2024 TUBERCULOSIS LABORATORY AGGREGATE REPORT

SEVENTH EDITION

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

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For accessibility, a full explanation of figures can be found in **Appendix A: Explanation of Figures for Accessibility on page 28.**

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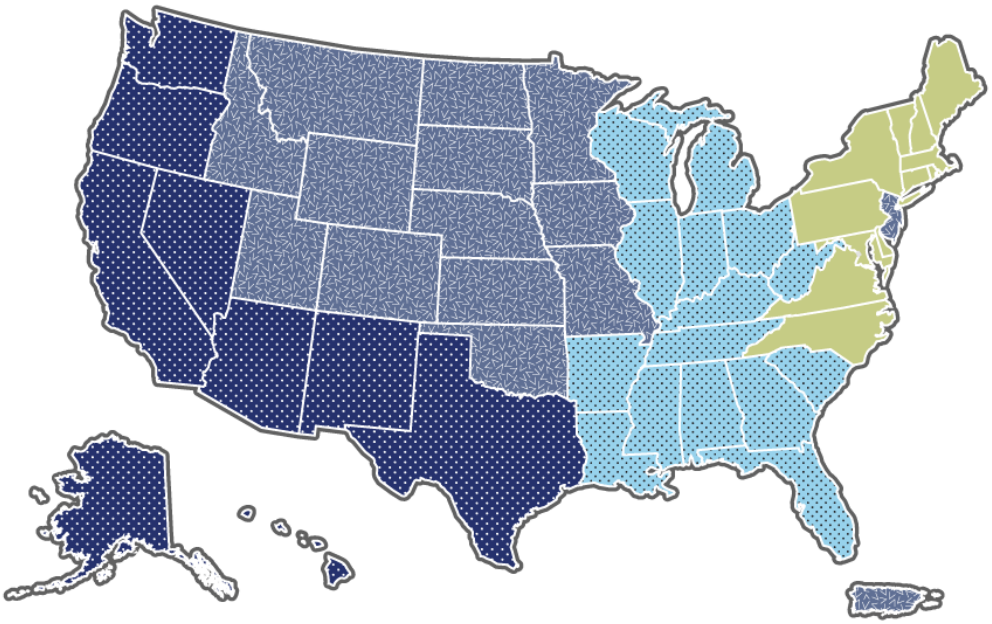

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Introduction

As part of the CDC Tuberculosis (TB) Elimination and Laboratory Cooperative Agreement PS-20-2001 (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: Seventh 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: Seventh Edition* include a comparison of aggregate workload volume data, *Mycobacterium tuberculosis* complex (MTBC) culture positivity, nucleic acid amplification test (NAAT) trends, and performance TAT data for calendar years 2020, 2021, and 2022. Also included in this report is the most recent information received (2023) regarding PHLs' TB testing methods.

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

- The pandemic appears to have significantly affected workload volumes, particularly in 2020 and 2021, as evidenced by the fluctuations and decreases in several workload metrics.
- An increase was observed for most workload indicators from 2020 to 2022. Notable increases were seen for volume of specimens processed for culture, patient specimens and isolates positive for MTBC, NAAT testing and number of patients positive for MTBC by NAAT, growth-based drug susceptibility testing (DST), and patients with molecular DST performed (particularly on specimens).
- Since 2020, the national average for specimen receipt within 1 day improved from 51% to 55%. Moreover, 19 PHLs met or exceed the national target of 67% in 2022, an increase from 15 PHLs in 2020.
- National average of MTBC cases that are later culture confirmed diagnosed using NAAT within 48 hours of specimen receipt remained stable at 49% in 2022, compared to 2020. However, national TAT averages decreased in 2022 for acid-fast bacilli (AFB) smear result, identification (ID), and DST.
- Discontinuation of the Hologic® AccuProbe® MTBC identification assay necessitated many PHLs to validate and implement a new primary culture identification assay. As a result, the use of MALDI-TOF, real-time PCR, and Xpert® MTB/RIF assay increased during this time period.

Laboratories are encouraged 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 mycoli acids.
ID	Identification from culture growth
IGRA	Interferon-gamma release assay; who-blood test used to measure a person's immune reactivity to MTBC.
In-House	Testing performed at the public health laboratory
INNO-LiPA®	A commercial line probe assay by Fujirebio that identifies MTBC and can detect mutations associated with rifampin resistance.
LCT	Laboratory Capacity Team
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 tuberculosi*s complex
NAAT	Nucleic acid amplification test; in this report, generic terminology for molecular methods used for direct detection of MTBC in clinical specimens.
National DST Reference Center for MTBC	National PHL Drug Susceptibility Testing Reference Center for *Mycobacterium tuberculosis*
PHLs	Public health laboratories
PRA	PCR restriction analysis; analysis of amplified DNA fragments produced by the cleaving DNA by restriction of 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 broth microdilution plat by ThermoScientific for determination of minimum inhibitory concentration (MIC) of 12 antituberculosis drugs, simultaneously.
T-SPOT® TB	A commercial IGRA blood test by Revvity 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

- 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.
- For Table 3 and Figure 4, PHLs were asked to describe their NAAT algorithms for inclusion in the analysis.
- For Figures 9-15, data regarding test methods were interpreted as accurately as possible from APR narratives.

Laboratory Workload

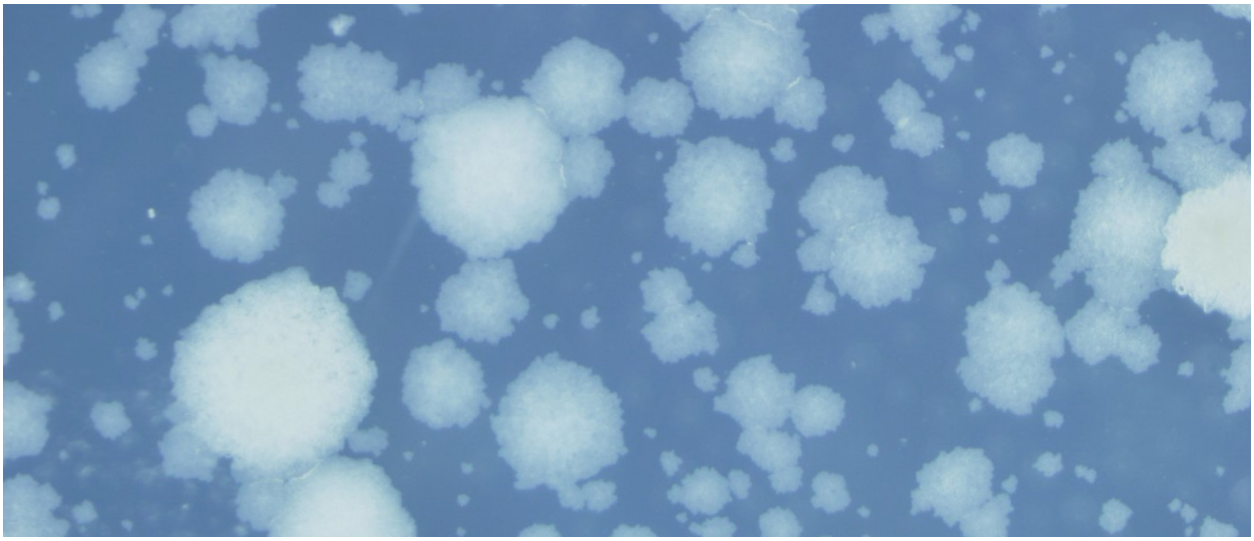
Table 1 **National Workload Data from 58 PHLs, 2019-2022**

Workload Variable	Total No. 2019[a]	Total No. 2020	Total No. 2021	Total No. 2022	2020-2022 No. Change (%)
Clinical specimens[b] processed for smear and culture	186,849 (105-17,458)	135, 853 (14-12,359)	147, 257 (1-16,126)	161,772 (5-17,214)	**25,919 (19.1%)**
Patients for whom a specimen was processed	77,208 (51-9,687)	58,078 (12-6,512)	63,345 (1-9,625)	65,049 (3-9,952)	**6,971 (12.0%)**
Patients culture positive for MTBC	3,298 (0-926)	2,689 (0-425)	2,2870 (0-416)	3,170 (0-425)	**481 (17.9%)**
MTBC culture positive patients that were NAAT positive	2,023 (0-282)	1,526 (0-222)	1,723 (0-274)	1,932 (0-297)	**406 (26.6%)**
MTBC culture positive patients that were initially NAAT positive and results reported in 48 hours	1,668 (0-267)	1,311 (0-222)	1,444 (0-256)	1,660 (0-282)	**349 (26.6%)**
Patients for whom a clinical specimen was tested by NAAT	19,124 (0-4,105)	11,732 (0-2,582)	13,819 (0-2,931)	17,201 (1-3,449)	**5,469 (46.6%)**
Patients for whom a clinical specimen was NAAT positive for MTBC[c]	2,632 (0-356)	2,035 (0-274)	2,512 (0-333)	2,558 (0-376)	**523 (25.7%)**
Patients for whom a reference isolate was submitted to rule out or confirm ID of MTBC	13,324 (0-2,279)	10,577 (0-1,709)	10,175 (0-1,550)	10,084 (0-1,720)	**-493 (-4.7%)**
Patients for whom a reference isolate was identified as MTBC	2,700 (0-559)	2,641 (0-512)	2,744 (0-550)	3,067 (0-643)	**426 (16.1%)**
Patients for whom growth-based DST was performed/referred	5,437 (1-1,037)	4,405 (0-493)	4,847 (0-541)	5,430 (0-586)	**1,025 (23.3%)**
Patients for whim an in-house molecular DST was performed[d]	5,425 (0-640)	4,990 (4-507)	6,771 (0-1,085)	6,325 (0-1,451)	**1,335 (26.8%)**
Patients for whom an in-house molecular DST of a specimen was performed[d]	4,245 (0-485)	3,775 (3-423)	5,334 (0-1,085)	5,118 (0-1,451)	**1,343 (35.6%)**
Patients for whom an in-house molecular DST of an isolate was performed[d]	1,517 (0-552)	1,451 (0-507)	1,401 (0-543)	1,339 (0-640)	**-112 (-7.7%)**
Patients for whom an MTBC isolate was referred for genotyping[e]	7,349 (1-1766)	5,598 (0-958)	6,085 (0-1,030)	5,783 (0-949)	**185 (3.3%)**
IGRA performed in-house	116,707 (0-35,307)	91,718 (0-27,978)	94,163 (0-32,884)	95,606 (0-37,002)	**3,888 (4.2%)**

[a] 2019 data included as it was the last year of data in the *TB Laboratory Aggregate Report, Sixth Edition* and as a baseline prior to pandemic, [b]Processed and cultured, not including isolates referred from other laboratories, [c]Included sediments received only for NAAT, [d]Laboratories may have tested patient samples as both specimens and isolates, [e]Does not include submission of FASTQ files to CDC. Note—MTBC: *Mycobacterium tuberculosis*, NAAT: nucleic acid amplification test, DST: drug susceptibility testing, IGRA: Interferon gamma release assay.

