<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Benchmark</th>
<th>Performance Target$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote rapid delivery of specimens to the laboratory</td>
<td>Receipt within 1 day of specimen collection</td>
<td>$\geq 67%$ of specimens received within 1 day</td>
</tr>
<tr>
<td>Use fluorescent acid-fast staining and promptly transmit results by phone, FAX, or electronically</td>
<td>Report AFB$^b$ smear result within 1 day from specimen receipt</td>
<td>$\geq 92%$ of specimens with AFB smear result reported within 1 day of receipt</td>
</tr>
<tr>
<td>Promote use of NAAT$^d$</td>
<td>Report the percent of patients tested by NAAT that had a positive result reported within 48 hours of specimen receipt</td>
<td>$\geq 77%$ of patients with a positive NAAT result reported within 48 hours of specimen receipt</td>
</tr>
<tr>
<td>Use rapid methods to identify and report isolates as MTBC$^c$ as soon as possible</td>
<td>Report identification results within 21 days from specimen receipt</td>
<td>$\geq 74%$ of MTBC isolates identified from initial diagnostic specimens reported as MTBC within 21 calendar days of receipt</td>
</tr>
<tr>
<td>Determine the growth-based susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report results promptly</td>
<td>Report susceptibilities to first-line drugs within 17 days of MTBC identification from culture</td>
<td>$\geq 69%$ of rifampin results reported for initial diagnostic specimens within 17 days of MTBC identification from culture</td>
</tr>
<tr>
<td>For laboratories that perform in-house molecular sequencing DST methods, report specimen and/or MTBC isolate results</td>
<td>Report molecular sequencing DST results within 11 days from date of receipt</td>
<td>$\geq 75%$ of molecular sequencing DST results reported within 11 days of date of receipt (specimen or referred isolate) or date of ID (if ID is performed in-house)</td>
</tr>
<tr>
<td>For laboratories that perform in-house IGRA$^e$ testing methods, report results promptly</td>
<td>Report IGRA results within 4 days of collection</td>
<td>$\geq 75%$ of IGRA results reported within 4 days of collection</td>
</tr>
</tbody>
</table>

$^a$ Performance targets represent the median percent of diagnostic specimens meeting benchmark turnaround time (TAT) as calculated from a multicenter evaluation, except for NAAT, molecular sequencing DST, and IGRA; $^b$ AFB – Acid-fast bacilli; $^c$ MTBC – *Mycobacterium tuberculosis* complex; $^d$ NAAT – Nucleic Acid Amplification Test; $^e$ IGRA – Interferon Gamma Release Assay
LABORATORY GLOSSARY

The following definitions should be used for the purposes of this program. These terms are used in the program announcement.

1. **Calendar day**: successive days, not working days. This includes days that the laboratory is not open for business (weekends, holidays).

2. **Clinical specimen**: sample derived directly from a patient (e.g., sputum, CSF) that is submitted to the laboratory for testing. These are also known as primary or “raw” specimens.

3. **Individual patient**: unique person.

4. **Isolate**: organism obtained by processing and culturing a clinical specimen. This would include, for example, a positive MGIT or other broth tube, or an LJ slant or 7-H-11 plate with visible growth.

5. **Initial diagnostic specimen**: first clinical specimen received in your laboratory from an individual patient, that has a positive result (identification or drug susceptibility test). This does not include follow-up specimens. This should include clinical specimens referred to another laboratory for testing.

6. **Initial *M. tuberculosis* complex isolate**: first *M. tuberculosis* complex (MTBC) isolate recovered from an individual patient. For example, if 2 sputum specimens were submitted on Patient “A,” one on 9/10 and one on 9/12, and the first *M. tuberculosis* isolate identified was from the specimen submitted on 9/12, then this would be the “initial isolate,” even if *M. tuberculosis* grows from the 9/10 specimen.

7. **Jurisdiction**: state, city, or county covered by the cooperative agreement program.

8. **NAAT**: nucleic acid amplification test for the detection of *M. tuberculosis* complex performed directly on a clinical specimen, *e.g.*, real-time PCR, GenProbe MTD™, Cepheid GeneXpert MTB/RIF™.

9. **Direct, or rapid detection test**: test for the detection of *M. tuberculosis* complex performed directly on a clinical specimen (*e.g.*, NAAT, direct HPLC). This does not include species identification tests performed on isolates, such as ACCUPROBE™.

10. **Reference isolate, Referred isolate**: organism obtained by processing and culturing a clinical specimen in another laboratory that is referred to your laboratory for testing. This includes isolates referred on solid and in liquid media. See “Isolate”, above.

