National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Informational Call for Notice of Funding Opportunity (NOFO)

CDC-RFA-PS-25-0003

Tuberculosis Elimination and Laboratory Cooperative Agreement

Field Services Branch, Division of Tuberculosis Elimination
Laboratory Branch, Division of Tuberculosis Elimination
Office of Grant Services, Financial Resources Office

This funding supports the 5-year funding cycle of the Tuberculosis Elimination and Laboratory Cooperative Agreement

Period of Performance: January 1, 2025—December 31, 2029

Call Date: Friday, July 12, 2024 | 2:00—3:00 p.m. EST

Agenda

- Goal / Objective
- Key Changes
- NOFO Background and Overview of Approach
- Logic Model Strategies
- Prevention and Control Strategies
- Program Planning, Evaluation and Improvement Strategy
- Work Plan
- Reporting Requirements and Application Review
- Funding Availability and Estimators
- Laboratory Strengthening
- OGS Comments
- Contact and Additional Information

Webinar Goal and Objective

Andy Heetderks

Goal

- Assist applicants with the application process for CDC-RFA-PS 25-0003

Objective

- Provide an overview of the content of the NOFO and application submission process

Key Changes

Andy Heetderks

Key Changes from PS 20-2001 Cooperative Agreement (CoAg)

NOFO Section	Changes
Application Process	The 2025 NOFO is competitive NOFOs in prior years were limited competition
A. Funding Opportunity Description	-Targeted testing program is required for all applicants, not just programs with more than 150 cases -Provide **drug shortage contingency plan**
C2. Additional information on Eligibility	The applicant must upload two attachments in the application entitled Attachment A-"TB Prevention and Control Elimination Plan" and Attachment B-"Evidence of Jurisdiction Infrastructure"
G. Executive Summary	Anticipate up to 57 awards this funding cycle; reduced from previous 61
E. Review and Selection Process Workplans for Prevention and Control (P&C)	**Specify the name and responsibilities of the clinician serving as the state or local TB medical consultant for the jurisdiction**
2. CDC Project Description	Updated laboratory workload volume and turnaround time indicators

NOFO Background and Overview of Approach

Andy Heetderks

NOFO Background

- Continues 40 years of federal support to state & local TB prevention & control activities and laboratory services
- NOFO authorized under Section 317E of the Public Health Service Act
- Provides funds to support TB Prevention & Control (P&C), Human Resource Development (HRD), and Laboratory services
- Funding for P&C activities is based on a data-driven formula developed in collaboration with National Tuberculosis Coalition of America (NTCA)
- Laboratory funding for each jurisdiction is determined according to workload volume-based formula

NOFO Overview of Approach

- **The goal of this NOFO is to reduce morbidity and mortality caused by TB, and the approach is to:**
  - Describe why TB is a problem worth addressing through the NOFO
  - Outline strategies and activities to achieve desired outcomes that meet the goals of the NOFO
  - Contain a logic model outlining the short term, intermediate, and long-term outcomes for the 5-year project period

Logic Model Strategies

Andy Heetderks

Logic Model Strategies

- **1. Diagnosis and Treatment of persons with TB disease**
  - Advise providers on TB diagnosis and treatment
  - Manage cases and ensure treatment adherence
  - Promote infection control

- **2. Conduct contact investigations for infectious TB cases**
  - Elicit, examine, test and treat contacts with TB infection

Logic Model Strategies (2)

3. Test and treat populations at higher risk for TB and Latent Tuberculosis Infection (LTBI)

- Select and conduct targeted testing among population (s) at higher risk for TB/LTBI
- Engage TB control program and local community organizations to reach populations at higher risk for TB/LTBI and provide effective and culturally appropriate services
- Examine immigrants and refugees with Class B notification

Logic Model Strategies (3)

- **4. Program planning, monitoring, evaluation, and improvement**
  - Conduct program evaluation and implement remediation activities to improve performance
  - Implement TB elimination plans
  - Establish contingency plans to manage drug shortages and distribution issues

Logic Model Strategies (4)

- **5. Surveillance**
  - Report TB cases in a timely, accurate, and complete manner
  - Link genotype results to surveillance records in a timely and complete manner
  - Routinely review TB genotype clusters and prioritize investigation and public health action
  - Promote standardized collection and reporting of case-level LTBI surveillance data
  - Report on contacts to cases and persons who were part of targeted testing among populations at higher risk