Summary of workload volume changes for 2020-2022:

- The pandemic appears to have significantly affected workload volumes, particularly in 2020 and 2021, as evidenced by the fluctuations and decreases in several workload metrics.
- An increase was observed for most workload indicators from 2020 to 2022. Notable increases were seen for volume of specimens processed for culture, patient specimens and isolates positive for MTBC, NAAT testing and number of patients positive for MTBC by NAAT, growth-based DST, and patients with molecular DST performed (particularly on specimens).
- From 2020 to 2022, decreases were observed for two workload indicators. A decrease of 4.7% was observed in the number of patients for whom a reference isolate was submitted to rule out or confirm ID of MTBC. There was also a decrease of 7.7% in the number of patients for whom an in-house molecular DST of an isolate was performed.



M. tuberculosis on agar media. Picture courtesy of APHL.

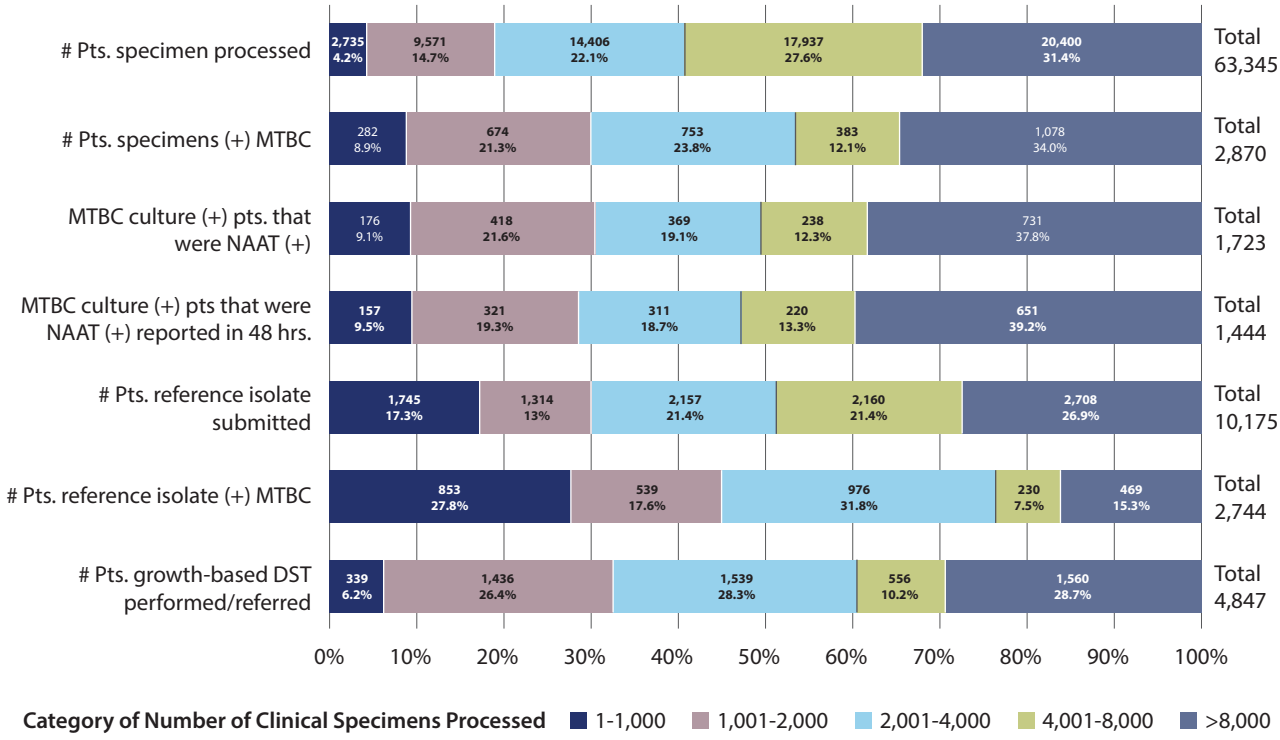
Table 2 **Mean and Range for PHL Key Workload Indicators, Stratified by Category of Number of Clinical Specimens Processed, 2022**

Key Workload Indicators	1-1,000 Clinical Specimens Processed by Each PHL (16 [27.6%])[a]	1,001-2,000 Clinical Specimens Processed by Each PHL (17 [29.3%])[a]	2,001-4,000 Clinical Specimens Processed by Each PHL (13 [22.4%])[a]	4,0001-8,000 Clinical Specimens Processed by Each PHL (8 [13.8%])[a]	>8,000 Clinical Specimens Processed by Each PHL (4 [6.9%])[a]
Clinical specimens processed	454 (5-828)	1,468 (1,062-1,797)	2,860 (2,015-3,883)	4,756 (4,026-6,342)	13,580 (8,739-17,214)
Patients for whom a specimen was processed	171 (3-431)	563 (156-1,168)	1,108 (536-1,511)	2,242 (1,004-4,461)	5,100 (2,615-9,952)
Patients culture positive for MTBC	18 (0-62)	40 (4-96)	58 (5-119)	48 (15-130)	267 (76-425)
Patients culture positive for MTBC that were also NAAT positive	11 (0-60)	25 (1-62)	28 (3-82)	30 (4-71)	181 (42-297)
MTBC culture positive patients that had NAAT positive results reported in 48 hours	10 (0-60)	19 (1-56)	24 (3-61)	28 (4-66)	161 (34-282)
Patients tested by NAAT	79 (1-431)	182 (28-377)	178 (54-459)	386 (81-756)	1,862 (599-3,449)
Patients NAAT positive for MTBC	15 (0-66)	41 (2-252)	31 (4-80)	35 (4-82)	236 (46-376)
Patients for whom a reference isolate was submitted to rule out or confirm ID of MTBC	109 (0-963)	86 (0-272)	166 (0-568)	270 (0-724)	640 (0-1,720)
Patients with a reference isolate identified as MTBC	53 (0-643)	34 (0-186)	75 (0-377)	29 (0-80)	116 (0-250)
Patients for whom growth-based DST was performed	21 (0-76)	85 (3-225)	118 (6-517)	70 (15-170)	387 (119-586)

[a] (Number of PHLs [% of total]) Note—MTBC: *Mycobacterium tuberculosis* complex, NAAT: nucleic acid amplification test, DST: drug susceptibility testing

United States PHLs receive varying amounts of clinical specimens for TB testing 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 (mean and range) presented.

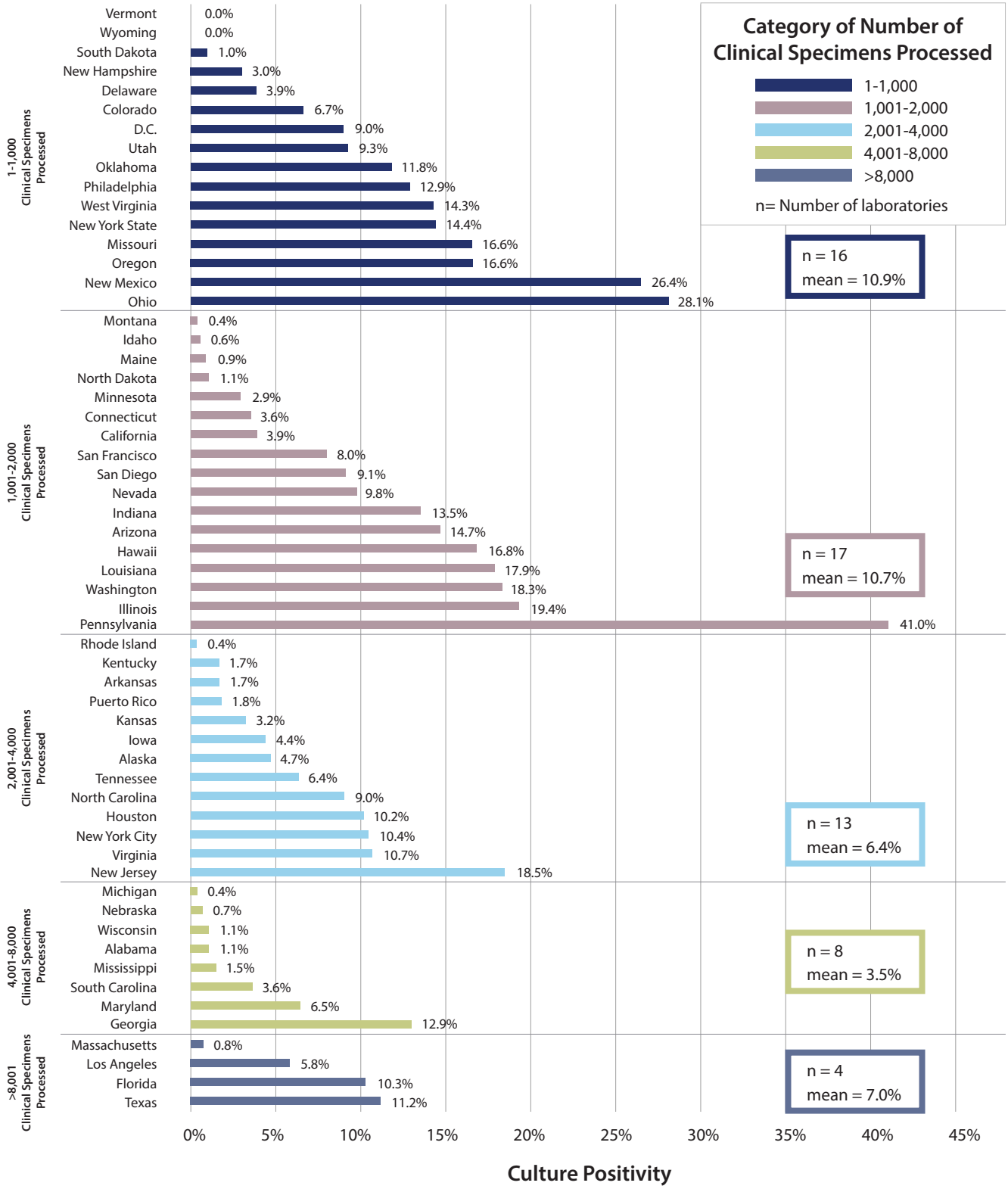
Figure 1 Total workload Volume and Proportion of Total for Selected Indicators, Stratified by Category of Number of Clinical Specimens Processed, 2022



