**PREVENTION AND CONTROL**

**NTIP Summary Report (NTIP data updated 7/8/20)**

|  |  |  |  |
| --- | --- | --- | --- |
| **National TB Program Objective** | **2020 Target** | **2025 Target** | **2020 Results** |
| **Q1** | **Q2** | **Q1 + Q2** |
| **Goals for Reducing TB Incidence** |  |
| * TB Incidence
 |  | 1.3 |  |  |  |
| * U.S.-born Persons
 | 0.4 | 0.4 |  |  |  |
| * Non-U.S.-Born Persons
 | 11.1 | 8.8 |  |  |  |
| * U.S.-born non-Hispanic Blacks or African Americans
 | 1.5 | 1.0 |  |  |  |
| * Children Younger than 5 Years of Age
 | 0.3 | 0.1 |  |  |  |
| **Objectives on Case Management and Treatment** |  |
| * Known HIV Status
 | 98% | 99% | 97.0% | 92.3% | 94.9% |
| * Treatment Initiation
 | 97% | 96% | 81.2% | 100% | 89.3% |
| * Recommended Initial Therapy
 | 97% | 97% | 100% | 92.3% | 96.7% |
| * Sputum Culture Result Reported
 | 98% | 99% | 100% | 81.0% | 92.2% |
| * Sputum Culture Conversion
 | 73% | 83% | 40.0% | 0.0% | 26.7% |
| * Completion of Treatment
 | 95% | 95% | 3.0% | 0.0% | 1.8% |
| **Objectives on Laboratory Reporting** |  |
| * Turnaround Time—Culture
 | 78% | 78% | 47.8% | 25.0% | 31.1% |
| * Turnaround Time—Nucleic Acid Amplification Test (NAAT)
 | 92% | 97% | 80.0% | 72.7% | 76.9% |
| * Drug-Susceptibility Results
 | 100% | 100% | 84.0% | 40.0% | 67.5% |
| * Universal Genotyping
 | 100% | 100% | 100% | 66.7% | 87.5% |
| **Objectives on Contact Investigations** | **2017** | **2018** | **2019** |
| * Contact Elicitation
 | 100% | 100% | 100% | 97.7% | 95.7% |
| * Examination
 | 93% | 94% | 82.3% | 87.6% | 85.3% |
| * Treatment Initiation
 | 91% | 92% | 84.5% | 65.2% | 73.3% |
| * Treatment Completion
 | 81% | 93% | 91.4% | 80.0% | 93.2% |
| **Objectives on Examination of Immigrants and Refugees** |  |
| * Examination Initiation
 | 84% | 72% | 20.0% | 50.0% | 26.3% |
| * Examination Completion
 | 76% | 78% | 26.7% | 50.0% | 31.6% |
| * Treatment Initiation
 | 93% | 87% | 50.0% | --- | --- |
| * Treatment Completion
 | 83% | 87% | 0.0 | --- | --- |
| **Objectives on Data Reporting** |  |
| * RVCT
 | 100% | 100% | 81.5% | 78.5% | --- |
| * EDN
 | 93% | 93% | * EDN
 | 93% | 93% |
|  | **2017** | **2018** | **2019** |
| * ARPE
 | 100% | 100% | 100% | 100% | 88.9% |