Logic Model Strategies (5)

- **6. Human Resource development (HRD) and partnerships**
  - Develop and implement HRD plans
  - Collaborate with organizations and providers serving high-risk populations

- **7. Laboratory Strengthening**
  - Use laboratory data to address or evaluate methods, algorithms, and testing needs of populations served
  - Ensure availability of high-quality and timely core TB laboratory services
  - Collaborate with partners to serve patient populations

Prevention and Control (P&C) Strategies

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Prevention and Control (P&C) Strategies

- Mostly unchanged from the previous cooperative agreement, although targeted testing is required for all recipients (no longer identifies cutoff of 150 cases as high/low incidence)
- Outlined under NOFO “Approach” in the CDC Project Description section
- Provide clear description of the activities your program intends to employ that aligns with your category
- Ensure justifications in budget narrative align with stated activities

Prevention and Control (P&C) Surveillance

- Enhance identification, reporting, and follow-up of cases and suspects
- Ensure complete, accurate, and timely reporting of cases
- Ensure prompt investigation of genotype cluster and response to outbreak
- If feasible,
  - Promote standardized collection and reporting case-level LTBI surveillance data
  - Provide data on case-based surveillance for LTBI

HRD and Partnerships Strategy

Andy Heetderks

HRD and Partnerships Strategy

- Designate a focal point for training and education
- Identify training and HRD needs
- Provide competency-based in-service TB training and human resource development
- Establish evaluation strategies to improve existing trainings and to identify ongoing training and HRD needs
- Improve patient education and communications capacity within the program
- Collaborate with organizations and providers serving high-risk populations

Program Planning, Evaluation, and Improvement Strategy

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Program Planning, Evaluation and Improvement Strategy

- Each recipient must designate a focal point for program evaluation
- At the beginning of each year, recipients should:
  - Identify an evaluation focus area, describing the justification
  - Describe the evaluation plan
- At the end of each year, recipients should be able to describe findings, lessons learned, and remediation plans resulting from the prior year's evaluation

Work Plans

Mark Miner

Work Plans

- Work plans should contain elements supporting the scope of their activities in relationship to TB control program strategies and target populations and laboratory services
- Example work plans can be found on the TB NOFO resource page at https://www.cdc.gov/tb-programs/php/funding/elimination-and-laboratory-cooperative-agreement.html?CDC_AAref_Val=https://www.cdc.gov/tb/education/SampleWorkPlans.htm
- Align work plan to the strategies and activities, including the relevant performance objectives

Application Submission Process

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Application Submission Process

- Requirements are outlined in section D. Application and Submission Information in the NOFO
- Application package can be found at www.grants.gov, using funding opportunity number CDC-RFA-PS25-0003
- Applicants may e-mail or call CDC OGS staff for assistance at (678) 475-4500 or Grants.gov customer service at 800-518-4726 or e-mail support@grants.gov

Application Submission Process (2)

- **Application Due Date**
  - September 9, 2024, at 11:59 p.m. Eastern Standard Time
- **Project Narrative should include:**
  - Table of Contents
  - Project Abstract
- **Maximum of 20 pages, single spaced, 12-point font, 1-inch margins and number all pages**
- **PDF attachments allowed—please add titles to PDF attachments for ease of identification**

Application Review

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Application Review

- **Phase 1 Review:**
  - All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services (OGS)
  - Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials
  - Non-responsive applications will not advance to Phase II review
  - Applicants will be notified that their applications did not meet eligibility and/or published submission requirements

Application Review (2)

- **Phase 2 Review:**
  - NOFO reviewers will follow CDC's merit review process by evaluating eligible and responsive applications in accordance with the criteria outlined in Section E: Review and Selection Process. These criteria include:
    - Approach
    - Evaluation and Performance Measurement
    - Applicant's Organizational Capacity to Implement the Approach

Application Review (3)

