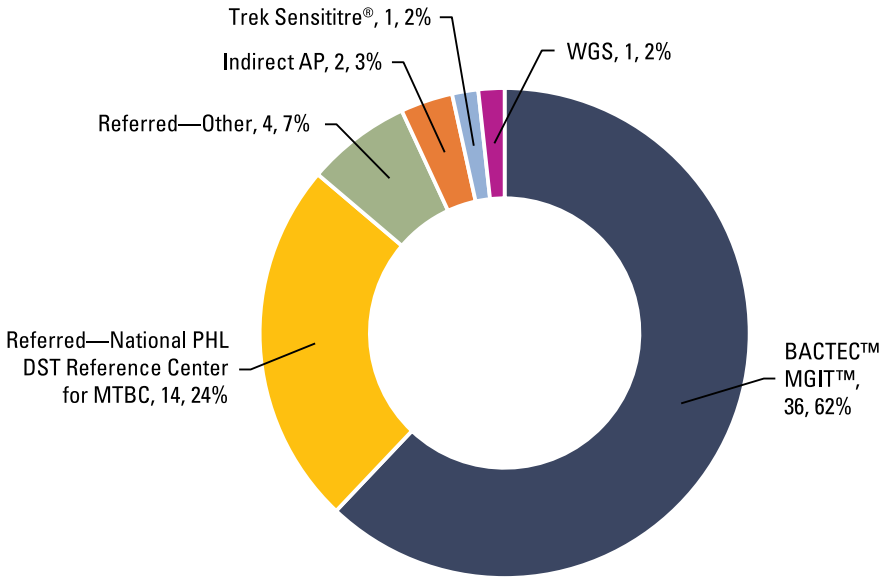
Figure 10. Primary ID Methods, 2020 (n=58).



Note—Data label indicates method/approach, number of laboratories, percentage

Current primary ID methods utilized within all PHLs are included in Figure 10. In 2020, the majority of PHLs (25/58, 43%) continued to use AccuProbe® as the primary method of ID followed by MALDI-TOF (8/58, 14%) and real-time PCR (8/58, 14%).

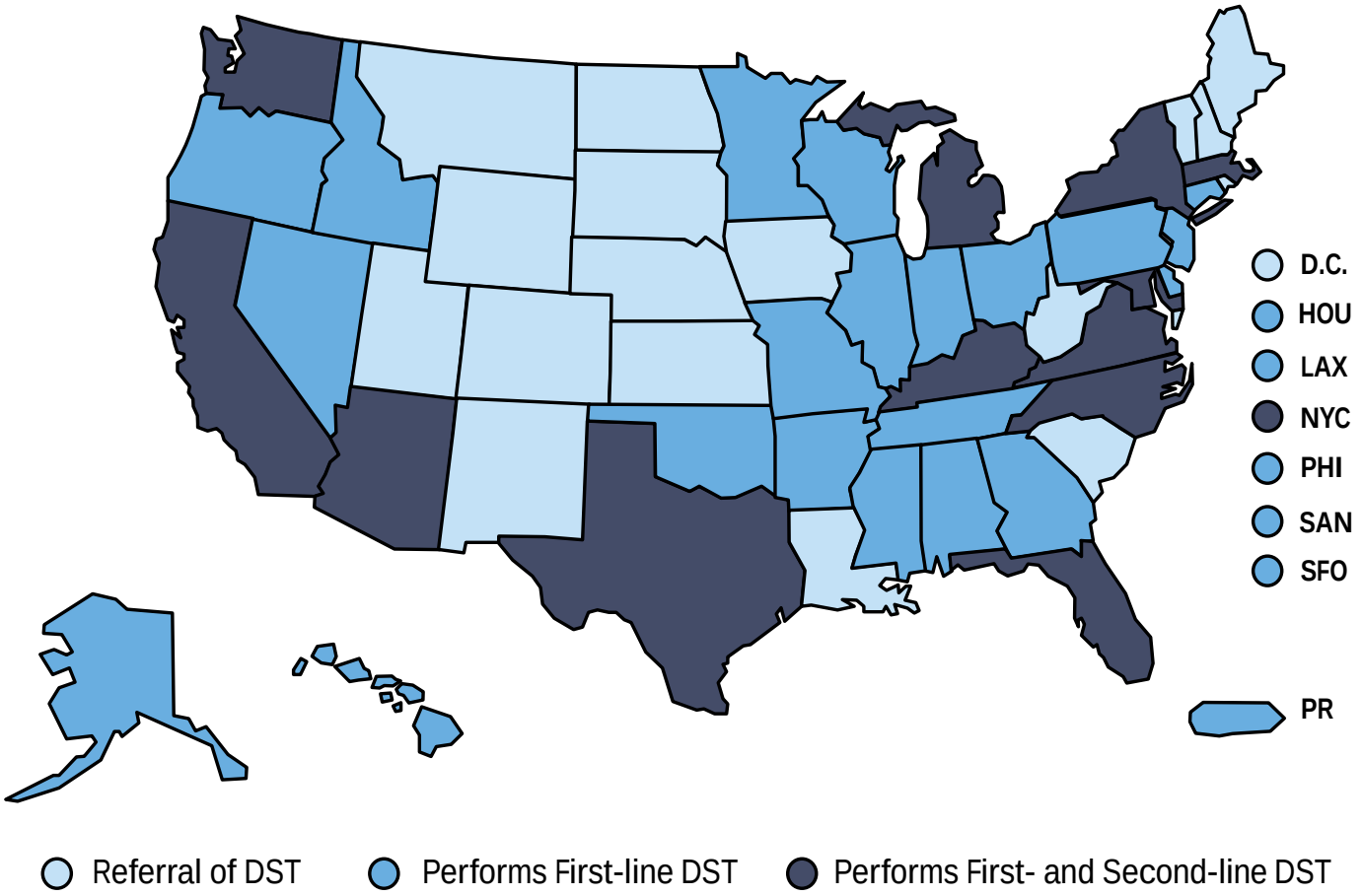
Figure 11. Growth-based DST Approach for First-line Antituberculosis Drugs, 2020 (n=58).