11. **Sediment, Referred sediment**: concentrated or processed specimen or centrifuged sediment from a patient, that is sent from another laboratory.

12. **First-Line Drugs**: isoniazid, ethambutol, rifampin, and pyrazinamide.

13. **Growth-based DST**: Drug susceptibility test that is phenotypic, or growth-based, *e.g.*, MGIT DST or agar-proportion DST.

14. **Molecular sequencing DST**: Drug susceptibility test that is genotypic, *e.g.*, targeted next generation sequencing (tNGS) or whole genome sequencing (WGS).

15. **IGRA**: Interferon gamma-release assay to detect latent TB infection, performed on blood specimens, *e.g.*, QuantiFERON-Gold-in- Tube™, T-Spot.TB™.
HOW TO CALCULATE TURNAROUND TIMES (TAT)

For all TAT indicators:
All indicators should be measured in calendar days, not working days and should include weekends and holidays (e.g., a specimen that arrives at the laboratory on a Friday afternoon and is processed with the acid-fast bacilli (AFB) smear read and the result reported on the following Monday would have a TAT of three days). For all TAT indicators, percent can be determined by the general formula below, using specimen receipt in one calendar day for 2023 as an example.

\[
\frac{\text{Number of specimens received in one calendar day}}{\text{All specimens received in laboratory in 2023}} \times 100
\]

Specimen receipt:
This indicator should measure the time (in calendar days) it takes for a clinical specimen to reach the laboratory from time of collection to time of delivery to the laboratory building itself (not the TB section). Weekends and holidays should be included. Calculate the percent reaching the laboratory within 1, 2, and 3 calendar days. This calculation should be cumulative (e.g., the percent within 3 days includes the percent within 1 and 2 days).

AFB smear results:
This indicator should measure the time (in calendar days) it takes for a clinical specimen to have an AFB smear result reported from specimen receipt in the laboratory. Calculate the percent of specimens having AFB smear results reported within 1, 2, and 3 calendar days. This calculation should also be cumulative (see Specimen receipt).

NAAT (nucleic acid amplification test) within 48 hours of specimen receipt:
NAAT TAT indicator should measure the percentage of patients tested by NAAT that had a positive result reported within 48 hours of specimen receipt. To calculate, determine the number of patients with a positive NAAT result (denominator), and of those, the number that were reported within 48 hours of specimen receipt (numerator).

ID (identification) of MTBC within 21 days:
This indicator should measure the time (in calendar days) it takes for an initial diagnostic specimen to be identified as Mycobacterium tuberculosis complex (MTBC) (from a culture of the specimen) from specimen receipt in the laboratory. This does not include ID of referred isolates, nor does it pertain to direct detection of MTBC from clinical specimens such as NAAT. To calculate, determine the number of IDs of MTBC from initial diagnostic specimens (the denominator), and of those, the number that were identified within 21 days of specimen receipt (the numerator).

Growth-based DST (drug susceptibility testing) of MTBC within 17 days of ID:
This indicator should measure the time (in calendar days) it takes to report rifampin results (from a culture of MTBC from an initial diagnostic specimen) after ID of MTBC (see above). This indicator does not include DSTs performed on referred isolates or by molecular testing. To calculate this indicator, determine the number of growth-based DSTs performed from initial diagnostic clinical specimens (the denominator), and of those, the number that were reported within 17 days of the date of MTBC ID (the numerator).

Note: For laboratories using the DST Reference Center or another reference laboratory, TAT for DST should be calculated in the same manner as above—from ID of MTBC in your laboratory to report of rifampin results by your laboratory.
Molecular Sequencing DST:
For laboratories that perform in-house molecular sequencing DST methods for specimens and/or isolates, this indicator should measure the time it takes to report a molecular sequencing DST result. *Probe-based methods such as Xpert® MTB/RIF and line probe assays should not be included.*

- To calculate this indicator, determine the number of molecular sequencing DSTs performed (denominator), and of those, the number reported within 11 days (numerator).
  - For specimens, calculate from date of receipt to results report.
  - For MTBC isolates, calculate from date of receipt (if a referred isolate) or date of ID (if in-house ID is performed) to results report.
- Also, calculate the mean and range TAT, in days, for each method and for specimens and/or MTBC isolates separately.