- **Phase 3 Review:**
  - Applicants will be selected based on a panel assessment of the applicant's organizational capacity to implement the approach.
  - CDC Division of Tuberculosis Elimination (DTBE) may fund out of rank order based on any of the following criteria, using the best available data at the time:
    - To ensure complete national geographic coverage
    - Jurisdictions with the highest number of TB disease cases
  - CDC DTBE will provide justification for any decision to fund out of rank order

Reporting Requirements and Application Review

Mark Miner

Reporting Requirements

- Guidance on reporting requirements can be found in the “Award Administration Information” section F

- Evaluation and Performance Measurement Plan (A Sample is provided on the DTBE website) TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

  - Within first 6 months of the project period
  - Describe how TB performance indicators (found in the National TB Indicators Project or NTIP) will be used to monitor TB program performance and that an annual evaluation will be done on at least one area where indicator performance is below the performance target
  - No more than 20 pages

Reporting Requirements—Annual Performance Report (Looking Ahead)

- Annual Performance Report (APR)
  - Within the 65-page limit of the APR, recipients should use a maximum of:
    - 40 pages for P&C;
    - 10 pages for HRD; and
    - 15 pages for Laboratory Strengthening

  to cover performance reporting and the funding application
- Submit via www.grantsolutions.gov 120 days before end of budget period (instructions in the NoA, usually 8/31 but OGS will announce)
- Information in APR serves purpose of both reporting on performance and as an application for continued funding

Reporting Requirements—Annual Performance Report (2)

- APR should cover each budget period (BP) throughout the 5-year project period as follows:
  - In BP 2025, APR will be due May 1, 2025, as part of the previous project period close out report. Include a detailed analysis and progress made in year 4 (2023) and year 5 (2024) in the close out report (existing Recipients)
  - For BPs 2026-2029, APRs will be due on August 31 each year. Each covers activities for prior calendar year (January 1–December 31), and provide update on activities and outcomes achieved during the first 6 months (January 1–June 30) of the current year (new Recipients)
  - Data and associated information should be stratified by budget year (i.e., do not report as a single 18-month period)

Performance Measure Reports (Looking Ahead)

- May be required in addition to the APR in certain instances such as a jurisdiction's response to large TB outbreaks
- Minimum content of report identified in NOFO
- Submit 90 days following response to large outbreaks and quarterly thereafter for the first year of outbreak response, and at least semi-annually thereafter until the outbreak subsides
- See guidance in the "Award Administration Information" section

Aggregate Report for Program Evaluation (ARPE)

- **Due by March 31st for contacts and targeted testing projects (all programs)**

***Note for existing Recipients: programs that were not required to submit a targeted testing (TT) ARPE in 2020-2024 will be now be required to submit the form if funded under PS 25-0003**

- While it is encouraged that these programs submit an ARPE in 2025, we realize that there may not be sufficient data for programs who were not required to report in 2024 and prior.
- Because there is a lag time for ARPE data, it is allowable for these programs to submit a preliminary 2025 ARPE in March of 2026, and a Final 2025 ARPE & Preliminary 2026 ARPE in March of 2027.
- Programs who had 150 TB cases or more under PS 20-2001 will continue to submit the TT ARPE on schedule.

Funding Availability and Estimators

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TB CoAg Funding Availability

- There is $74,891,211 in proposed annual funding for PS 25-0003
- Of special note: Although the NOFO lists **$1,313,880** as the approximate average **total** award, actual award amounts may be significantly lower or significantly higher than this average, as awards are based on the **Funding Estimator** to ensure equitable distribution of resources based on changing TB epidemiology, program, and laboratory data or performance
- This amount is subject to availability of funds
- The 5-year funding life cycle is January 1, 2025—December 31, 2029

Funding Estimators Provided

- Specific estimators for P&C, HRD, and Laboratory
- Be sure to use these estimators to calculate your total funding amounts for each component
- States should include all subunit data (such as big cities) when calculating budgets with the Funding Estimator
- For P&C, use the Frozen 2023 Dataset, Funding Formula Variables Snapshot Indicator Report located in the National TB Indicators Project (NTIP) database