Note—Data label indicates method/approach, number of laboratories, percentage

PHLs growth-based DST approaches for first-line antituberculosis drugs are shown in Figure 11. BACTEC™ MGIT™ (36/58, 62%) was the most commonly performed DST method. Fourteen (24%) PHLs submitted isolates to the National PHL DST Reference Center for MTBC as these sites performed less than 50 DST per year and 4 (7%) PHLs referred DST to another laboratory for testing.

Figure 12. Map of PHL DST Availability, 2020 (n=58).

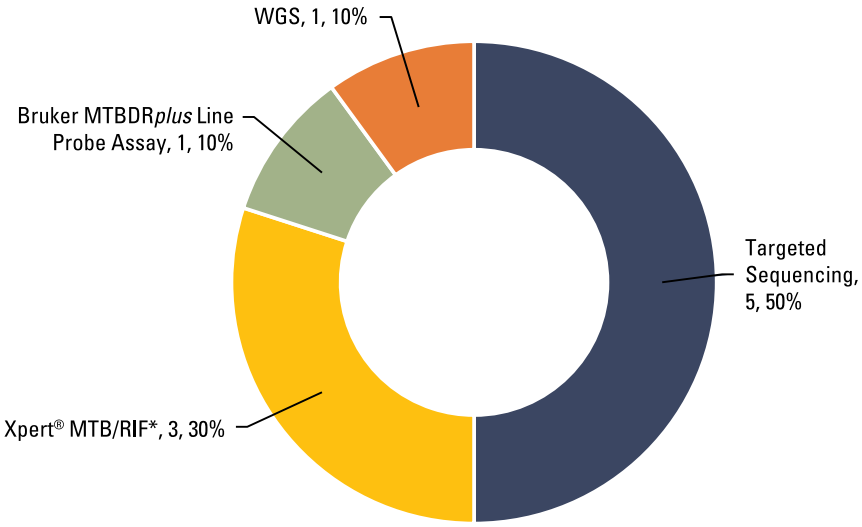


PHLs provide or assure DST services through different approaches. Eighteen PHLs (31%) referred DST to another laboratory. Twenty-five PHLs (43%) solely performed first-line DST in-house, while 15 PHLs (26%) performed both in-house first- and some second-line DST. Drugs included in second-line DST panels differed by laboratory and are largely based on treatment practices of a TB Program and clinicians within a jurisdiction.

Table 6. PHLs that Perform Second-line DST by Method, 2020.