**Table 1: Program Strategies, Activities, Successes, and Barriers**

|  |  |  |  |
| --- | --- | --- | --- |
| **Strategy** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| (1) | Diagnosis/treatment of persons with TB disease | 1. For hospitalized patients, health departments should review hospital records for HIV result; if no result, ask hospital to draw HIV, or draw HIV at first clinic visit
 |  | Delays in notifications of persons hospitalized with suspected TB disease; difficulty identifying if HIV was drawn in hospital;  |
| 1. Ensure that providers are aware of the reportable disease requirements and timeframes
 |  |  |
| 1. Encourage health departments to collect specimen from hospital for transport to TDH Division of Laboratory Services, when feasible
 |  |  |
| 1. Stress the importance of using X-pert for release from isolation
 |  |  |
| 1. Continue use of TDM for patients who are slow to convert AFB smears and cultures and for patients with risk factors for malabsorption
 |  |  |
| 1. Use MDDR testing when drug-resistance is suspected, when appropriate
 |  |  |
| 1. Expand use of eDOT
 | The Tennessee TB Elimination Program (TTBEP) procured the emocha® asynchronous DOT platform and trained TB staff in two (2) regions identified to serve as pilot regions. | Due to the COVID-19 pandemic, planning for implementation of emocha® in the two (2) pilot regions has not been completed. Finalization of documentation in the state’s electronic medical records system is underway. |
| Due to the COVID19 pandemic, the Tennessee TB Elimination Program (TTBEP) developed interim guidelines that relaxed the previous inclusion criteria for use of eDOT which resulted in an increase in the number of TB and TBI patients utilizing eDOT. | The emocha® asynchronous platform has not been implemented in the two (2) previously-identified pilot regions, leaving FaceTime and VSee as the only two options for eDOT statewide. |
| (2a) | Conduct contact investigations for infectious TB cases | 1. Ensure that all staff performing contact investigations are adequately trained in contact investigation (i.e., interviewing skills)
 |  |  |
| 1. Routinely review contact investigations
 |  |  |
| 1. Review and submit ARPEs to CDC
 |  |  |
| (2b) | Examination of immigrants and refugees with TB or TB infection (TBI) | 1. Partner with organizations providing primary care to immigrants and refugees
 |  |  |
| 1. Provide culturally-appropriate education
 |  |  |
| 1. Consider providing clinic-level access to EDN to regional TB program staff
 | Nashville/Davidson County receives the majority of the state’s B-notifications. The B-notification point-of-contact and nurse practitioner for that region were identified as  |  |
| 1. Identify opportunities for expanded use of 3HP or other short-course TBI regimens
 |  | Shortages of Rifapentine resulted in the TTBEP temporarily suspending placing any newly diagnosed patient with TBI on the 3HP regimen. |
| (2c) | Targeted testing and treatment of TB infection in high-risk populations | 1. Implement “Community Partnerships to End TB”
 | Introductory training sessions were held with each regional TB program; regional TB data were provided to each regional TB program; and regional TB programs submitted plans for their “Community Partnerships to End TB” project | Each regional TB plan for this initiative was reviewed by Tennessee TB Elimination Program leadership. Based on these reviews, it was evident that the goals and action steps to complete those goals were not completely comprehended by regional staff. Due to this, the initiative was placed temporarily suspended.  |
| 1. Designate a liaison from the TB program to providers who serve high-risk populations
 | Two (2) staff members from the Tennessee TB Elimination Program have been identified to serve as programmatic liaisons to organizations that serve high-risk populations:Jason Cummins, program manager: Tennessee Department of Correction (TDOC) – state prisonsDr. Jon Warkentin, medical director: Tennessee Department of Mental Health and Substance Abuse (TDMHSAS), Tennessee Sheriffs’ Association (county jails), and Tennessee Primary Care Association |  |
| 1. Identify and stratify high-risk populations for each public health region
 |  |  |
| (3) | Program planning, evaluation, and improvement | 1. Review NTIP indicators for state and regional TB programs on a quarterly basis
 |  |  |
| 1. Develop program evaluation plan using NTIP data
 |  |  |
| 1. Review best practices from other TB programs
 |  |  |
| 1. Identify areas where processes could be improved/streamlined
 |  |  |
| 1. Identify areas of duplication of effort or redundancy
 |  |  |
| (4) | Epidemiologic surveillance and response | 1. Implement QA procedures following CDC’s Quality Assurance for TB Surveillance Data Guide and Toolkit
 |  |  |
| 1. Provide ongoing training on surveillance data variables
 |  |  |
| 1. Ensure all new TB case managers and staff receive training on NBS TB Program Area Module (TB PAM)
 |  |  |
| 1. Ensure at least one (1) isolate for each culture-positive TB case is sent for genotyping
 |  |  |
| 1. Ensure at least one (1) specimen from each hospitalized patient is sent to the Tennessee Department of Health Division of Laboratory Services for testing
 |  |  |
| 1. Ensure providers are ware of reportable conditions and timeframes associated with these conditions
 |  |  |
| 1. Provide genotyping results and matching cases to regional TB programs
 |  |  |
| 1. Provide whole-genome sequencing (WGS) results to regional TB programs
 |  |  |
| 1. Ensure that TBI surveillance data are consistent with TBI variables recommended by CDC
 |  |  |
| (5) | Human resource development (HRD) and partnerships | 1. Develop training calendar for regional TB programs
 |  |  |
| 1. Ensure access to culturally-sensitive and related training for all regional TB programs
 |  |  |
| 1. Provide competency-based education and training for all regional TB programs
 |  |  |
| 1. Identify and partner with organizations that serve high-risk populations
 |  |  |
| 1. Ensure educational material is written in plain language
 |  |  |
| (6) | Laboratory strengthening | 1. Develop and implement cross-contamination/false-positive protocol
 |  |  |
| 1. Ensure specimens are received in a timely manner from date of collection to avoid batching specimen transport
 |  |  |
| 1. Improve communication and data sharing between laboratory and TB elimination program
 |  |  |
| 1. Implement QA procedures to reduce the number of transcription and documentation errors
 |  |  |
| 1. Improve reporting format for internal and external partners
 |  |  |