Prevention and Control Funding Estimator

NEEDS COMPONENT	$ per Case	3 yr Awardee Ave	Sub Total		Subtotal
Incident Cases	$3,371	x		=	
U.S. Born Minorities & Non U.S. Born	$775	x		=	
Smear Positive Pulmonary	$2,537	x		=	
MDR TB	$43,719	x		=	
Medical Risk Factors	$1,091	x		=	
Social Risk Factors	$2,460	x		=	
Class B Arrivals	$224	x		=	
Total Needs Component					$
PERFORMANCE COMPONENT	$ per Case	3-yr Awardee Ave	Sub Total		Subtotal
Completion of Treatment	$1,077	x		=	
Drug Susceptibility Testing	$558	x		=	
Contact LTBI Treatment Completion	$984	x		=	
Immigrants and Refugees Examined	$625	x		=	
Total Performance Component					$
Total Estimated P&C Funding					$

Human Resource Development Funding Estimator

Part 2 – Human Resource Development	
Incidence levels	HRD Funding Amount
0 – 49 Cases	$ 18,000
50 – 499 Cases	$ 24,629
>= 500 Cases	$ 41,781

Laboratory Strengthening

Stephanie Johnston

Laboratory Strengthening

Ensures strategies and activities for high quality and timely core laboratory services for TB, ability to address or evaluate laboratory methods, algorithms, and testing needs for patient populations served, and collaborate with partners.

Public health laboratory narrative should include:

- a designated point of contact (name, telephone number, and email),
- an organizational chart with staff members (including those funded through the CoAg),
- a description of testing methods (laboratory methods within the narrative and visual flowchart of testing algorithm)
- laboratory workload volume (years 2021-2023) and turnaround time (year 2023) PDF data forms
- a laboratory work plan addressing Laboratory Elements 1, 2, and 3 as described below.
  - Laboratory Element 1: Ensure availability of high quality and timely core TB laboratory services.
  - Laboratory Element 2: Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data.
  - Laboratory 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.
- a line-item budget reflecting estimated laboratory funding

Laboratory Funding Formula

Laboratory funding is allocated using a workload-based formula approach to ensure equitable distribution of resources. The funding formula is calculated using a 3-year average (currently, 2021 through 2023) of reported data for each of the below indicators:

		Per patient basis				
	Total # specimens (Indicator 1)	TB culture inoculated (Indicator 2)	Isolates received for ID (Indicator 4)	NAA testing of clinical specimen (Indicator 2 & 3a)	DST for first-line drugs (Indicator 5)	Lab System-Equal Amounts
FY2025	10% split across sites proportionately	15% split across sites proportionately	15% split across sites proportionately	25%* split across sites by base amounts & remaining proportionately	25% split across sites proportionately	10% split across sites evenly

*Base amount determined by number of patients for whom clinical specimen is received/processed with remaining funds distributed by number of patients positive by direct detection of *M. tuberculosis*.

Laboratory Funding Estimator

- For funding estimation, applicants should use the formula variables at the following funding amounts to calculate an estimated maximum laboratory funding amount using **2023** workload volume data:
  - $10 per total number of clinical specimens processed for smear and culture (Indicator 1)
  - $20 per number of individual patients who whom a clinical specimen was processed for smear and culture (Indicator 2)
  - $100 per number of individual patients for whom a reference isolate was received to rule out or confirm the identification of MTBC (Indicator 4)
  - $700 per number of individual patients for whom a NAAT result was positive for MTBC (Indicator 3a)
  - $340 per number of individual patients for whom first-line MTBC DST was performed and/or, if DST was not performed in-house, for whom an isolate was referred to another laboratory for DST (Indicator 5)
  - $12,908 for laboratory systems

  These amounts are then totaled to estimate amount of laboratory funding to request for FY2025.

Laboratory Funding Estimator (2)