Note—Pt: patient; MTBC: *Mycobacterium Tuberculosis* complex; NAAT: nucleic acid amplification test; DST: drug susceptibility testing

- For 2022, the proportion of testing contributed for each of 5 workload volume categories (identified in Table 2 based on the number of clinical specimens processed) for 7 selected workload indicators is shown. It is important to note that although the laboratories are subdivided into 5 categories by the total number of clinical specimens processed, the 7 selected workload indicators are reported by PHLs on a per-patient basis (i.e., each patient was considered uniquely even though more than 1 specimen or isolate may have been tested).
- 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 22.1%, 27.6%, and 31.4%, respectively. Thus, PHLs processing ≥2,001 clinical specimens in 2022 processed 81.1% of all clinical specimens received by PHLs.
- PHLs that processed between 2,001–4,000 clinical specimens contributed the largest proportion (31.8%) of patient reference isolates positive for MTBC in 2022, with PHLs with a volume of 1–1,000 performing similarly at 27.8%.
- High-volume PHLs (>8,000 clinical specimens) contributed the largest proportion (34.0%) of patient specimens positive for MTBC by culture in 2022; yet these PHLs accounted for the second smallest percentage (15.3%) of patients with reference isolates positive for MTBC, reflecting potential differences in how PHLs may function (i.e., primarily diagnostic versus reference) within their jurisdiction.

Figure 2 Culture Positivity by Site, Stratified by Category of Number of Clinical Specimens Processed, 2022



Culture positivity in 2022 for the 58 PHLs is presented as the same 5 categories as in Table 2 and Figure 1, stratified by number of clinical specimens processed.

- MTBC culture positivity (percent of patients' clinical specimens that were positive for MTBC in culture) ranged from 0.0% to 41% among all PHLs.
- Among all categories, PHLs processing less than 2,000 specimens (n = 33) had a mean culture positivity of 10.8%; nearly twice as high as PHLs processing greater than 2,000 specimens (n = 25) with a mean culture positivity of 5.6%.

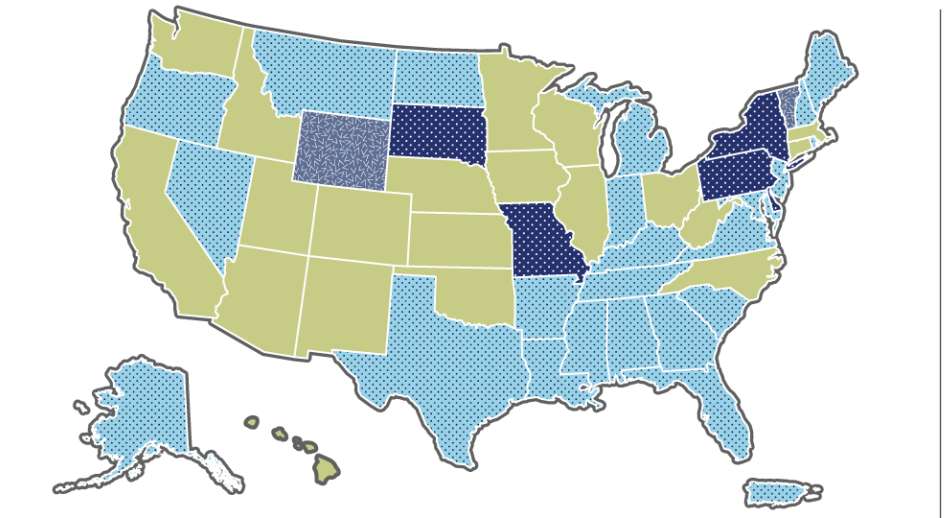
M. tuberculosis on Löwenstein-Jensen agar.
Picture courtesy of APHL.

The differences in culture positivity may be influenced by several factors. 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 serve as a reference laboratory receiving post-diagnosis follow-up specimens and therefore, might maintain a relatively high MTBC culture positivity. Other factors that may influence MTBC culture positivity include the nature of the regional patient population served by the PHL, differences in clinicians' test ordering, or local disease prevalence.

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 demonstrate a true increase in the number of cases or could indicate potential laboratory issues including pre- and post-analytical factors, contaminated reagents, or false-positive cultures. In these instances, communication should occur with the jurisdictional TB Program.

Trends in Nucleic Acid Amplification Testing

Figure 3 **Map of PHLs Meeting or Exceeding NAAT TAT Performance Targets, 2022**



*Two laboratories did not identify MTBC in 2022; these laboratories were excluded from the analysis.

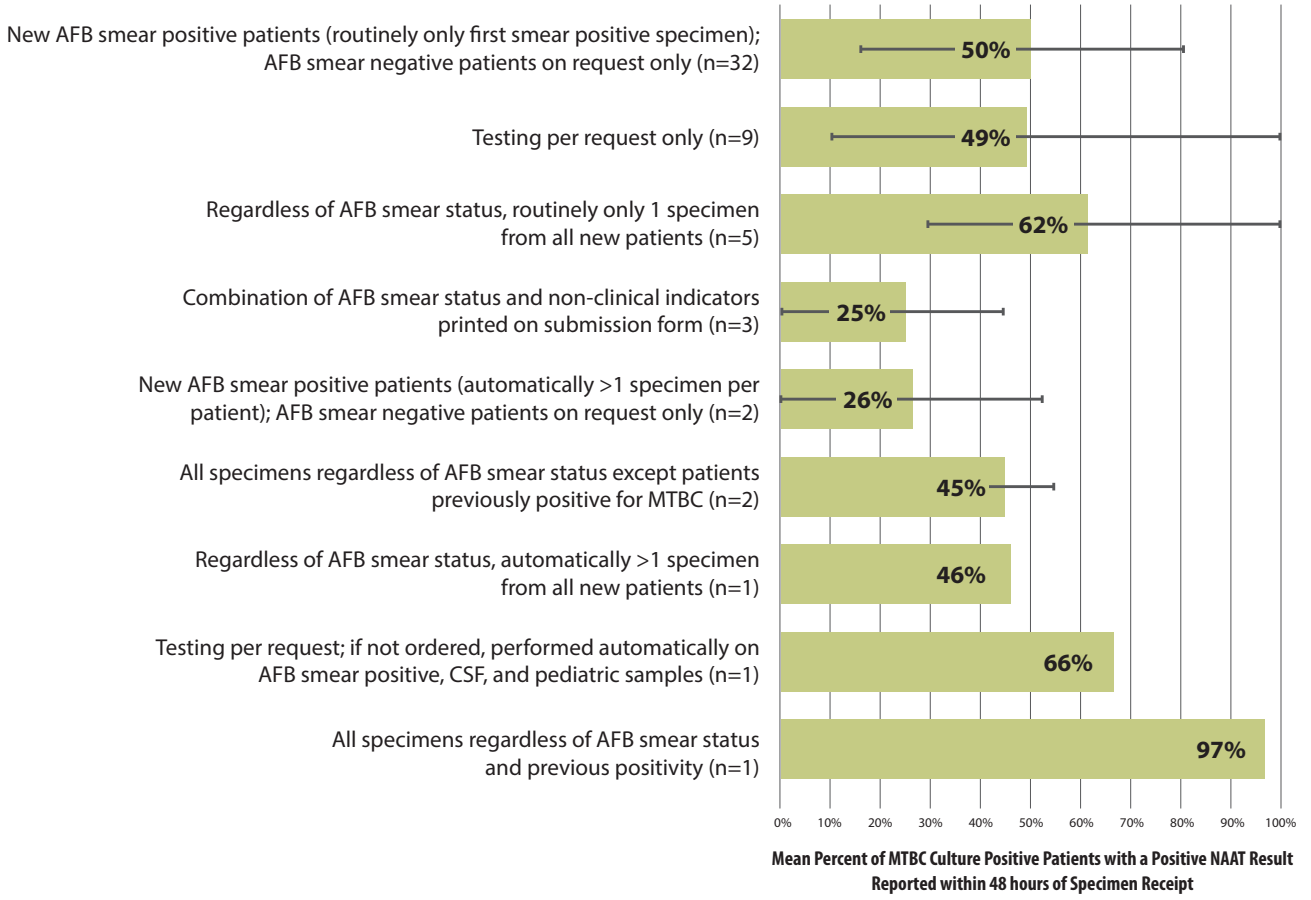
The national target for the NAAT indicator is defined as ≥77% of MTBC cases that are later culture confirmed diagnosed using NAAT within 48 hours of specimen receipt. The national average is a mean of the 58 PHLs' NAAT TAT percents, each calculated as the number of MTBC culture positive patients (denominator), and of those, the number that had a positive NAAT reported within 48 hours of specimen receipt (numerator).

- National average remained the same as 2020 at 49% in 2022
- 26 (45%) PHLs met or exceeded the national average of 49% but not the national target of 77%
- 5 (9%) PHLs met or exceeded the national target of 77%
  - » This was a decrease from 7 PHLs that met or exceeded the national target of 77% in 2020

Table 3 **NAAT Algorithm by PHL, 2022**

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

Figure 4 Mean Percent of MTBC Culture Positive Patients with a Positive NAAT Results Reported within 48 Hours of Specimen Receipt, Stratified by NAAT Algorithm, 2022



Note—Two laboratories did not identify MTBC in 2022 and were excluded from the analysis.