Second-line DST Method	Public Health Laboratory
Indirect Agar Proportion	AZ, KY, MA, MD, MI, NC, NYC, TX, VA, WA
BACTEC™ MGIT™	CA
Trek Sensititre®	FL
WGS (Agar Proportion if mutation found)	NY

Figure 13. Molecular Testing for Detection of Drug Resistance, 2020 (n=10).



*Performed on culture growth.
Note—Data label indicates method/approach, number of laboratories, percentage

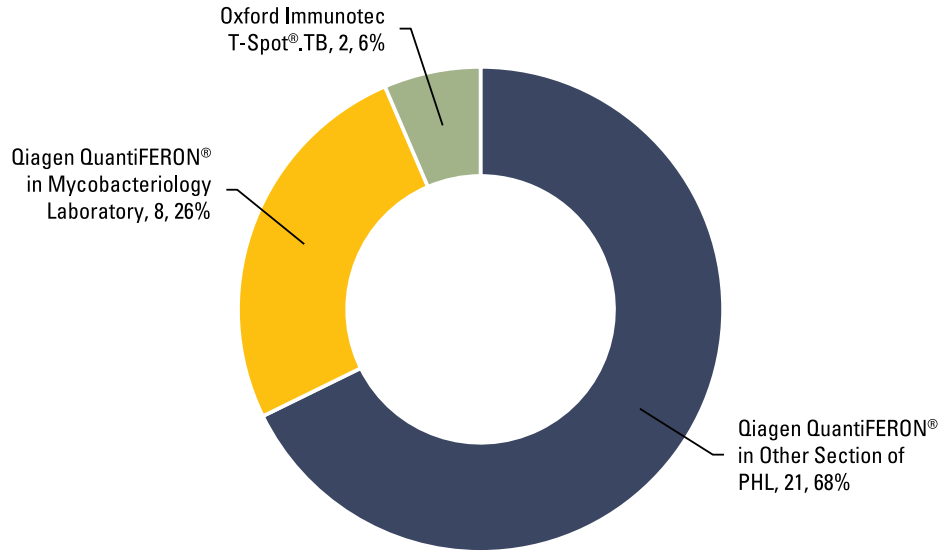
PHL methods performed for molecular testing of detection of drug resistance are shown in Figure 13. Ten PHLs (17%) performed molecular testing for detection of drug resistance. Since 2018, one additional PHL began performing this type of testing, specifically the Cepheid Xpert® MTB/RIF. Five of the 10 (50%) PHLs performing in-house molecular testing for detection of drug resistance utilized targeted sequencing.

Table 7. CoAg PHLs that Perform Molecular Testing for Detection of Drug Resistance by Method, 2020.

Method	Public Health Laboratory
Targeted Sequencing	CA, FL, IN, MO, NY
Cepheid Xpert® MTB/RIF*	IL, NV, SAN
Bruker MTBDR*plus* Line Probe Assay	FL
WGS	NY

* Only includes laboratories performing the assay on culture growth, does not include laboratories performing the assay for direct detection.

Figure 14. IGRA Approaches, 2020 (n=31).



Note—Data label indicates method/approach, number of laboratories, percentage

IGRA methods performed or accessed by PHLs are shown in Figure 14. Not all PHLs provide IGRA testing services. In 2020, 31 of 58 (59%) funded PHLs performed IGRA testing. Since 2018, 1 additional PHL added IGRA testing, specifically the Qiagen QuantiFERON; the majority (68%) of CoAg funded PHLs utilized this method for IGRA testing. Two laboratories referred T-Spot®.TB IGRA testing to Oxford Immunotec for testing.

Table 8. CoAg PHLs that Perform/Access IGRA by Method, 2020.

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

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2. APHL. National Public Health Laboratory Drug Susceptibility Testing Reference Center. Silver Springs, MD. 2015.
3. APHL. TB Laboratory Cooperative Agreement Toolkit. Silver Springs, MD. 2020.

RESOURCES

APHL TB Website https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/default.aspx

APHL False-positive Investigation Toolkit https://www.cdc.gov/tb/publications/guidestoolkits/false_positive/False-Positive.htm

CDC TB Website http://www.cdc.gov/tb/

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

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

Guide to the Application of Genotyping to Tuberculosis Prevention and Control http://www.cdc.gov/tb/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/

ARTICLES OF INTEREST

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Kamela C, Ng S, Supply P, et. al. How Well do Routine Molecular Diagnostics Detect Rifampin Heteroresistance in Mycobacterium tuberuclosis? *J Clin Micro*. 2019;57(11).