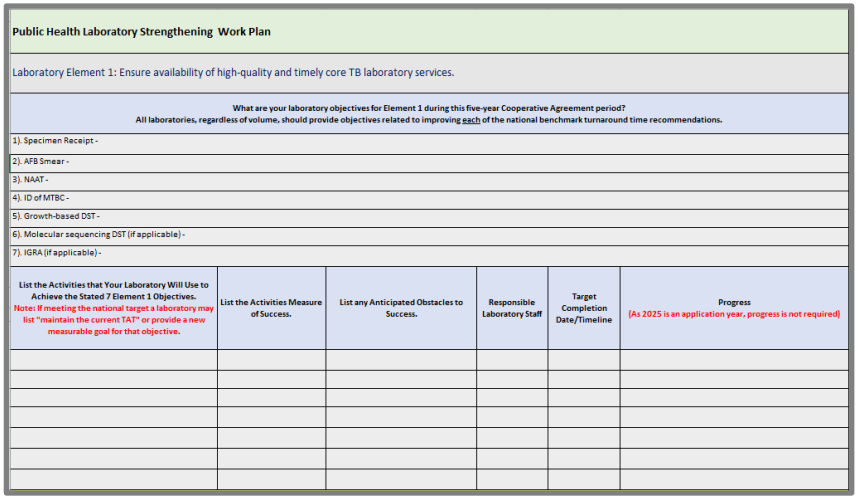
Example: Laboratory A estimates FY2025 laboratory funding using the calculations below:

- 1257 clinical specimens processed x $10 = $12,570
- 281 patients with specimens processed for smear and culture x $20 = $5,620
- 0 patients with reference isolate received x $100 = $0
- 44 patients with NAAT positive result x $700 = $30,800
- 47 patients with first-line DST performed x $340 = $15,980
- Laboratory systems = $12,908

Total funding amount for laboratory budget: $77,878

Note: A revised budget may be requested once the final funding formula is applied.

Work Plan, Workload Volume, & Turnaround Time Data Reports



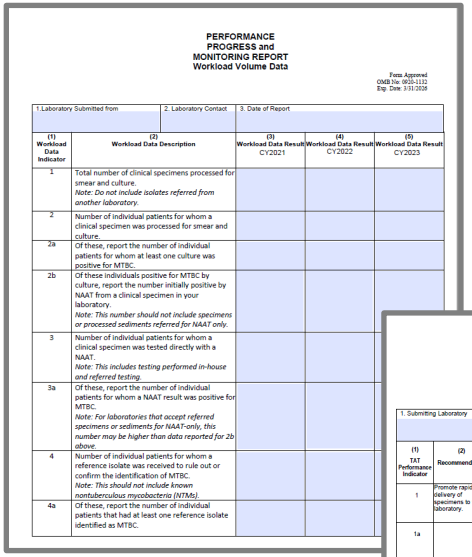
Public Health Laboratory Strengthening Work Plan

Laboratory Element 1: Ensure availability of high-quality and timely core TB laboratory services.

What are your laboratory objectives for Element 1 during this five-year Cooperative Agreement period?
All laboratories, regardless of volume, should provide objectives related to improving each of the national benchmark turnaround time recommendations.

1). Specimen Receipt -
2). AFB Smear -
3). NAAT -
4). ID of MTBC -
5). Growth-based DST -
6). Molecular sequencing DST (if applicable) -
7). IGRA (if applicable) -

List the Activities that Your Laboratory Will Use to Achieve the Stated 7 Element 1 Objectives. Note: If meeting the national target a laboratory may list "maintain the current TAT" or provide a new measurable goal for that objective.	List the Activities Measure of Success.	List any Anticipated Obstacles to Success.	Responsible Laboratory Staff	Target Completion Date/Timeline	Progress (As 2025 is an application year, progress is not required)