Although the CDC TB CoAg NAAT TAT indicator is grouped with traditional TAT calculations, this indicator also 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. Laboratories use a variety of algorithms to determine which specimens routinely receive NAAT. Although multiple laboratories may use the same algorithm, differences in NAAT TAT were observed (as depicted by range bars).

PHLs are encouraged to assess their NAAT algorithm through analysis of laboratory-specific data and discussions with TB Programs to determine whether adjustments could be made that would increase the number of patients with MTBC-positive cultures detected earlier in the testing process. Laboratories could examine results for patients with MTBC positive cultures that did not have a NAAT performed, or those patients with results not reported within 48 hours as a means of evaluating the algorithm. Note: NAAT data presented in this report are limited to those reported by PHLs and as such, do not represent all NAAT performed. Clinical and commercial laboratories may initially perform NAAT.

Turnaround Times

Table 4 **TAT Indicators, 2020-2022**

	TAT Benchmark			
	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[1]: (% of specimens that should meet the benchmark)	**67%**	**92%**	**74%**	**69%**
Number of laboratories meeting or exceeding National Target (2020 to 2022)	15 to 19	35 to 33	28 to 27	17 to 18
National Average: (reported % of specimens meeting the benchmark) (2020 to 2022)	51% to 55%	92% to 87%	71% to 67%	52% to 50%
Number of laboratories at or above National Average (2020 to 2022)	31 (no change)	35 to 42	30 to 32	30 (no change)

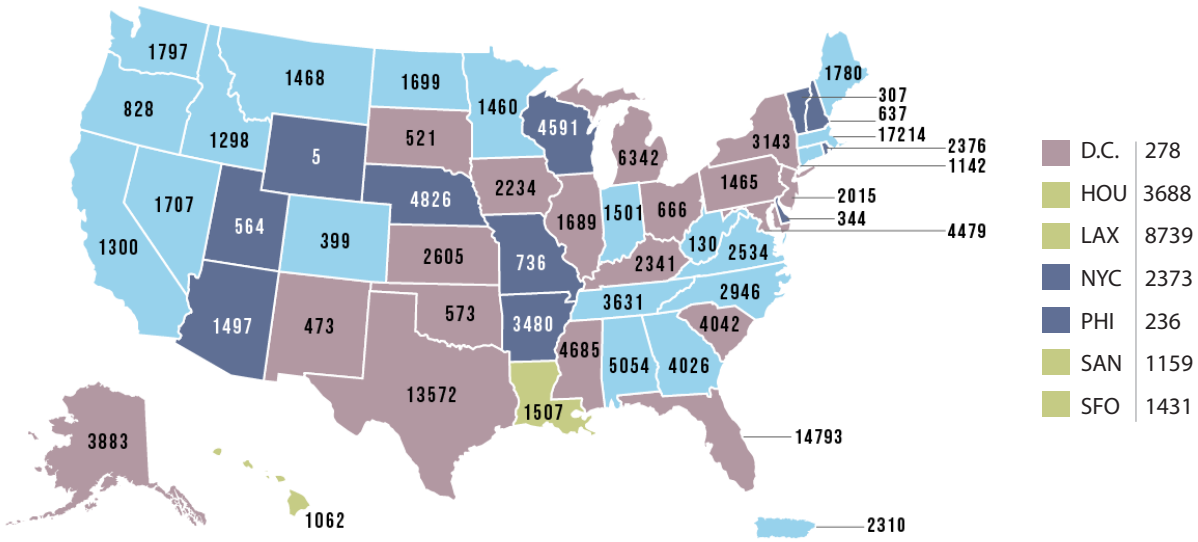
*Number of laboratories = 56 in 2020 and 56 in 2022. Two PHLs did not identify MTBC in 2020 and two PHLs did not in 2022; data from these PHLs were excluded from the analysis.

†Number of laboratories = 57 in 2020 and 56 in 2022. One PHL did not perform growth-based MTBC DST in 2020 and two PHLs did not in 2022; data from these PHLs were excluded from the analysis.

In 2022, national averages for the four TAT benchmarks were below national targets.

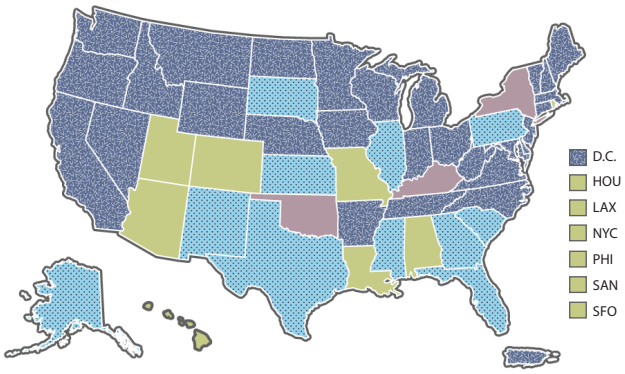
- Since 2020, the only national average that increased/improved was specimen receipt within one day (51% to 55%).
- The number of PHLs in 2022 that met or exceeded the national targets increased for specimen receipt (n=19) and AFB smear (n=33).
- The number of PHLs in 2022 that met or exceeded the national average increased for AFB smear (n=42) and ID of MTBC (n=32).

Figure 5 **Maps of Percent Specimens Received within 1, 2, and 3 Days from Specimen Collection, with Total Number of Specimens Received by PHL, 2022**

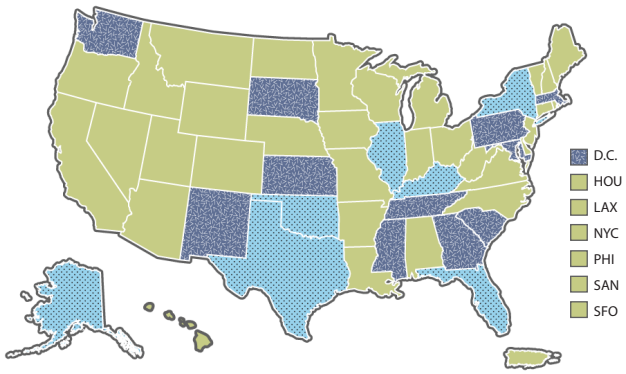


Specimen Receipt within 1 day: (National Target 67%) 0-40% 41-66% 67-85% 86-100%

Specimen Receipt within 2 days:



Specimen Receipt within 3 days:

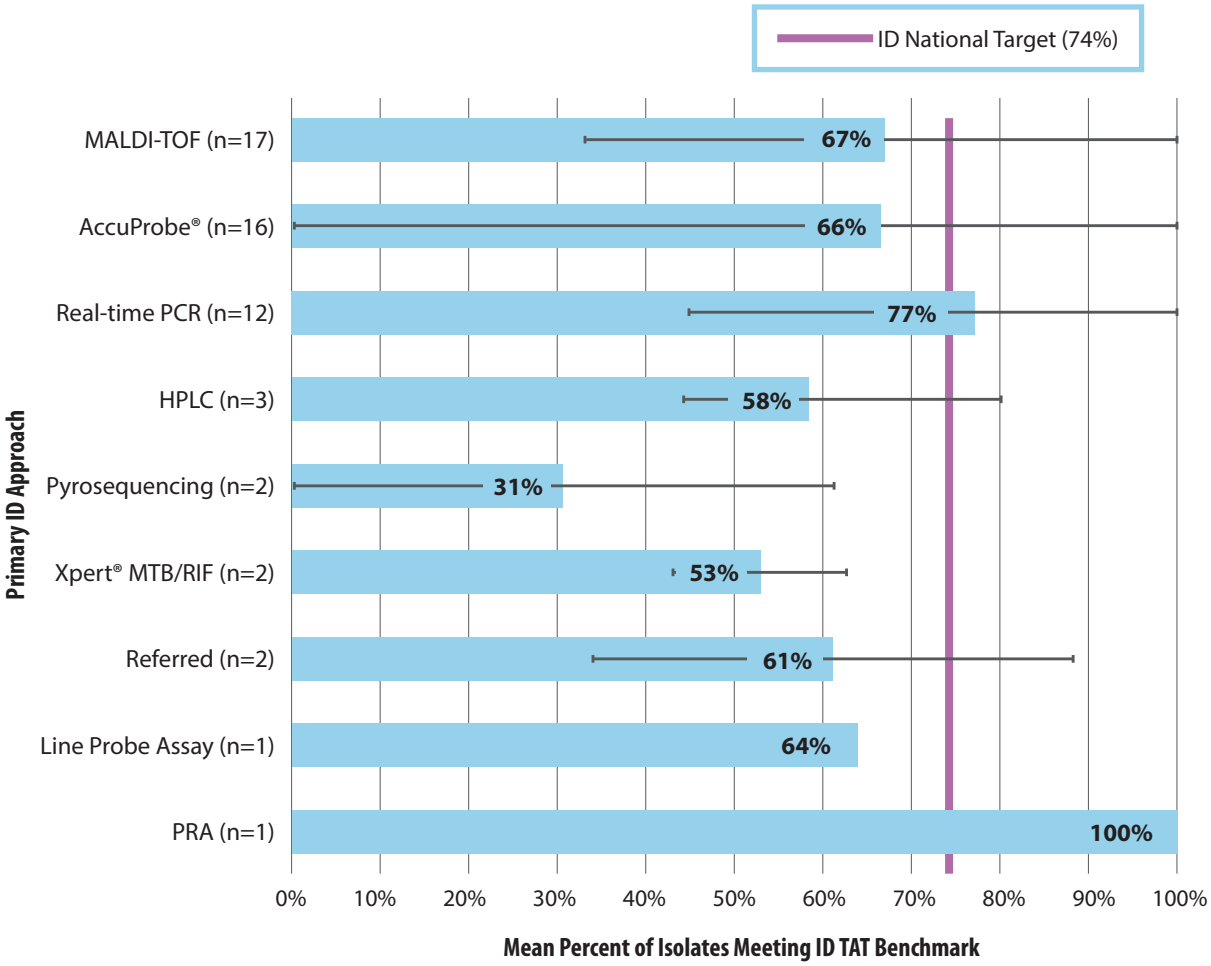


0-40% 41-66% 67-85% 86-100%

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 in 2022 and the percent of specimens received within 1 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 2022, 13 state PHLs (22%) and 6 local PHLs (10%) met or exceeded the national target of 67% for specimen receipt within 1 day of collection. This demonstrates an increase in the number of PHLs that met or exceeded the national target since 2020 [9 state PHLs (16%) and 6 local PHLs (10%)].
  - » The 19 PHLs that met or exceeded the national target processed as few as 5 specimens and as many as 8,739 specimens.
- 20 PHLs (34%) had a specimen receipt range of 41–66% within 1 day of collection.
  - » 8 of these 20 PHLs had specimen receipt at the high end (60–66%) of the range.
- PHLs greatly improved specimen receipt TAT by day 3 as seen by transition of states from purple and blue to green on day 2 and 3 maps (indicating a higher percent of specimens received).
- Average percent of specimens received by day 1 was 55%, by day 2 was 74%, and by day 3 was 86%.