**Work Plan**

|  |
| --- |
| **Strategy 1: Diagnosis/Treatment of Persons with TB Disease** |
| **Related Outcomes** | **Measures of Success** |
| 1. Earlier patient diagnosis; (2) increase in TB cases with HIV results; (3) cases with drug-susceptibility testing (DST) results; and (4) patients on/responding to appropriate treatment
 | National TB objectives for case management and treatment can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm> |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| For patients with newly diagnosed TB disease for whom ≤12 months of treatment is recommended, increase the proportion who complete within 12 months | Review all case records; identify opportunities for incentives and enablers; cohort review with two (2) public health regions; review NTIP quarterly; ensure case management of all TB patients | 95% by 2024 | Weekly report is generated that tracks timeline for treatment completion; cohort review held with one (1) public health region; two (2) quarterly regional NTIP reports sent to regional TB program managers (March and June 2020); case manager documented in chart for each confirmed and suspected TB case | Scheduled cohort review with second public health region was cancelled due to COVID; patients have more extensive co-morbid conditions that may result in prolonged treatment due to medication interactions or adverse medication events |
| For TB patients with positive AFB sputum smear results, increase the proportion who initiated treatment within 7 days of specimen collection | Identify and contact providers who do not start patients on treatment within 7 days of specimen collection; ensure case management of all TB cases and suspects; review NTIP objectives quarterly | 97% by 2024 | Providers who do not start patients on treatment within 7 days of specimen collection are identified through reports and cohort reviews | Hospitalists will often collect specimens for AFB testing and (1) not start patient on empiric treatment and/or (2) notify public health in a timely manner |
| Increase the proportion of TB patients who have a positive or negative HIV test reported | Ensure case management for all TB cases and suspects; ensure HIV opt-out testing for all patients receiving a TST or QFT; educate providers on the importance of collecting HIV when testing for TB infection; quarterly cross-match with HIV program database | 98% by 2024 | Cross-matches with the HIV program database were conducted in March and June 2020; QA performed on every RVCT submitted for notification | HIV testing as part of a QFT draw is accomplished with one needle stick; drawing an HIV when administering a TST involves a second needle stick and staff may forget or the patient opts out |
| For patients whose diagnosis is likely TB disease, increase the proportion who are started on the recommended initial 4-drug regimen | Create a database of patients not started on recommended initial 4-drug therapy that includes rationale for not starting the regimen; educate providers on the importance of initiating 4-drug regimen for suspected TB; ensure access to recommended 4 drugs for all patients | 97% by 2024 | Language included in the TTBEP TB Manual about central office notification by regional TB staff any time a patient is started on an atypical (non-standard 4-drug regimen); increased communication between TTBEP leadership and state pharmacist regarding medication supply | Central office is not always notified when a patient starts on a non-standard regimen; non-public health providers are hesitant to start patients on certain medications due to age or co-morbid conditions |
| For TB patients ages ≥12 years with a pleural or respiratory site of disease, increase the proportion who have a sputum culture result reported | Ensure case management for all TB cases; identify processing laboratories for hospitals statewide; identify which commercial laboratories perform reflex testing; ensure providers are aware of reportable conditions and timeframes | 98% by 2024 |  |  |
| For patients with positive sputum culture results, increase the proportion who have documented conversion to negative within 60 days of treatment initiation | Maintain sputum culture conversion log; ensure case management for all TB cases; maintain laboratory summary log | 73% by 2024 | Sputum culture conversion log updated weekly; laboratory summary log revised to include more detailed information |  |
| **Strategy 2A: Contact Investigations for Infectious Cases** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) contacts elicited/examined and (2) contacts initiating TBI treatment | National TB objectives for contact investigation can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm> |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| For TB patients with positive AFB sputum-smear results, increase the proportion who have contacts elicited | Ensure that all staff conducting contact investigations are adequately training in contact investigation (i.e., interviewing skills); assess contact investigation data to determine if re-interviews of index case are needed | 100% by 2024 |  |  |
| For contacts to sputum AFB smear-positive TB cases, increase the proportion who are examined for infection and disease | Ensure all TB clinicians know the criteria for “fully evaluated”; ensure that contact investigations are prioritized | 93% by 2024 |  |  |
| For contacts to sputum AFB smear-positive TB cases diagnosed with LTBI, increase the proportion who start treatment | Ensure patients receive culturally-appropriate education about TB infection and progression to TB disease; ensure contacts are prioritized for treatment  | 91% by 2024 |  |  |
| For contacts to sputum AFB smear-positive TB cases who have started treatment for LTBI, increase the proportion who complete treatment | Increase use of 3HP and 4R regimens; expand use of eDOT (synchronous and asynchronous); ensure case management of all cases of TBI | 81% by 2024 |  |  |