INTERFERON GAMMA RELEASE ASSAY

Venkatappa TK, Punnoose R, Katz DJ, et al. Comparing QuantiFERON-TB Gold Plus with Other Tests To Diagnose *Mycobacterium tuberculosis* Infection. *J of Clin Micro*. 2019;57(11).

UPDATES

Biosafety in Microbiological and Biomedical Laboratories: 6th Edition https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

APHL Essentials for the Mycobacteriology Laboratory: Promoting Quality Practices Training Modules https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Training-Modules.aspx

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.

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APPENDIX A: EXPLANATION OF FIGURES FOR ACCESSIBILITY

Laboratory Capacity Team (LCT) Contact Details. Map of the U.S. divided into four sections by LCT consultant.

- Stephanie Johnston, MS (Yellow)—Alaska, Arizona, California, Hawaii, Nevada, New Mexico, New York City, Oregon, Texas, Washington
- Sean Buono, PhD (Orange)—Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Pennsylvania, Philadelphia, 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

Figure 1. PHLs' 2019 workload volume and proportion of total for selected indicators, stratified by number of clinical specimens processed is presented in a horizontal 100% stacked bar graph.

The number of clinical specimens processed in the 1–1,000 range are listed by indicator (7 rows in order top to bottom). # Pts. Specimen processed was 3,392 or 4.4% of a total of 77,203 (100%). # Pt specimens (+) MTBC was 292 or 7.4% of a total of 3,298 (100%). MTBC culture (+) pts that were NAAT (+) was 200 or 9.9% of a total of 2,023 (100%). MTBC culture (+) pts that were NAAT (+) reported in 48 hours was 177 or 10.6% of a total of 1,668 (100%). # Pts. reference isolate submitted was 2,210 or 16.5% or a total of 13,409 (100%). # Pts reference isolate (+) MTBC was 773 or 28.6% of a total of 2,700 (100%). # Pts growth-based DST performed/referred was 441 or 8.2% of a total of 5,389 (100%).

The number of clinical specimens processed in the 1,001–2,000 range are listed by indicator (7 rows in order top to bottom). # Pts. Specimen processed was 8,593 or 11.2% of a total of 77,203 (100%). # Pt specimens (+) MTBC was 510 or 13.0% of a total of 3,298 (100%). MTBC culture (+) pts that were NAAT (+) was 270 or 13.4% of a total of 2,023 (100%). MTBC culture (+) pts that were NAAT (+) reported in 48 hours was 226 or 13.6% of a total of 1,668 (100%). # Pts. reference isolate submitted was 2,102 or 15.7% or a total of 13,409 (100%). # Pts reference isolate (+) MTBC was 352 or 13.0% of a total of 2,700 (100%). # Pts growth-based DST performed/referred was 898 or 16.7% of a total of 5,389 (100%).

The number of clinical specimens processed in the 2,001–4,000 range are listed by indicator (7 rows in order top to bottom). # Pts. Specimen processed was 22,188 or 28.7% of a total of 77,203 (100%). # Pt specimens (+) MTBC was 683 or 17.4% of a total of 3,298 (100%). MTBC culture (+) pts that were NAAT (+) was 382 or 18.9% of a total of 2,023 (100%). MTBC culture (+) pts that were NAAT (+) reported in 48 hours was 299 or 17.9% of a total of 1,668 (100%). # Pts. reference isolate submitted was 2,109 or 15.7% or a total of 13,409 (100%). # Pts reference isolate (+) MTBC was 566 or 21.0% of a total of 2,700 (100%). # Pts growth-based DST performed/referred was 1,063 or 19.7% of a total of 5,389 (100%).

The number of clinical specimens processed in the 4,001–8,000 range are listed by indicator (7 rows in order top to bottom). # Pts. Specimen processed was 20,073 or 26.0% of a total of 77,203 (100%). # Pt specimens (+) MTBC was 787 or 20.0% of a total of 3,298 (100%). MTBC culture (+) pts that were NAAT (+) was 444 or 21.9% of a total of 2,023 (100%). MTBC culture (+) pts that were NAAT (+) reported in 48 hours was 382 or 22.9% of a total of 1,668 (100%). # Pts. reference isolate submitted was 3,252 or 24.2% or a total of 13,409 (100%). # Pts reference isolate (+) MTBC was 517 or 19.2% of a total of 2,700 (100%). # Pts growth-based DST performed/referred was 1,086 or 20.1% of a total of 5,389 (100%).