Figure 6 Mean Percent of MTBC Identified* from Culture within 21 Days of Specimen Receipt, by Primary ID Approach, 2022



n= Number of laboratories using each approach

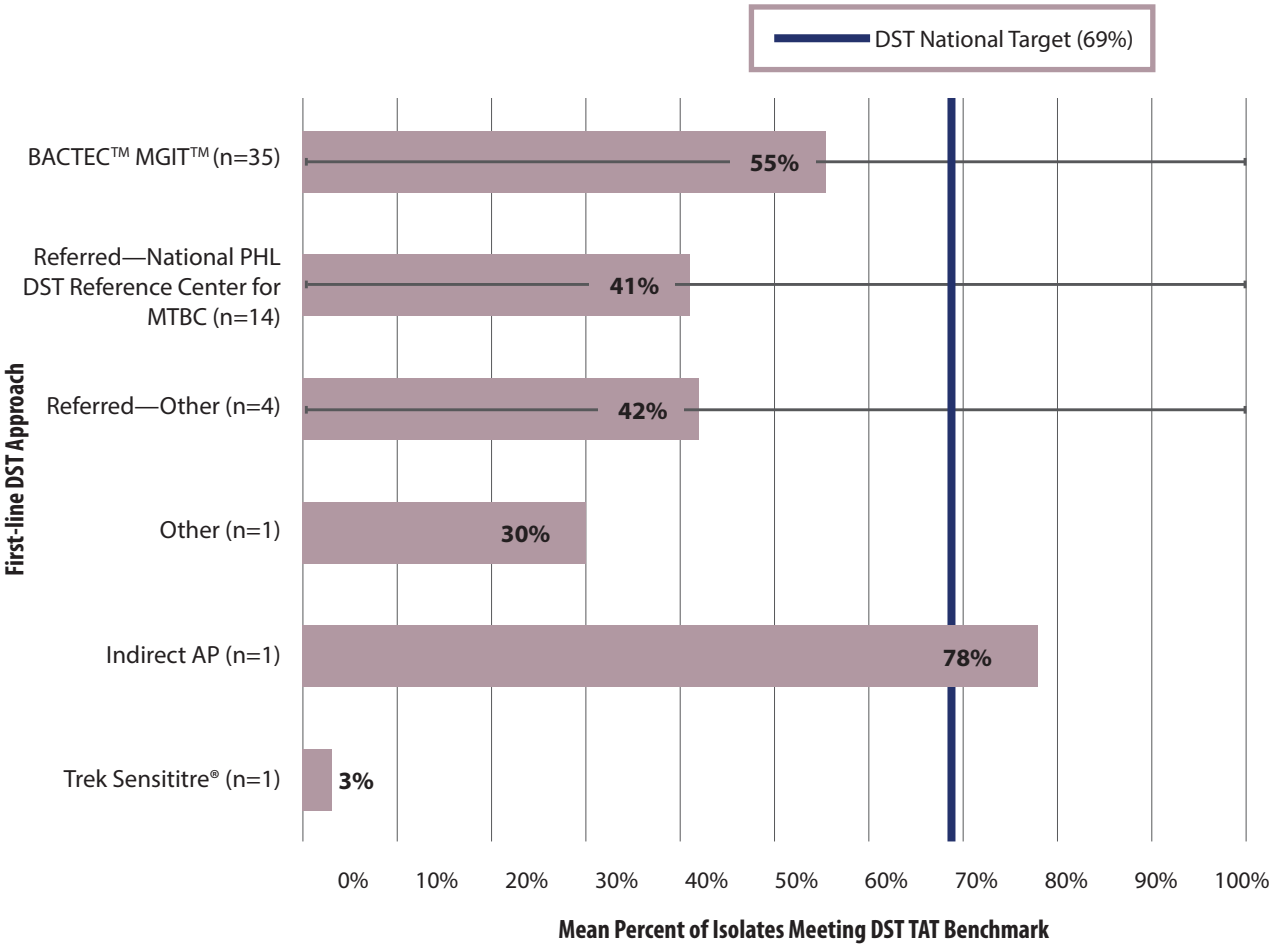
* Two laboratories did not identify MTBC in 2022 and were excluded from the analysis.

In 2022, 56 PHLs identified MTBC from diagnostic specimens. Individual PHLs' percent of MTBC identified from culture within 21 days of specimen receipt ranged from 31% to 100%. Each PHL indicated their primary ID approach; 9 different ID approaches were reported.

- Most PHLs (n=17) performed matrix-assisted laser desorption ionization-time of flight (MALDI-TOF) with a mean percent of MTBC identified within 21 days of specimen receipt equal to 67% and a range of 33% to 100%.
- The 13 PHLs performing real-time polymerase chain reaction (PCR) and PCR restriction analysis (PRA) as their primary ID methods had a mean percent of MTBC identified above the national target (74%), while the majority of PHLs (n=43) mean percent of MTBC identified within 21 days of specimen receipt was below the national target.

In the TB Laboratory Aggregate Report: Sixth Edition, 25 PHLs utilized AccuProbe® as their primary method of ID from culture, whereas in 2022, there were only 16 PHLs using AccuProbe®. This shift is a result of Hologic®, the manufacturer of AccuProbe®, discontinuing all *Mycobacterium* AccuProbe® assays in December 2022. The number of PHLs using AccuProbe® as their primary method of ID will continue to decline as the supply of kits and reagents are consumed and new methods are validated.

Figure 7 **Mean Percent of Isolates with Growth-based DST Results Reported within 17 Days of ID*, by Primary DST Approach, 2022**



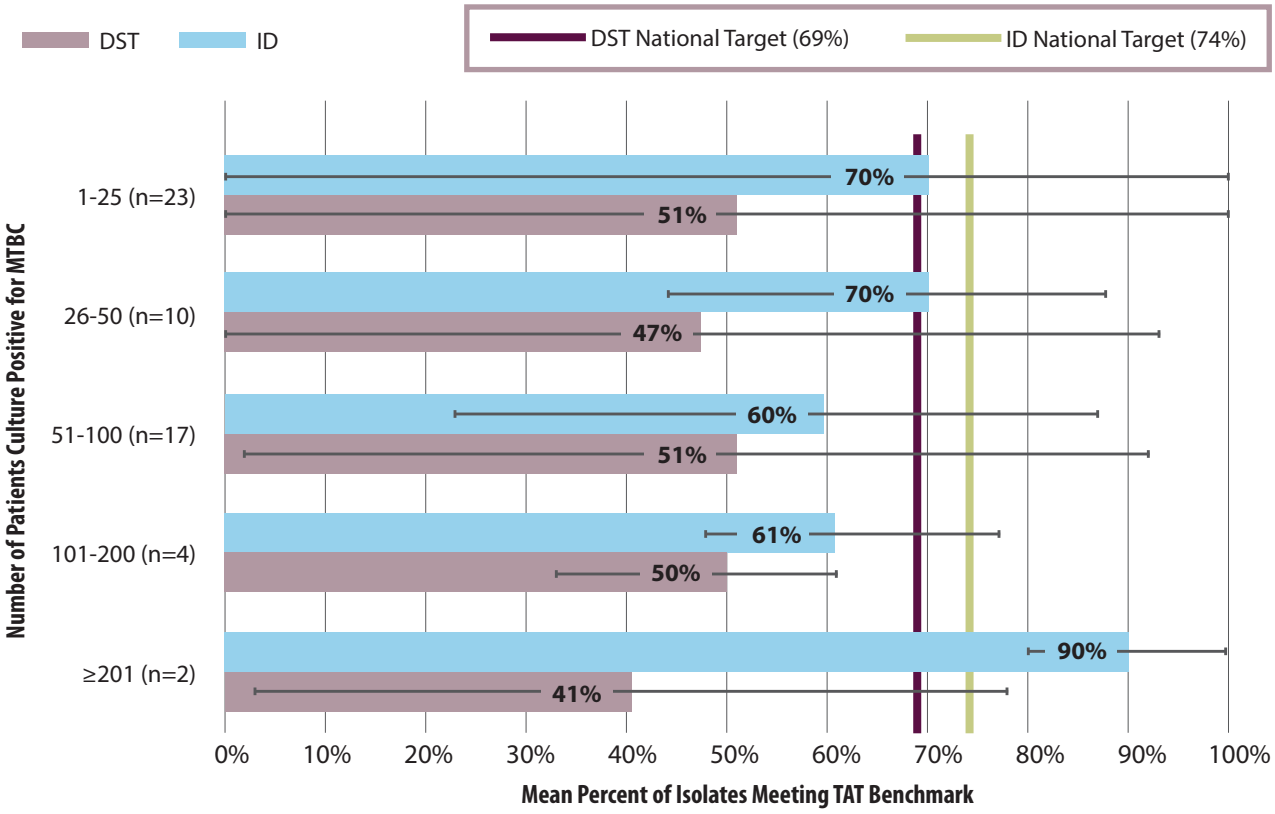
n= Number of laboratories using each approach

* Two laboratories did not identify MTBC, therefore DST was not performed on the initial diagnostic specimen in 2022 and were excluded from the analysis.

All PHLs that identified MTBC from culture growth in 2022 (n=56) ensured first-line DST was performed. Each PHL indicated their first-line DST method or referral strategy; there were 6 different DST approaches among the PHLs.

- Mean percent of isolates with growth-based DST performed within 17 days of ID ranged from 0% to 100%.
- The one laboratory performing Indirect AP had a mean percent above the national target (69%).
- The DST approach utilized by most PHLs (n=35) was the BACTEC™ MGIT™ with a mean percent of 55%. Laboratories should 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, 2022



n= Number of laboratories using each approach

* Two laboratories did not identify MTBC in 2022 and were excluded from the analysis.

