

Tuberculosis Elimination Cooperative Agreement Checklist—2027

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).** Note: Indicate which staff are awarded under this cooperative agreement.
3. ☐ **A brief description of laboratory methods and instrumentation used and/or accessed through referral testing**
4. ☐ **A visual flowchart of the mycobacteriology laboratory testing algorithm**
5. ☐ **Complete laboratory workload volume (year 2025 and half-year 2026) and turnaround time (TAT) (year 2025 and half-year 2026) PDF data forms (testing for your jurisdiction only)**
6. ☐ **Updated Laboratory Work Plan using previously submitted Excel spreadsheet or the Excel spreadsheet CDC's Laboratory Capacity Team sent by email**
 - ☐ **Element 1—Ensure availability of high-quality and timely core TB laboratory services**
 - ☐ Updates for previously listed activities to include progress, obstacles experienced, and updated completion date (if applicable)
 - ☐ Description of new activities for achieving stated objectives
 - ☐ Measure of success, anticipated obstacles, responsible staff, and anticipated completion date for each new activity
 - ☐ **Element 2*—Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data**
 - ☐ Updates for previously listed activities to include progress, obstacles experienced, and updated completion date (if applicable)
 - ☐ Description of new activities related to improvements
 - ☐ Measure of success, anticipated obstacles, responsible staff, and anticipated 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**
 - ☐ Updates for previously listed activities to include progress, obstacles experienced, and updated completion date (if applicable)
 - ☐ Description of new activities related to improvements
 - ☐ Measure of success, anticipated obstacles, responsible staff, and anticipated completion date for each new activity
7. **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](#))
 - Justification required for Personnel, 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 list percentage rate(s)
 - Equipment is defined as tangible, non-expendable property with useful life of more than one year and a cost of \$10,000 or more per unit
 - Supplies category should individually list each item requested with number needed, unit cost of each item, and subtotal amount
 - Office Supplies, Shipping (e.g., postage, shippers), Instrument Maintenance/Service, and Conference Registration Fees should be categorized under "Other"
 - Courier services may be categorized as "Other" or "Contractual" based on how the laboratory invoices

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

HOW TO CALCULATE TURNAROUND TIMES (TAT)

TAT Indicator/Benchmark	National Targets: % within recommended time
Specimen receipt within 1 day of specimen collection	67%
AFB smear results reported within 1 day of specimen receipt	92%
Patients tested by NAAT that had a positive result reported within 48 hours of specimen receipt	77%
ID of MTBC from initial diagnostic specimen reported within 21 days of specimen receipt	74%
Growth-based DST results reported within 17 days of ID of MTBC from culture	69%
Molecular Sequencing DST results reported within 11 days of specimen receipt or ID	75%
IGRA results reported within 4 days of specimen collection	75%

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 2025 as an example.

$$\frac{\text{Number of specimens received in one calendar day}}{\text{All specimens received in laboratory in 2025}} \times 100$$

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).

Acid-Fast Bacilli (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).

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.

Nucleic Acid Amplification Test (NAAT) 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).

Identification (ID) of MTBC within 21 days:

This indicator should measure the time (in calendar days) it takes for an **initial diagnostic specimen**¹ 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 Drug Susceptibility Testing (DST) 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**¹) **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.

Interferon Gamma Release Assay (IGRA):

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.

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.