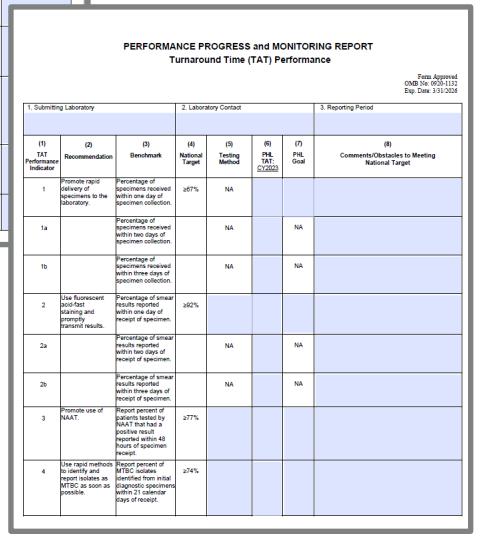


PERFORMANCE PROGRESS and MONITORING REPORT
Workload Volume Data

Form Approved
OMB No. 0920-1132
Exp. Date: 3/31/2026

1. Laboratory Submitted from | 2. Laboratory Contact | 3. Date of Report

(1) Workload Data Indicator	(2) Workload Data Description	(3) Workload Data Result CY2021	(4) Workload Data Result CY2022	(5) Workload Data Result CY2023
1	Total number of clinical specimens processed for smear and culture. *Note: Do not include isolates referred from another laboratory.*			
2	Number of individual patients for whom a clinical specimen was processed for smear and culture.			
2a	Of these, report the number of individual patients for whom at least one culture was positive for MTBC.			
2b	Of these individuals positive for MTBC by culture, report the number initially positive by NAAT from a clinical specimen in your laboratory. *Note: This number should not include specimens or processed sediments referred for NAAT only.*			
3	Number of individual patients for whom a clinical specimen was tested directly with a NAAT. *Note: This includes testing performed in-house and referred testing.*			
3a	Of these, report the number of individual patients for whom a NAAT result was positive for MTBC. *Note: For laboratories that accept referred specimens or sediments for NAAT-only, this number may be higher than data reported for 2b above.*			
4	Number of individual patients for whom a reference isolate was received to rule out or confirm the identification of MTBC. *Note: This should not include known nontuberculous mycobacteria (NTMs).*			
4a	Of these, report the number of individual patients that had at least one reference isolate identified as MTBC.			



PERFORMANCE PROGRESS and MONITORING REPORT
Turnaround Time (TAT) Performance

Form Approved
OMB No. 0920-1132
Exp. Date: 3/31/2026

1. Submitting Laboratory | 2. Laboratory Contact | 3. Reporting Period

(1) TAT Performance Indicator	(2) Recommendation	(3) Benchmark	(4) National Target	(5) Testing Method	(6) PHL TAT CY2023	(7) PHL Goal	(8) Comments/Obstacles to Meeting National Target
1	Promote rapid delivery of specimens to the laboratory.	Percentage of specimens received within one day of specimen collection.	≥67%	NA			
1a		Percentage of specimens received within two days of specimen collection.		NA		NA	
1b		Percentage of specimens received within three days of specimen collection.		NA		NA	
2	Use fluorescent acid-fast staining and promptly transmit results.	Percentage of smear results reported within one day of receipt of specimen.	≥92%				
2a		Percentage of smear results reported within two days of receipt of specimen.		NA		NA	
2b		Percentage of smear results reported within three days of receipt of specimen.		NA		NA	
3	Promote use of NAAT.	Report percent of patients tested by NAAT that had a positive result reported within 48 hours of specimen receipt.	≥77%				
4	Use rapid methods to identify and report isolates as MTBC as soon as possible.	Report percent of MTBC isolates identified from initial diagnostic specimens within 21 calendar days of receipt.	≥74%				

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

https://www.cdc.gov/tb -programs/php/funding/elimination-and-laboratory-cooperative-agreement.html

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

Contact Information

Martha Boisseau

Contact Information

- **Program Questions**
  - Martha Boisseau (Deputy Chief, Field Services Branch)
  - mboisseau@cdc.gov
  - 770-488-6261
- **Laboratory Questions**
  - Stephanie Johnston (Team Lead, Laboratory Capacity Team, Laboratory Branch)
  - sjohnston@cdc.gov
  - 404-639-5019

Contact Information (2)

- **Fiscal Questions**
  - Ms. Terrian Dixon (Grants Management Officer)
  - tdixon@cdc.gov
  - 770-488-2774

- **CDC DTBE Program/Laboratory Consultant**

Additional Information

- A recording of this call and a copy of the PowerPoint presentation will be made available on the TB NOFO Resource Page on the website at:

  https://www.cdc.gov/tb-programs/php/funding/elimination-and-laboratory-cooperative-agreement.html?CDC_AAref_Val=https://www.cdc.gov/tb/education/SampleWorkPlans.htm
- Questions may also be submitted after the informational call to the 2025 Tuberculosis Elimination and Laboratory NOFO mailbox at 2025nofo@cdc.gov
- FAQ document will be created and posted at:

https://www.cdc.gov/tb-programs/php/funding/elimination-and-laboratory-cooperative-agreement.html

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov
Follow us on X (Twitter) @CDCgov & @CDCEnvironment

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.