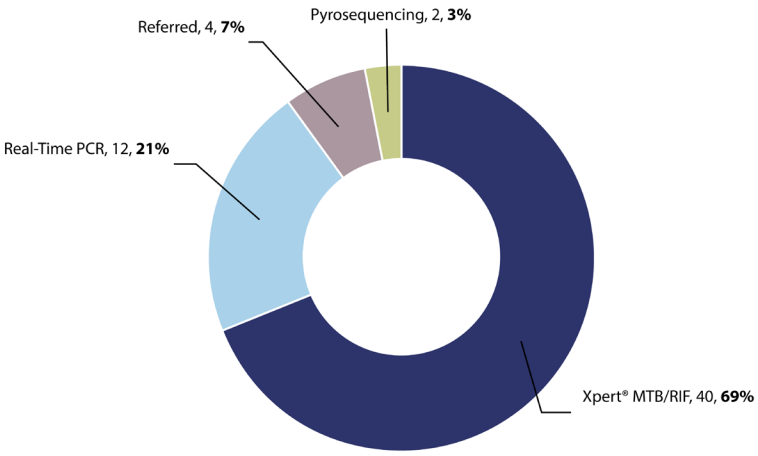
In Figure 8, PHLs were grouped based on the number of patients that were culture positive for MTBC ranging from 3–425. The mean percent of isolates meeting recommended TATs for ID reported within 21 days from specimen receipt and first-line DST results reported within 17 days of ID were evaluated for each PHL group.

- The two laboratories with ≥201 MTBC culture positive patients had a mean percent of MTBC isolates identified from culture within 21 days (90%) that exceeded the national target (74%), with individual percents of 80% and 100%. The mean percent of isolates for PHLs in this group with DST performed within 17 days of ID (41%) was below the national target, with individual percents of 3% and 78%.
- Two groups (1–25 and 26–50) had means close to the national target for MTBC identified from culture within 21 days, each with a mean percent of 70%.
- None of the groups met or exceeded the national target (69%) for isolates with DST performed within 17 days of ID.

Methods in Public Health Laboratories

Methods performed or accessed in 2023 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 9–15. As new technology emerges and laboratories adjust testing algorithms, methods performed will continue to evolve.

Figure 9 NAAT Approaches, 2023 (n=58)



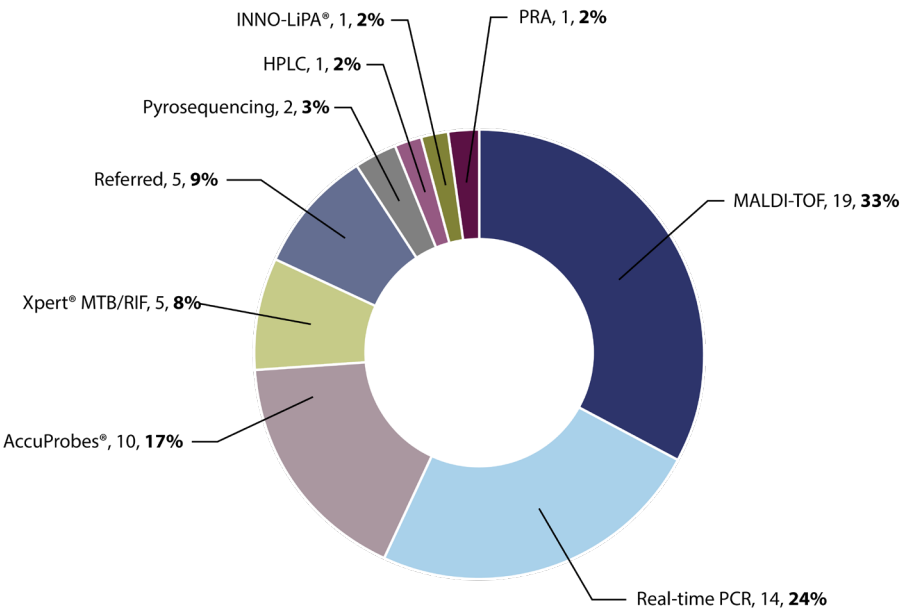
NAAT approaches continue to provide the earliest opportunity for rapid detection of MTBC for initiation of treatment and public health intervention. Data are reported from 58 CoAg PHLs. Cepheid® Xpert® MTB/RIF was widely used by PHLs (40/58, 69%) followed by laboratory developed real-time PCR assays (12/58, 21%). Together, these 2 methods accounted for 90% of NAAT methods performed by PHLs in 2023. Additionally, laboratories referred testing (4/58, 7%) and performed pyrosequencing (2/58, 3%).

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

Table 5 NAAT Approaches by PHL, 2023 (n=58)

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

Figure 10 Primary ID Approaches, 2023 (n=58)



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

Current primary ID approaches utilized within all PHLs are included in Figure 10. In 2023, the majority of PHLs (19/58, 33%) use MALDI-TOF as the primary method of ID for TB, followed by AccuProbe® (10/58, 17%) and real-time PCR (14/58, 24%).

Figure 11 Changes in Primary ID Approaches, 2020-2023 (n=58)

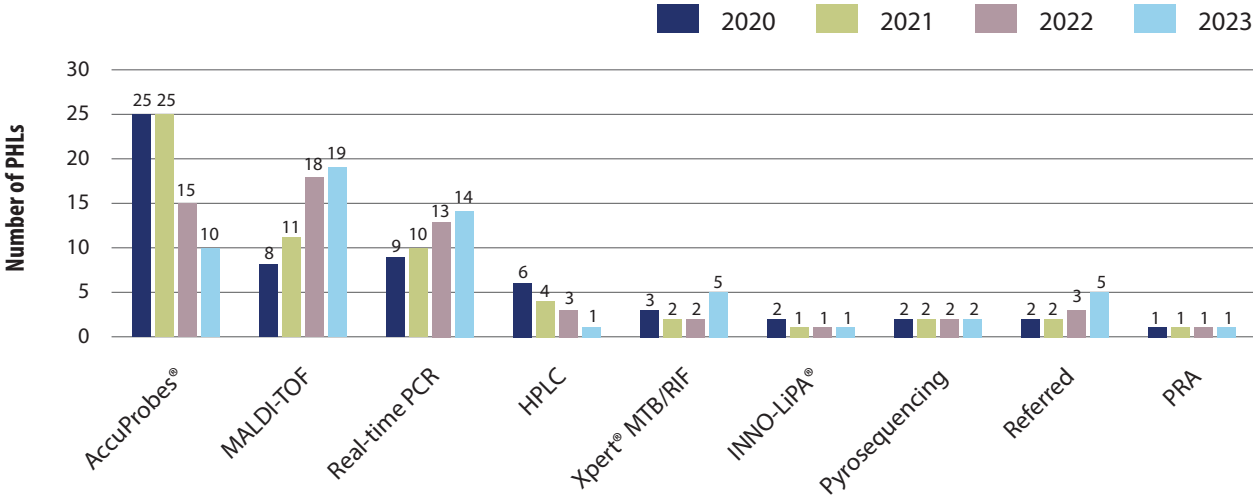
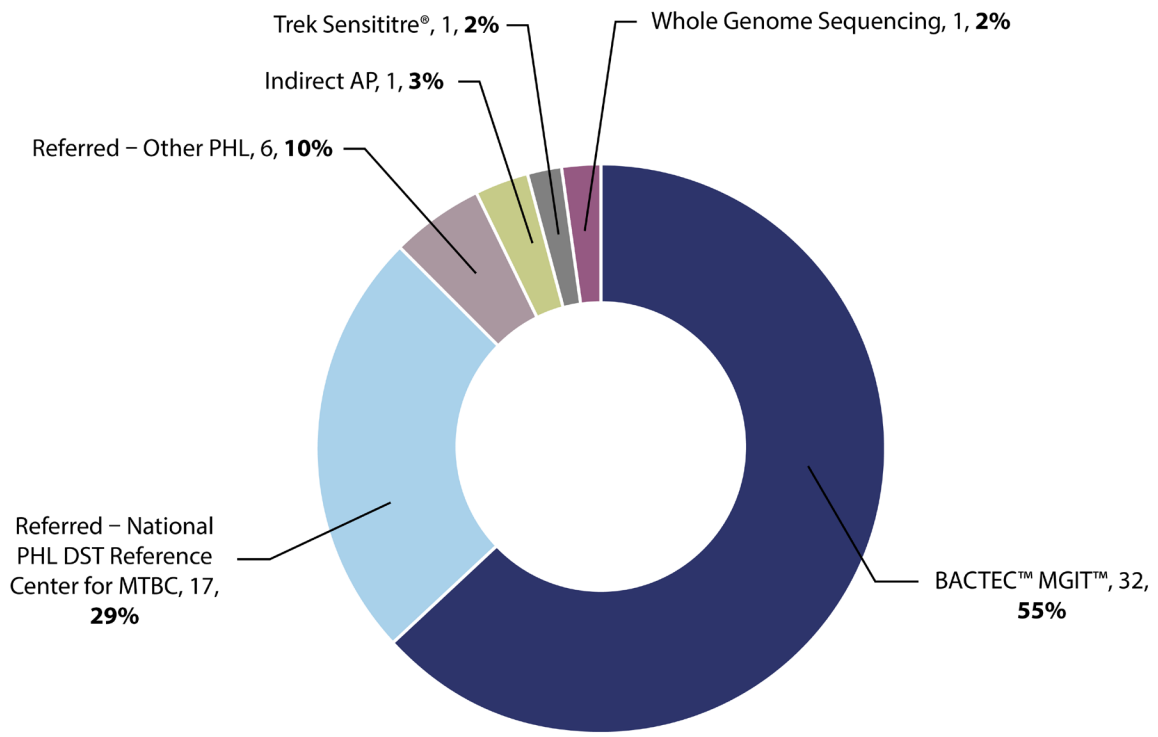