The number of clinical specimens processed in the >8,000 range are listed by indicator (7 rows in order top to bottom). # Pts. Specimen processed was 22,957 or 29.7% of a total of 77,203 (100%). # Pt specimens (+) MTBC was 1,656 or 42.2% of a total of 3,298 (100%). MTBC culture (+) pts that were NAAT (+) was 727 or 35.9% of a total of 2,023 (100%). MTBC culture (+) pts that were NAAT (+) reported in 48 hours was 584 or 35.0% of a total of 1,668 (100%). # Pts. reference isolate submitted was 3,736 or 27.9% or a total of 13,409 (100%). # Pts reference isolate (+) MTBC was 492 or 18.2% of a total of 2,700 (100%). # Pts growth-based DST performed/referred was 1,901 or 35.3% of a total of 5,389 (100%).

Figure 2. PHLs' 2019 culture positivity is presented in a horizontal bar graph. The vertical y-axis contains a list of PHLs, grouped by number of specimens processed, and the horizontal x-axis is MTBC culture positivity ranging from 0% to 40%, by increments of 5%. PHLs who processed 1–1,000 specimens and their corresponding culture positivity (14 rows from top to bottom) are: West Virginia (0.6%), New Hampshire (1.3%), Vermont (1.5%), Wyoming (1.7%), Delaware (3.9%), Utah (5.5%), D.C. (5.7%), New Mexico (8.0%), Ohio (8.3%), Missouri (12.3%), Philadelphia (14.8%), Colorado (15.9%), California (17.6%), and New York State (25.1%). The mean culture positivity for this group was 8.7%. PHLs who processed 1,001–2,000 specimens and their corresponding culture positivity (14 rows from top to bottom) are: Montana (0.0%), Maine (1.2%), South Dakota (1.2%), Minnesota (1.4%), Connecticut (2.8%), Nevada (4.0%), Arizona (6.7%), Indiana (10.6%), San Diego (11.4%), Louisiana (11.5%), Washington (13.0%), Oregon (17.0%), Hawaii (22.0%), and Pennsylvania (38.1%). The mean culture positivity for this group was 10.1%. PHLs who processed 2,001–4,000 specimens and their corresponding culture positivity (17 rows from top to bottom) are: Idaho (0.3%), Nebraska (0.4%), Rhode Island (0.7%), North Dakota (1.1%), Kentucky (1.1%), Iowa (1.4%), South Carolina (1.7%), Wisconsin (2.1%), Puerto Rico (2.1%), Alaska (2.5%), Kansas (2.8%), Arkansas (3.0%), Virginia (7.0%), San Francisco (7.8%), North Carolina (12.8%), New Jersey (15.3%), and Illinois (18.9%). The mean culture positivity for this group was 4.8%. PHLs who processed 4,001–8,000 specimens and their corresponding culture positivity (9 rows from top to bottom) are: Michigan (0.8%), Oklahoma (1.1%), Mississippi (1.5%), Alabama (1.8%), Maryland (6.8%), Houston (7.2%), New York City (9.9%), Georgia (10.3%), and Tennessee (11.2%). The mean culture positivity of this group was 5.6%. PHLs who processed >8,000 specimens and their corresponding culture positivity (4 rows from top to bottom) are: Massachusetts (1.0%), Los Angeles (7.5%), Florida (8.3%), and Texas (17.2%). The mean culture positivity for this group was 8.5%.

Figure 3. Map of U.S. indicating 2019 data for PHLs meeting or exceeding NAAT TAT performance targets. Each level is assigned a color.