IGRA (interferon gamma release assay):
For laboratories that perform in-house IGRA testing, this indicator should measure the time it takes to report an IGRA result. To calculate, determine the number of IGRAs performed (denominator), and of those, the number reported within 4 days of specimen collection (numerator). Also, report the mean number of days between specimen collection and reporting of IGRA test result.

Data checking—common errors:
- For specimen receipt and for AFB smear results, the percents should be cumulative. For example, the percent within 2 calendar days should be greater than the percent within 1 calendar day and the percent within 3 calendar days should be greater than the percent within 2 calendar days.
- If the percent within 1 calendar day for specimen receipt and for AFB smear result is reported as 100%, please double check to make sure you are using calendar days, not working days in your calculations. Laboratories that are not open on weekends or holidays are unlikely to truly meet these indicators 100% of the time in one calendar day.

<table>
<thead>
<tr>
<th>TAT Indicator/Benchmark</th>
<th>National Targets: % within recommended time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen receipt within 1 day</td>
<td>67%</td>
</tr>
<tr>
<td>AFB smear results within 1 day of specimen receipt</td>
<td>92%</td>
</tr>
<tr>
<td>NAAT within 48 hours of specimen receipt</td>
<td>77%</td>
</tr>
<tr>
<td>ID within 21 days of specimen receipt</td>
<td>74%</td>
</tr>
<tr>
<td>Growth-based DST results within 17 days of ID of MTBC</td>
<td>69%</td>
</tr>
<tr>
<td>Molecular Sequencing DST results within 11 days</td>
<td>75%</td>
</tr>
<tr>
<td>IGRA within 4 days of sample collection</td>
<td>75%</td>
</tr>
</tbody>
</table>

1 Initial diagnostic specimen: first clinical specimen received in your laboratory from an individual patient that has a positive result (identification or drug susceptibility test). This does not include follow-up specimens. This should include clinical specimens referred to another laboratory for testing.
Laboratories regardless of volume, should provide at least two measurable objectives and related activities for Elements 2 and 3

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**Tuberculosis Elimination Cooperative Agreement 2025 Checklist**

**Laboratory Strengthening Component**

1. □ One designated laboratory point of contact with associated contact information (name, title, email, and telephone number)
2. □ An organizational chart of mycobacteriology laboratory managers and personnel performing TB testing including names of staff in each position (list vacant if vacant). Indicate staff awarded under this cooperative agreement.
3. □ A brief description of laboratory methods used and/or accessed through referral and a visual flowchart of the mycobacteriology laboratory testing algorithm
4. □ Complete laboratory workload volume (years 2021-2023) and turnaround time (TAT) (year 2023) PDF data forms (testing for your jurisdiction only)
5. □ Complete the Laboratory Work Plan (Excel document located at TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC)

   - □ Element 1—Ensure availability of high-quality and timely core TB laboratory services
     - □ Laboratory-specific measurable goals for achieving or exceeding each TAT indicator.
     - □ Specific objectives and activities for achieving stated goals.
     - □ Measure of success, anticipated obstacles, responsible staff, and target completion date for each new activity.

   - □ Element 2*—Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data
     - □ Measurable objectives to improve efficiency and quality assurance for your laboratory.
     - □ Specific activities related to improvements.
     - □ Measure of success, anticipated obstacles, responsible staff, and target completion date for each new activity.

   - □ Element 3*—Communicate and collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information
     - □ Measurable objectives to improve communication and collaboration with partners.
     - □ Specific activities related to improvements.
     - □ Measure of success, anticipated obstacles, responsible staff, and target completion date for each new activity.

6. **Budget**
   - □ A line-item Laboratory budget reflecting estimated funding categorized as Personnel, Fringe Benefits, Consultant Costs, Equipment, Supplies, Travel, Other, Contractual Costs, Total Direct Costs, and Total Indirect Costs (for more information see CDC’s Budget Preparation Guidelines document)
     - Justification required for equipment, supplies, travel, other, and contractual costs
     - Requests for personnel support should include position title, name of individual (or if position is vacant), and brief description of laboratory responsibilities
     - Fringe benefits and indirect funding amounts should include percentage rate(s).
     - Equipment is defined as tangible, non-expendable property with useful life of more than one year and a cost of $5,000 or more per unit
     - Supplies category should individually list each item requested with number needed, unit cost of each item, and total amount
     - Office Supplies, Shipping (postage, shippers), and Conference Registration Fees should be categorized under “Other”
     - Courier services may be categorized as “Other” or “Contractual” based on how the laboratory invoices

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*Laboratories regardless of volume, should provide at least two measurable objectives and related activities for Elements 2 and 3*