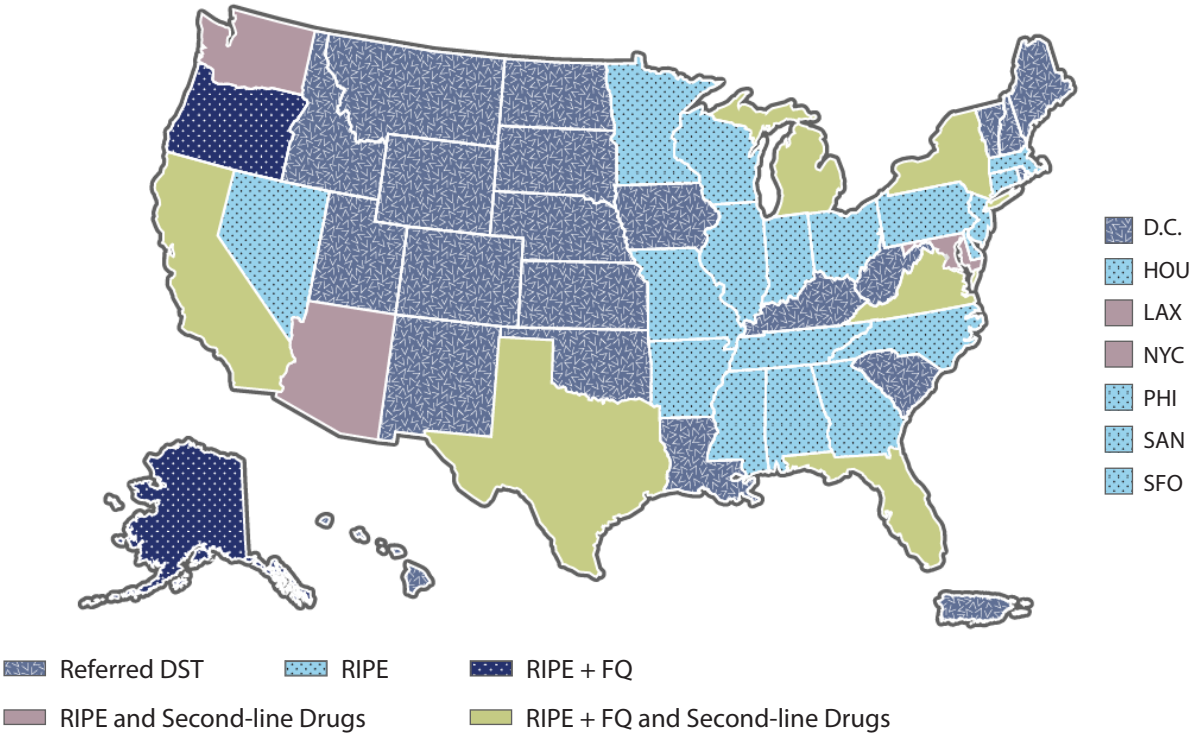
Figure 12 **Growth-based DST Approaches for Initial Antituberculosis Drug Panel, 2023 (n=58)**



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

Growth-based DST approaches for initial antituberculosis drug panel are shown in Figure 12. BACTEC™ MGIT™ (32/58, 55%) was the most performed DST method. Seventeen (29%) PHLs submitted isolates to the National PHL DST Reference Center[2] for MTBC as these sites performed less than 50 DST per year and 6 (10%) PHLs referred DST to another laboratory for testing.

Figure 13 Map of PHL DST Approaches and Drug Panels, 2023 (n=58)



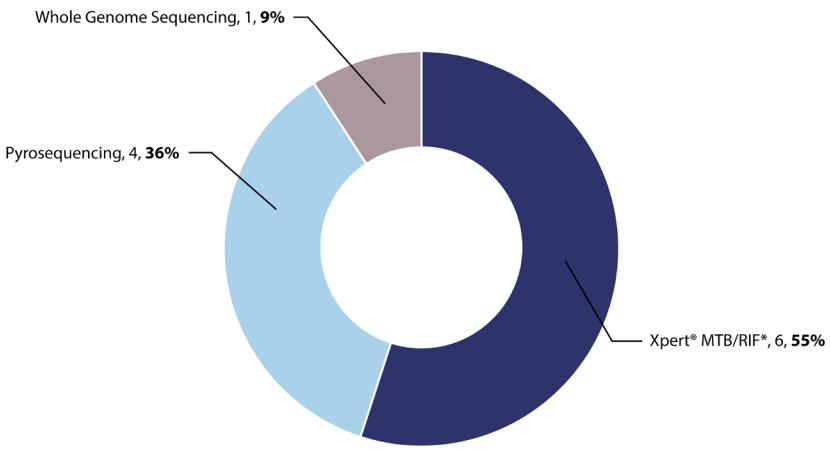
Note—DST: drug susceptibility testing; RIPE: rifampin, isoniazid, pyrazinamide, and ethambutol; FQ: Fluoroquinolone

PHLs provide or assure DST services through different approaches. Twenty-three PHLs (40%) referred DST to another laboratory. Twenty-two PHLs (38%) solely performed RIPE DST in-house, while 5 PHLs (8%) performed both in-house RIPE and some second-line DST. With the addition of the alternative 4-month rifapentine-moxifloxacin (RPT-MOX) regimen[3], some PHLs have implemented fluoroquinolone (FQ) testing as part of their initial drug panel. Two PHLs (3%) perform an initial DST panel of both RIPE + FQ and 6 (10%) PHLs perform RIPE + FQ and additional second-line DST. Drugs included in second-line DST panels differed by laboratory.

Table 6 Second-line DST Method by PHL, 2023

Second-line DST Method	PHL
Indirect Agar Proportion	AZ, MD, MI, NY, NYC, TX, WA
BACTEC™ MGIT™	CA, LAX, NY, VA
Trek Sensititre®	FL
WGS (Agar Proportion if mutation found)	NY

Figure 14 Molecular Testing for Detection of Drug Resistance, 2023 (n=11)



PHL methods performed for molecular testing of detection of drug resistance (MDDR) are shown in Figure 14. Eleven PHLs (19%) performed molecular testing for detection of drug resistance. Since 2020, a decrease from 14 PHLs to 11 PHLs performing molecular testing for detection of drug resistance has occurred but an increase of 3 PHLs to 6 PHLs performing Xpert® MTB/RIF® on isolates was observed.

*Performed on culture growth.

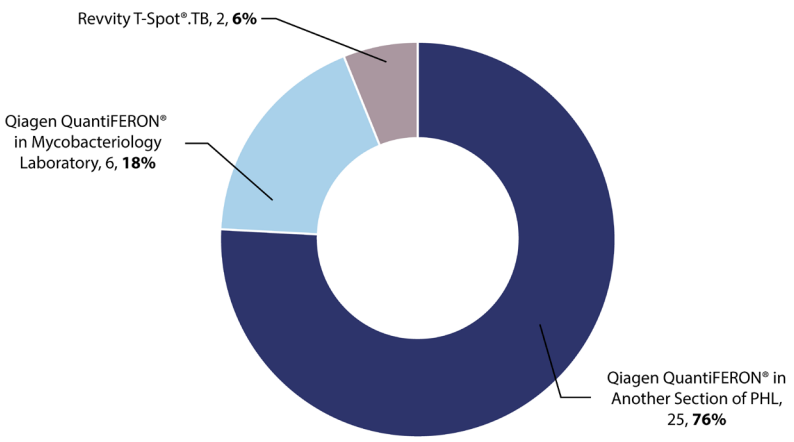
Note—Data label indicates approach, number of laboratories, percentage

Table 7 Molecular Testing for Detection of Drug Resistance Method by PHL, 2023

MDDR Method	PHL
Cepheid® Xpert® MTB/RIF*	AL, FL, IL, ND, SAN, WI
Pyrosequencing	CA, IN, MO, NY
Whole Genome Sequencing	NY

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

Figure 15 IGRA Approaches, 2023 (n=33)



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

PHLs' IGRA approaches are shown in Figure 15. Not all PHLs provide IGRA testing services. In 2023, 33 of 58 (57%) funded PHLs performed IGRA testing. Since 2020, 3 additional PHLs added IGRA testing, specifically the Qiagen QuantiFERON®; 2 PHLs switched from performing the Qiagen QuantiFERON® in the TB laboratory to another section of the PHL. The majority (94%) of CoAg funded PHLs utilized this method for IGRA testing. Two laboratories referred T-Spot®.TB IGRA testing to Revvity for testing.

Table 8 IGRA Approach by PHL, 2023

IGRA Approach	PHL
Qiagen QuantiFERON® in Another Section of PHL	CO, CT, FL, GA, HI, IN, IA, LAX, ME, MS, MO, MT, NE, NJ, NM, ND, OR, PA, SAN, SFO, SC, SD, UT, VT, WY
Qiagen QuantiFERON® in Mycobacteriology Laboratory	DE, HOU, KS, MD, NV, PHI, TN
Revvity T-Spot® .TB (referral)	AR, LA

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Resources

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

CDC Molecular Detection of Drug Resistance (MDDR) Service https://www.cdc.gov/tb/php/laboratory-information/index.html

Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories (cdc.gov) https://stacks.cdc.gov/view/cdc/131520

False-Positive Investigation Toolkit | Guides & Toolkits | Publications | TB | CDC https://www.cdc.gov/tb/php/false-positive-investigation-toolkit/index.html

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition (2020) https://www.cdc.gov/labs/bmbl/

Guide to the Application of Genotyping to Tuberculosis Prevention and Control https://stacks.cdc.gov/view/cdc/146304

Interim Guidance: 4-Month Rifapentine-Moxifloxacin Regimen for the Treatment of Drug-Susceptible Pulmonary Tuberculosis — United States, 2022 | MMWR (cdc.gov) https://www.cdc.gov/mmwr/volumes/71/wr/mm7108a1.htm

CDC Model Performance Evaluation Program https://www.cdc.gov/tb/php/laboratory-information/model-performance-evaluation-program.html

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

TB Notes Newsletter https://www.cdc.gov/tb/connect/index.html

FIND TB Education and Training Resources https://www.finddx.org/what-we-do/programmes/tuberculosis/

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Drug Resistance

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The Use of Next-Generation Sequencing for the Surveillance of Drug-Resistant Tuberculosis: an Implementation Manual. Geneva: World Health Organization; 2023. License: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications-detail-redirect/WHO-CDS-TB-2018.19

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Technical Report on Critical Concentrations for Drug Susceptibility Testing of Isoniazid and the Rifamycins (rifampicin, rifabutin and rifapentine). Geneva: World Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240017283

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Appendix A: Explanation of Figures for Accessibility

Laboratory Capacity Team (LCT) Contact Details

Map of the U.S. divided by LCT consultant. Each consultant is assigned a color and pattern:

Stephanie Johnston, MS (navy with white dot pattern)—Alaska, Arizona, California, Hawaii, Houston, Los Angeles, Nevada, New Mexico, New York City, Oregon, San Diego, San Francisco, Texas, Washington

Stephanie Swint, MLS(AMT) (green)—Connecticut, D.C., Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Pennsylvania, Philadelphia, Rhode Island, Vermont, Virginia

Cortney Stafford, MPH, MT(ASCP) (light blue with black dot pattern)—Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Michigan, Mississippi, Ohio, South Carolina, Tennessee, West Virginia, Wisconsin

Monica Youngblood, MPH, M(ASCP) (blue-gray with arrow pattern)—Colorado, Idaho, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, New Jersey, North Dakota, Oklahoma, Puerto Rico, South Dakota, Utah, Wyoming

Figure 1.