Not meeting national average (49%) (White)—Alaska, Arizona, Colorado, Connecticut, D.C., Georgia, Hawaii, Houston, Idaho, Illinois, Indiana, Kansas, Los Angeles, Massachusetts, Missouri, Montana, New Hampshire, New Jersey, New York City, North Dakota, Ohio, Oregon, Philadelphia, San Diego, San Francisco, South Dakota, Texas, Virginia, Wisconsin

Meeting/exceeding national average (49%) (Light Blue)—Alabama, Arkansas, California, Florida, Kentucky, Maine, Maryland, Minnesota, Mississippi, Nebraska, Nevada, North Carolina, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Utah, Vermont, West Virginia, Washington

Meeting/exceeding national target (77%) (Dark Blue)—Delaware, Iowa, Louisiana, Michigan, New Mexico, New York, South Carolina, Wyoming

Figure 4. 2019 NAAT TAT data, grouped by testing algorithm, are displayed in a horizontal bar graph. The vertical y-axis contains a list of NAAT algorithms and the horizontal x-axis is the mean percent of MTBC culture positive patients with a positive NAAT result reported within 48 hours of specimen receipt, ranging from 0% to 100%, by increments of 10%. There are 8 horizontal bars (top to bottom) with each bar representing the average NAAT TAT for PHLs using that testing

algorithm. Thirty-two PHLs used the 'New AFB smear positive patients (routinely only first smear positive specimen); AFB smear negative patients on request only' algorithm and had a mean of 49.7% and range of 12%–100%. 13 PHLs used the 'Testing per request only' algorithm and had a mean of 34.9% and range of 16.2%–75.0%. Four PHLs used the 'Combination of AFB smear status & non-clinical indicators printed on submission form' algorithm and had a mean of 57.2% and range of 32.3%–80.0%. Four PHLs used the 'One specimen from all new patients regardless of AFB smear status' algorithm and had a mean of 52.3% and range of 24.2%–81.0%. 2 PHLs used the 'New AFB smear positive patients (automatically testing >1 specimen per patient); AFB smear negative patients on request only' algorithm and had a mean of 44.9% and range of 42.1%–47.6%. One PHL used the 'Testing per request; if not ordered, performed automatically on AFB smear positive, CSF, and pediatric samples' algorithm and had a mean of 60.1%. One PHL used the 'All specimens regardless of AFB smear status except patients previously positive for MTBC' algorithm and had a mean of 78.9%. One PHL used the 'All specimens regardless of AFB smear status and previous positivity' algorithm and had a mean of 96.7%.

Figure 5. Maps of U.S. divided by groupings of TAT for specimen receipt within one, two, and three days from specimen collection. Number of specimens processed in 2019 is included for each site on the specimen receipt within one day map.

Specimen receipt within one day:

0–40% (White)—California, D.C., Florida, Georgia, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Mississippi, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas, Washington, West Virginia.

41–66% (Light Blue)—Alabama, Alaska, Arizona, Connecticut, Delaware, Indiana, Iowa, Maine, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, North Dakota, Oregon, Puerto Rico, Tennessee, Virginia, Wyoming.

67–85% (Medium Blue)—Arkansas, Colorado, Idaho, Louisiana, Nebraska, New York City, Philadelphia, Rhode Island, Utah, Vermont, Wisconsin.

86–100% (Dark Blue)—Hawaii, Houston, Los Angeles, San Diego, San Francisco.

Specimen receipt within two days:

0–40% (White)—D.C., Kentucky, New York.

41–66% (Light Blue)—Alabama, Alaska, California, Florida, Georgia, Illinois, Kansas, Maryland, Massachusetts, Mississippi, Nevada, North Carolina, Ohio, Oklahoma, Pennsylvania, South Dakota, Texas, West Virginia.

67–85% (Medium Blue)—Arizona, Arkansas, Connecticut, Delaware, Idaho, Indiana, Louisiana, Maine, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New Mexico, North Dakota, Oregon, Philadelphia, Puerto Rico, Rhode Island, South Carolina, Tennessee, Virginia, Washington, Wisconsin, Wyoming.

86–100% (Dark Blue)—Colorado, Hawaii, Houston, Iowa, Los Angeles, Montana, New Hampshire, New York City, San Diego, San Francisco, Utah, Vermont.

Specimen receipt within three days:

0–40% (White)—(none)

41–66% (Light Blue)—Florida, Kansas, Kentucky, New York, Texas.

67–85% (Medium Blue)—Alabama, Alaska, Arizona, California, D.C., Georgia, Illinois, Louisiana, Maryland, Mississippi, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Virginia, West Virginia.

86–100% (Dark Blue)—Arkansas, Colorado, Connecticut, Delaware, Hawaii, Houston, Idaho, Indiana, Iowa, Los Angeles, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New York City, North Dakota, Oregon, Philadelphia, Puerto Rico, Rhode Island, San Diego, San Francisco, Tennessee, Utah, Vermont, Washington, Wisconsin, Wyoming.