| **Strategy 2B: Evaluation of Immigrants and Refugees with TB or TBI** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) treatment initiation for patients with TBI/prior pulmonary TB, and (2) TBI diagnoses in high-risk patients who initiate treatment | National TB objectives for the evaluation of immigrants and refugees can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm> |
| **Objectives** | **Activities**  | **Timeline** | **Successes** | **Barriers** |
| For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB, increase the proportion who initiate a medical examination within 30 days of notification | Decrease the time from notification from central office to regional TB programs; increase the number of clinic-level EDN users; provide 30-day evaluation initiation target date when B-notification paperwork is sent (**NEW ACTIVITY**) | 84% by 2024 |  |  |
| For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB, increase the proportion who complete a medical examination within 90 days of notification | Provide regional TB program managers a report that includes 90-day evaluation targets dates for each B-notification received; provide 90-day evaluation completion target date when B-notification paperwork is sent (**NEW ACTIVITY**) | 76% by 2024 |  |  |
| For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB who are diagnosed with TBI or have radiographic findings consistent with prior pulmonary TB based on examination in the U.S., for whom treatment was recommended, increase the proportion who start treatment | Ensure culturally-sensitive education is provided; partner with agencies providing primary care to immigrants/refugees; ensure providers stress the importance of TBI treatment and possibility of progressing to active disease; ensure educational materials are translated appropriately and in plain language | 93% by 2024 |  |  |
| For immigrants and refugees with abnormal chest X-rays read overseas as consistent with TB who are diagnosed with TBI or have radiographic findings consistent with prior pulmonary TB based on examination in the U.S., and who have started on treatment, increase the proportion who complete treatment | Ensure case management of patients with TBI; increase use of 3HP; increase use of incentives and enablers, when appropriate; partner with agencies providing primary care to immigrants/refugees; ensure information is provided in patient’s primary language | 83% by 2024 |  |  |
| **Strategy 2C: Targeted Testing and Treatment of TBI** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) treatment initiation for high-risk patients with TBI; (2) treatment completion for high-risk patients with TBI. Decrease in the number of TBI patients who progress to active TB disease | 1. 100% of regional TB programs in Tennessee will identify at least one high-risk population for prioritized education and testing activities; (2) At least 30% of each regional high-risk population identified will be evaluated for TB infection; (3) At least 75% of each high-risk population identified and diagnosed with TBI will start treatment; and (4) At least 65% of each high-risk population identified who start on treatment for TBI will complete treatment
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Implement “Community Partnerships to End TB” initiative statewide | Conduct meetings with leadership of each regional TB program to discuss initiative | All meetings by January 1, 2020 |  |  |
| Identify one (1) high-risk population for each public health region for prioritized education and testing | Review local/regional TB and TBI data with regional TB program manager | March 31, 2020 |  |  |
| Screen and test high-risk population | Develop a plan to screen and test high-risk population that includes culturally appropriate and plain language educational materials | December 31, 2021 |  |  |
| **Strategy 3: Program Planning, Evaluation, and Improvement** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) adoption of best practices; (2) meeting NTIP objectives; and (3) use of findings to inform policy changes and clinical practices | 1. Increase in performance on NTIP performance targets, and (2) annual review and update of TTBEP TB Manual
 |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Develop program evaluation plan | Review NTIP data; ensure objectives are SMART | Yearly (August) |  |  |
| Implement program evaluation plan | Create program evaluation team; monitor findings; report findings | Yearly (September) |  |  |
| Develop strategies to implement activities to address findings of program evaluation plan | Gather input from regional TB programs; review program evaluation plan; update TTBEP TB Manual | End of each fiscal year |  |  |
| **Strategy 4: Epidemiologic Surveillance and Response** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) accuracy and completeness of surveillance, genotyping, and WGS data; (2) linkage of genotyping and surveillance data; and (3) availability of data to inform cluster investigation. Submit TBI surveillance data to CDC | National TB objectives for data reporting can be accessed at: <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>Increase the proportion of TB patients with a positive culture result who have a MTBC genotype result reported |
| **Objectives** | **Activities** | **Timeline** | **Successes** | **Barriers** |
| Ensure completeness of each core RVCT data item reported to CDC | Provide quality assurance on each RVCT prior to submission to CDC | 100% by 2024 |  |  |
| Ensure the completeness of each core ARPE data item reported to CDC | Review contact investigation data; provide quality assurance on ARPE data | 100% by 2024 |  |  |
| Ensure the completeness of each core EDN system data item reported to CDC | Maintain state EDN database; review EDN data | 93% by 2024 |  |  |
| Report genotype cases and matches to regional TB programs | Provide genotype data and cluster snapshot data for each genotyped case | 100% within 5 days of receiving genotype results |  |  |
| Submit TBI surveillance data to CDC | Ensure state surveillance system contains all CDC-recommended TBI variables; ensure HL7 messaging | 100% of data elements by 2020 |  |  |