PHLs' 2022 workload volume and proportion of total for selected indicators, stratified by category of number of clinical specimens processed is presented in a horizontal 100% stacked bar graph. PHLs who processed 1–1,000 specimens are displayed as navy. PHLs who processed 1,001–2,000 specimens are displayed as mauve. PHLs who processed 2,001–4,000 specimens are displayed as light blue. PHLs who processed 4,001–8,000 specimens are displayed as green. PHLs who processed >8,000 specimens are displayed as blue-grey.

Figure 2.

PHLs' 2022 culture positivity, categorized by number of clinical specimens processed, is presented in a horizontal bar graph. PHLs who processed 1–1,000 specimens are displayed as navy. PHLs who processed 1,001–2,000 specimens are displayed as mauve. PHLs who processed 2,001–4,000 specimens are displayed as light blue. PHLs who processed 4,001–8,000 specimens are displayed as green. PHLs who processed >8,000 specimens are displayed as blue-grey.

Figure 3.

Map of U.S. indicating 2022 data for meeting or exceeding NAAT TAT performance targets. Each level is assigned a color and pattern.

Not meeting/exceeding national average (<49%) (green)— Arizona, California, Colorado, Connecticut, Hawaii, Houston, Idaho, Illinois, Iowa, Kansas, Massachusetts, Minnesota, Nebraska, New Mexico, New York City, North Carolina, Ohio, Oklahoma, Philadelphia, San Diego, San Francisco, Utah, West Virginia, Washington, Wisconsin

Meeting/exceeding national average (49%–76%) (light blue with black dot pattern)—Alabama, Alaska, Arkansas, D.C., Florida, Georgia, Indiana, Kentucky, Los Angeles, Louisiana, Maine, Maryland, Michigan, Mississippi, Montana, Nevada, New Hampshire, New Jersey, North Dakota, Oregon, Puerto Rico, Rhode Island, Tennessee, South Carolina, Texas, Virginia

Meeting/exceeding national target (≥77%) (navy with white dot pattern)—Delaware, Missouri, New York, Pennsylvania, South Dakota

NAAT TAT data not available since the laboratory did not identify MTBC (blue-gray with arrow pattern)— Vermont, Wyoming

Figure 4.

2022 NAAT TAT data, grouped by testing algorithm, are displayed in a horizontal bar graph. The vertical y-axis contains a list of NAAT algorithms with the number of laboratories using the particular NAAT algorithm. 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 20%. There are 8 horizontal bars with each bar representing the average NAAT TAT for PHLs using that testing algorithm; each bar includes a small thin line representing the range.

Figure 5.

Maps of U.S. divided by groupings of TAT for specimen receipt within one, two, and three days from specimen collection. Each level of specimen receipt is assigned a color. Number of specimens processed in 2022 is included for each site on the specimen receipt within one day map.

Specimen receipt within one day:

0–40% (mauve)—Alaska, D.C., Florida, Illinois, Iowa, Kansas, Kentucky, Maryland, Michigan, Mississippi, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas.

41–66% (light blue)—Alabama, California, Colorado, Connecticut, Georgia, Idaho, Indiana, Maine, Massachusetts, Minnesota, Montana, Nevada, North Carolina, North Dakota, Oregon, Puerto Rico, Tennessee, Virginia, Washington, West Virginia.

67–85% (blue-gray)—Arkansas, Arizona, Delaware, Missouri, Nebraska, New Hampshire, New York City, Philadelphia, Rhode Island, Utah, Vermont, Wisconsin, Wyoming.

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

Specimen receipt within two days:

0–40% (mauve)—Kentucky, New York, Oklahoma.

41–66% (light blue with black dot pattern)—Alaska, D.C., Florida, Georgia, Illinois, Kansas, Mississippi, New Mexico, Pennsylvania, South Carolina, South Dakota, Texas.

67–85% (blue-gray with arrow pattern)—Arkansas, Connecticut, California, Delaware, Idaho, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Puerto Rico, Tennessee, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming.

86–100% (green)—Alabama, Arizona, Colorado, Hawaii, Houston, Los Angeles, Louisiana, Missouri, New York City, Philadelphia, Rhode Island, San Diego, San Francisco, Utah.

Specimen receipt within three days:

0–40% (mauve)—(none)

41–66% (light blue with black dot pattern)—Alaska, Florida, Illinois, Kentucky, New York, Oklahoma, Texas.

67–85% (blue-gray with arrow pattern)—D.C., Georgia, Kansas, Maryland, Massachusetts, Mississippi, New Mexico, Pennsylvania, South Carolina, South Dakota, Tennessee, Washington.

86–100% (green)—Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Houston, Idaho, Indiana, Iowa, Los Angeles, Louisiana, Maine, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York City, North Carolina, North Dakota, Ohio, Oregon, Philadelphia, Puerto Rico, Rhode Island, San Diego, San Francisco, Utah, Vermont, Virginia, West Virginia, Wisconsin, Wyoming.

Figure 6.

2022 turnaround times for ID, divided into groups by primary ID method, is presented in a horizontal bar graph. The vertical y-axis contains 9 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%. Each of the 9 groups has a horizontal bar representing the average percent of MTBC identified within 21 days; each bar includes a small thin line representing the range.

Figure 7.

2022 turnaround times for DST, divided by first-line DST method, is presented in a horizontal bar graph. The vertical y-axis contains 6 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%. Each of the 6 groups has a horizontal bar representing the average percent of DST performed within 17 days of ID; each bar includes a small thin line representing the range.

Figure 8.

2022 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%. Each of the 5 groups have two horizontal bars representing the average percent of MTBC identified within 21 days and DST performed within 17 days of ID; each bar includes a small thin line representing the range.

Figure 9.

NAAT approaches used by PHLs during 2023 are presented in a doughnut chart. The largest slice represents the 40 PHLs that performed Cepheid Xpert® MTB/RIF. The following three slices represent: 12 PHLs that performed real-time PCR, 4 PHLs that referred testing, and 2 PHLs that performed pyrosequencing.

Figure 10.

Primary ID methods used by PHLs in 2023 are presented in a doughnut chart. The largest slice represents the 19 PHLs that performed MALDI-TOF. The following eight slices represent: 14 PHLs that performed real-time PCR, 10 PHLs that performed Hologic® AccuProbe®, 5 PHLs that performed Cepheid® Xpert® MTB/RIF assay, 5 PHLs that referred testing, 2 PHL that performed pyrosequencing,

1 public health laboratory that performed HPLC, 1 public health laboratory that performed Fujirebio INNP-LiPA, and 1 public health laboratory that performed PRA.

Figure 11.

ID approaches used by PHLs during 2020–2023 are presented in a clustered bar graph, grouped by approach. The vertical y-axis is the number of PHLs, ranging from 0 to 30 by increments of 5, and the horizontal x-axis is ID approaches with four clustered bars for each approach. The clustered bars represent years; 2020 is displayed as navy, 2021 is displayed as green, 2022 is displayed as mauve, and 2023 is displayed as light blue.

Figure 12.

The growth-based DST approaches for initial drug panel used by PHLs in 2023 are presented in a doughnut chart. The largest slice represents the 32 PHLs that perform DST using BACTEC™ MGIT™. The next five slices represent 17 PHLs that referred testing to the National PHL DST Reference Center for MTBC, 6 PHLs that referred testing to another PHL, 1 public health laboratory that performed indirect agar proportion, 1 public health laboratory that performed Thermoscientific Sensititre®, and 1 public health laboratory that performed whole genome sequencing.

Figure 13.

Map of U.S. divided by DST approaches and drug panels. Each DST approach and drug panel is assigned a color and pattern.

Referral of DST (blue-gray with arrow pattern)—Colorado, D.C., Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Oklahoma, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, West Virginia, Wyoming

Performs RIPE (light blue with black dot pattern)—Alabama, Arkansas, Connecticut, Delaware, Georgia, Houston, Illinois, Indiana, Nevada, New Jersey, Massachusetts, Minnesota, Mississippi, Missouri, North Carolina, Ohio, Pennsylvania, Philadelphia, San Diego, San Francisco, Tennessee, Wisconsin

Performs RIPE & FQ (navy with white dot pattern)—Alaska, Oregon

Performs RIPE and Second-line Drugs (mauve)—Arizona, Los Angeles, Maryland, New York City, Washington

Performs RIPE & FQ and Second-line Drugs (green)—California, Florida, Michigan, New York, Texas, Virginia

Figure 14.

The molecular testing for detection of drug resistance used by PHLs in 2023 are presented in a doughnut chart. The largest slice represents the 6 PHLs that used the Cepheid® Xpert® MTB/RIF assay. The next two slices represent 4 PHLs that performed pyrosequencing and 1 public health laboratory that performed whole genome sequencing.

Figure 15.

The IGRA methods used by PHLs in 2023 are presented in a doughnut chart. The largest slice represents the 25 PHLs that perform Qiagen QuantiFERON® in another section of the PHL. The other two slices represent 6 PHLs that perform Qiagen QuantiFERON® in the mycobacteriology section of the PHL and 2 PHLs that use Revvity T-Spot®.

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