Figure 6. 2019 turnaround times for ID, divided into groups by primary ID method, is presented in a horizontal bar graph. The vertical y-axis contains 10 groupings of PHLs by primary method of ID and the horizontal x-axis is the mean percent of isolates meeting ID TAT benchmark ranging from 0% to 100%, by increments of 10%. The ID National Target is represented by a vertical bar at 74%. Twenty-five PHLs that used AccuProbe® had a mean percent of 76% and range of 39%–100%. Eight PHLs that used real-time PCR had a mean percent of 82% and range of 68%–100%. Seven PHLs that used HPLC had a mean percent of 75% and range of 42%–89%. Seven PHLs that used MALDI-TOF had a mean percent of 67% and range of 50%–77%. Two PHLs that used line probe assays had a mean percent of 75% and range of 71%–79%. Two PHLs that used pyrosequencing had a mean percent of 75% and range of 70%–80%. Two PHLs that referred ID testing had a mean percent of 76% and range of 61%–91%. Two PHLs that used Xpert® MTB/RIF had a mean of 55% and range of 32%–78%. One PHL that used PCR melting curve analysis had a mean percent of 80% and 1 PHL that used PRA had a mean percent of 100%.

Figure 7. 2019 turnaround times for DST, divided into groups by first-line DST method, is presented in a horizontal bar graph. The vertical y-axis contains 5 groupings of PHLs by first-line DST methods and the horizontal x-axis is the mean percent of isolates meeting DST TAT benchmark ranging from 0% to 100%, by increments of 10%. The DST National Target is represented by a vertical bar at 69%. 37 PHLs that used BACTEC™MGIT™ had a mean percent of 63% and range of 0%–100%. Thirteen PHLs that referred DST to National PHL DST Reference Center for MTBC had a mean percent of 58% and range of 0%–100%. Three PHLs that referred DST to another PHL had a mean percent of 43% and range of 0%–95%. Two PHLs that used Indirect AP had a mean percent of 41% and range of 0%–82%. One PHL that used Trek Sensititre® had a mean percent of 18%.

Figure 8. 2019 turnaround times for ID and DST, divided into groups by number of MTBC positive patients, is presented in a horizontal bar graph. The vertical y-axis contains 5 groupings of PHLs by number of MTBC positive patients and the horizontal x-axis is the mean percent of isolates meeting TAT benchmark ranging from 0% to 100%, by increments of 10%. The DST National Target is represented by a vertical bar at 69% and the ID National Target is represented by a vertical bar at 74%. Twenty-one PHLs that had between 1–25 patient specimens culture positive for MTBC had a mean percent of 80% and range of 39%–100% for ID and mean percent of 53% and range of 0%–100% for DST. Seventeen PHLs that had between 26–50 patient specimens culture positive for MTBC had a mean percent of 76% and range of 60%–92% for ID and mean percent of 60% and range of 0%–100% for DST. Eleven PHLs that had between 51–100 patient specimens culture positive for MTBC had a mean percent of 64% and range of 32%–86% for ID and mean percent of 59% and range of 31%–77% for DST. Six PHLs that had between 101–200 patient specimens culture positive for MTBC had a mean percent of 72% and range of 42%–89% for ID and mean percent of 79% and range of 62%–90% for DST. Two PHLs that had between ≥201 patient specimens culture positive for MTBC had a mean percent of 95% and range of 89%–100% for ID and mean percent of 50% and range of 18%–82% for DST.

Figure 9. NAAT methods used by PHLs during 2010–2020 are presented in a line graph. The vertical y-axis is number of PHLs and the horizontal x-axis is the year. Data for Xpert® MTB/RIF is 1 in 2010, 9 in 2011, 22 in 2012, 22 in 2013, 26 in 2014, 27 in 2015, 31 in 2016, 34 in 2017, 37 in 2018, 39 in 2019, and 40 in 2020. Data for real-time PCR is 8 in 2010, 10 in 2011, 11 in 2012, 14 in 2013, 16 in 2014, 18 in 2015, 17 in 2016, 17 in 2017, 17 in 2018, 15 in 2019, and 15 in 2020. Data for MTD® is 40 in 2010, 31 in 2011, 19 in 2012, 16 in 2013, 10 in 2014, 6 in 2015, 3 in 2016, 0 in 2017, 0 in 2018,