**Collaborations**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| 1. Collaborate with CDC programs and CDC-funded organizations
 | 1. Designated a liaison for the following programs within the Tennessee Department of Health: HIV/STD/Viral Hepatitis, Healthcare-Associated Infections (HAI), and Immunizations. Whenever possible, collaborate on presentations at programmatic conferences and other statewide meetings
 |  |  |
| 1. Partner with state HIV program to develop strategies to increase TBI treatment completion rate among persons living with HIV
 |  |  |
| 1. Collaborate with organizations no funding by CDC
 | 1. Designate a liaison for the Tennessee Department of Correction (TDOC) and Tennessee Department of Mental Health and Substance Abuse (TDMHSAS)
 |  |  |
| 1. Implement “Community Partnerships to End TB” initiative
 |  |  |

**Target Populations and Health Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Planned Program Activities** | **Accomplishments** | **Barriers** |
| 1. Collaborate with partners throughout Tennessee that serve high-risk populations
 | 1. Designate a liaison for the Tennessee Department of Correction (TDOC) and Tennessee Department of Mental Health and Substance Abuse (TDMHSAS)
 |  |  |
| 1. Provide plain language educational materials in 10 most commonly spoken languages of TB and TBI patients
 | 1. Identify 10 most commonly spoken languages of TB and TBI cases
 |  |  |
| 1. Utilize translation services contract to develop effective and culturally appropriate educational materials
 |  |  |

