

Recommendation	Benchmark	Performance Target <sup>a</sup>
<b>Promote rapid delivery of specimens to the laboratory</b>	Receipt within 1 day of specimen collection	≥67% of specimens received within 1 day
<b>Use fluorescent acid-fast staining and promptly transmit results by phone, FAX, or electronically</b>	Report AFB <sup>b</sup> smear result within 1 day from receipt of specimen	≥92% of specimens with AFB smear result reported within 1 day of receipt
<b>Identify growth as acid-fast and use rapid methods to identify and report isolates as MTBC<sup>c</sup> as soon as possible</b>	Report identification results within 14–21 days from receipt of specimen	≥74% of MTBC isolates identified from initial diagnostic specimens reported as MTBC within 21 days of receipt
<b>Determine the susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report results promptly</b>	Report susceptibilities to first-line drugs within 17 days of MTBC identification from culture	≥69% of rifampin results reported for initial diagnostic specimens within 17 days of MTBC identification from culture
<b>Reduce the average time for a laboratory to confirm and report tuberculosis cases using NAAT<sup>d</sup></b>	Report NAAT within 2 days from receipt of specimen	≥77% of MTBC cases that are later culture confirmed diagnosed using NAAT (or other direct detection method) within 2 days of receipt

<sup>a</sup>Performance targets represent the median percent of diagnostic specimens meeting benchmark turnaround time (TAT) as calculated from a multicenter evaluation, with the exception of NAAT.

<sup>b</sup> AFB – Acid-fast bacilli

<sup>c</sup> MTBC – *Mycobacterium tuberculosis* complex

<sup>d</sup> NAAT – Nucleic Acid Amplification Test

## 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. **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 AFB smear read and the result reported on the following Monday would have a TAT of three days. For specimen receipt, AFB smear, identification (ID) and drug susceptibility (DST) indicators, percent can be determined by the general formula below, using specimen receipt in one calendar day for 2022 as an example.

$$\frac{\text{Number of specimens received in one calendar day}}{\text{All specimens received in laboratory in 2022}} \times 100$$

### 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:

This indicator has been split into a workload indicator (2c) and a TAT indicator.

#### Workload Indicator:

NAAT within 48 hours workload indicator (2c) measures the number of individuals positive for MTBC by culture that were detected positive by NAAT within 48 hours of specimen receipt. To calculate this number, identify number of individual patients for whom a clinical specimen was processed for AFB smear and culture (workload indicator 2). Of these, determine number of individual patients for whom at least one culture was positive for MTBC (workload indicator 2a). Then, of these individuals positive for MTBC by culture, determine how many of these were initially positive by NAAT from a clinical specimen in your laboratory (workload indicator 2b). Finally, the NAAT within 48 hours of specimen receipt indicator is, of these (2b), how many were reported within 48 hours of specimen receipt. This number (2c) should be a subset of 2b, which is a subset of 2a, which is a subset of 2.

#### TAT Indicator:

NAAT TAT indicator should measure the percentage of MTBC positive patients that had a positive NAAT reported within 48 hours of specimen receipt. To calculate, determine the number of MTBC culture positive patients, workload indicator 2a (denominator), and of those, the number that had a positive NAAT reported within 48 hours of specimen receipt, workload indicator 2c (numerator).

### ID of MTBC within 21 days:

This indicator should measure the time (in calendar days) it takes for an **initial diagnostic specimen**<sup>1</sup> 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).

**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<sup>1</sup>** **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 DSTs performed from initial diagnostic clinical specimens (the denominator), and of those, the number that were reported within 17 days of the date of ID of MTBC (the numerator).

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 DST:**

Currently, no TAT benchmark exists for molecular DST. This TAT indicator should measure mean and range data for molecular DST assays performed on clinical specimens/sediments and MTBC isolates separately. The calculation should be stratified by each molecular DST method performed, e.g., Xpert and pyrosequencing. To calculate, determine the mean and range for molecular DST of clinical specimens/sediments by each method performed and/or determine mean and range for molecular DST of MTBC isolates by each method performed.

**IGRA (interferon gamma release assay):**

This indicator should measure the time it takes to report an IGRA result from testing performed within the public health laboratory. To calculate, determine the mean number of days between specimen collection to IGRA result reported for all IGRA testing performed in-house.

**Data checking—common errors:**

- For specimen receipt and for AFB smear results, the percent within 3 calendar days should be greater than the percent within 1 and 2 calendar days, and the percent within 2 calendar days should be greater than the percent within 1 calendar day.
- 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.
- For NAAT within 48 hours of specimen receipt, the number indicated (MTBC culture positive patients with positive NAAT within 48 hours of specimen receipt) should not exceed the number of patients tested by NAAT, workload indicator 2b of the Workload Data Collection Form.

TAT Indicator/Benchmark	National Targets: % within recommended time
Specimen receipt within 1 day	67%
AFB smear results within 1 day of specimen receipt	92%
ID of MTBC within 21 days of specimen receipt	74%
DST results within 17 days of ID of MTBC	69%
NAAT within 48 hours of specimen receipt	77%

<sup>1</sup> 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.

# Tuberculosis Elimination Cooperative Agreement Checklist

## Laboratory Strengthening Component

1.  One designated laboratory point of contact with associated contact information (name, email and telephone number)
2.  An organizational chart of TB laboratory personnel (names listed)
3.  A brief description of laboratory methods and testing algorithms (visual testing algorithm may also be included)
4.  Completed workload volume and turnaround time data sheets for 2022 (Jan–Dec) and 2023 (Jan–Jun)
5.  Updated Work Plan (Excel document with addition of Column F addressing Elements 1, 2 and 3 located at <https://www.cdc.gov/tb/education/SampleWorkPlans.htm>)
  - Element 1—Ensure availability of high-quality and prompt core laboratory services for TB**
    - Laboratory workload volume and turnaround time (TAT) data for 2022 (Jan–Dec) and 2023 (Jan–Jun) in tabular form
    - Updates for previously listed activities to include progress, obstacles experienced and updated timeline (if applicable)
    - Description of new specific activities for achieving stated objectives, if applicable
    - List 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 through use of local data**
    - Updates for previously listed activities to include progress, obstacles experienced and updated timeline (if applicable)
    - Description of new specific activities for achieving stated objectives, if applicable
    - List measure of success, anticipated obstacles, responsible staff and target completion date for each new activity
  - Element 3\*—Collaborate with partners (e.g., healthcare providers, TB Control and laboratory network) to ensure optimal use of laboratory services and timely flow of information**
    - Updates for previously listed activities to include progress, obstacles experienced and updated timeline (if applicable)
    - Description of new specific activities for achieving stated objectives, if applicable
    - List measure of success, anticipated obstacles, responsible staff and target completion date for each new activity
6. **Budget**
  - A line-item budget reflecting anticipated funding categorized as follows: Salaries and Wages, Fringe Benefits, Consultant Costs, Equipment, Supplies, Travel, Other, Contractual Costs, Total Direct Costs and Total Indirect Costs
    - Justification/description required for each category
    - Each line-item should include the number anticipated and per unit cost
    - Requests for personnel support should include the position title, the name of the individual (or if the position is vacant) and a brief description of responsibilities

\*Laboratory volume considerations for Elements 2 and 3:

- ≤1,000 clinical specimens each year should provide at least one measurable outcome for Elements 2 and 3
- 1,001-5,000 clinical specimens each year should provide at least two measurable outcomes for Elements 2 and 3
- ≥5,001 clinical specimens each year should provide at least three measurable outcomes for Elements 2 and 3