0 in 2019, and 0 in 2020. Data for referred testing is 8 in 2010, 7 in 2011, 5 in 2012, 5 in 2013, 4 in 2014, 4 in 2015, 4 in 2016, 4 in 2017, 3 in 2018, 3 in 2019, and 3 in 2020. Data for Bruker line probe assays is 0 in 2010, 0 in 2011, 0 in 2012, 0 in 2013, 0 in 2014, 1 in 2015, 1 in 2016, 1 in 2017, 0 in 2018, 0 in 2019, and 0 in 2020. Data for pyrosequencing is 1 in 2010, 1 in 2011, 1 in 2012, 1 in 2013, 2 in 2014, 2 in 2015, 2 in 2016, 2 in 2017, 2 in 2018, 2 in 2019, and 2 in 2020.

Figure 10. Primary ID methods used by PHLs in 2020 are presented in a doughnut chart. The largest slice represents the 25 PHLs or 43% of 58 (100%), that perform AccuProbe®. The following nine slices represent: 8 PHLs or 14% of 58 (100%) that performed MALDI-TOF; 8 PHLs or 14% of 58 (100%) that performed real-time PCR; 6 PHLs or 11% of 58 (100%) that performed HPLC; 3 PHLs or 5% of 58 (100%) that performed Xpert® MTB/RIF 2 PHLs or 3% of 58 (100%) that performed INNO-LiPA; 2 PHLs or 3% of 58 (100%) that performed pyrosequencing; 2 PHLs or 3% of 58 (100%) that referred testing; 1 PHL or 2% of 58 (100%) that performed PCR melting curve analysis; and 1 PHL or 2% of 58 (100%) that performed PRA.

Figure 11. The first-line growth-based DST methods used by PHLs in 2020 are presented in a doughnut chart. The largest slice represents the 36 PHLs or 62% of 58 (100%) that perform DST using BACTEC™ MGIT™. The next five slices represent: 14 PHLs or 24% of 58 (100%) that referred testing to the National DST Reference Center; 4 PHLs or 7% of 58 (100%) that referred testing to another laboratory; 2 PHLs or 3% of 58 (100%) that performed indirect agar proportion; 1 PHL or 2% of 58 (100%) that performed Trek Sensititre®; and 1 PHL or 2% of 58 (100%) that performed whole genome sequencing.

Figure 12. Map of U.S. divided by PHL DST availability in 2020

Referral of DST (Light Blue)—Colorado, D.C., Iowa, Kansas, Louisiana, Maine, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Rhode Island, South Carolina, South Dakota, Utah, Vermont, West Virginia, Wyoming.

Performed First-line DST (Medium Blue)—Alabama, Alaska, Arkansas, Connecticut, Delaware, Georgia, Hawaii, Houston, Idaho, Illinois, Indiana, Nevada, New Jersey, Los Angeles, Minnesota, Mississippi, Missouri, Ohio, Oklahoma, Oregon, Pennsylvania, Philadelphia, Puerto Rico, San Diego, San Francisco, Tennessee, Wisconsin.

Performed First- and Second-line DST (Dark Blue)—Arizona, California, Florida, Kentucky, Maryland, Massachusetts, Michigan, New York, New York City, North Carolina, Texas, Virginia, Washington.

Figure 13. The molecular testing for detection of drug resistance used by PHLs in 2020 are presented in a doughnut chart. The largest slice represents the 5 PHLs or 50% of 10 (100%) that performed targeted sequencing. The next three slices represent: 3 PHLs or 30% of 10 (100%) that used the Xpert® MTB/RIF; 1 PHL or 10% of 10 (100%) that performed Bruker MTBDRplus line probe assay; and 1 PHL or 10% of 10 (100%) that performed whole genome sequencing.

Figure 14. The IGRA approaches used by PHLs in 2020 are presented in a doughnut chart. The largest slice represents the 21 PHLs or 68% of 31 (100%) that perform Qiagen QuantiFERON® in another section of the PHL. The other two slices represent 8 PHLs or 26% of 31 (100%) that perform Qiagen QuantiFERON® in the Mycobacteriology section of the PHL and 2 PHLs or 6% of 31 (100%) that use Oxford Immunotec T-Spot®.TB.