**PROGRAM PLANNING, EVALUATION, AND IMPROVEMENT**

1. Results and Conclusions of Prior Year’s Evaluation Activities
	1. Status of Implementation of Program Evaluation Plan
	2. Findings, Barriers, Facilitators, and Lessons Learned
2. Remediation Plan Based on Prior Year’s Program Evaluation Activities
	1. Applying Findings and Lessons Learned to Improve Program Performance
	2. Sharing Findings and Lessons Learned to Promote Program Performance
3. Background for the 2020 Program Evaluation Focus Area
	1. Rational
	2. Use of Findings and Expected Programmatic Impact
4. Program Evaluation Plan for 2020
	1. Evaluation Objectives/Key Questions
	2. Data Sources, Methods, and Timelines for Data Collection and Analysis
5. Evaluation Focal Point

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1. Cohort Review

|  |  |
| --- | --- |
| **Element** | **Progress** |
| Date(s) of cohort review(s) | February 19, 2020—Nashville/Davidson County |
| Number of cases discussed (per review/total) | 11 cases |
| Summary of review process | Case presentations were made by case managers. Contact investigation outcomes were presented by communicable disease investigators assigned to each case. Cohort data summary was presented at the conclusion of the review as well as a NTIP cohort data summary. |
| Key issues identified and resolved | 1. Gaps in sputum collection or entering information on sputa that have been collected
2. Parents refusing testing/window therapy for children identified in contact investigations
 |
| Recommendations |  |
| New tools or trainings | N/A |

**HUMAN RESOURCES DEVELOPMENT**

1. Description of Use of HRD Funds
2. Training Courses Provided
3. Training Courses Attended
4. Educational Resources Purchased or Leased
5. Educational Materials Developed
6. Description of Collaboration with Partners, Such as Those Serving High-Risk Populations
7. Attendance at the TB ETN Conference and Focal Point Meeting
8. Salary for Training and Educational Personnel

|  |
| --- |
| **Strategy 5: Human Resource Development (HRD) and Partnerships** |
| **Related Outcomes** | **Measures of Success** |
| Increase in (1) availability/accessibility of competency-based education; (2) awareness and use of HRD resources; (3) awareness of TB among patients, providers, and community; and (4) capacity to diagnose/treat high-risk populations with TBI | 1. Number of training sessions held; (2) number of trainings attended
 |
| **Objectives** | **Activities** | **Timeline**  | **Successes** | **Barriers** |
| Designate a staff member to serve as TB training and education focal point | Identify staff member to serve as TB education and training focal point | Annually |  |  |
| Register focal point as a member of the TB Education and Training Network (TB ETN) | TB ETN membership form completed an emailed to CDC | Annually |  |  |
| Identify Centers of Excellence (CoE) trainings for regional TB program staff | Sign-up for CoE newsletter and training announcements | Monthly |  |  |
| Establish partnerships with organizations that serve high-risk populations | “Community Partnerships to End TB (CPET)” initiative meetings with regional TB staff and leadership | April 30, 2020 |  |  |
| Hold bi-monthly statewide conference calls with 100% regional attendance | Provide conference call calendar to regional TB program staff | Annually |  |  |
| Plan and present a TB clinical symposium | Convene symposium planning committee to develop agenda; identify external partners willing to present at the symposium | January 31, 2020 |  |  |
| Provide quarterly new case manager trainings | Develop calendar; identify new case managers in regional TB programs | At least two (2) annually |  |  |

**PUBLIC HEALTH LABORATORY STRENGTHENING**

1. Laboratory Organizational Chart



**Laboratory Contact**

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1. Description of Methods Used and Testing Algorithm

|  |  |
| --- | --- |
| **Test Method** | **Description** |
| Cepheid GeneXpert® | The GeneXpert® Dx System integrates and automates sample processing, nucleic acid amplification, and detection of the target sequences in simple or complex samples using real-time PCR and reverse transcriptase PCR. It consists of a self-contained test cartridge that eliminates cross-contamination between samples. Assay includes reagents for detection of *M. tuberculosis* and Rifampin (RIF) resistance as well as a sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR reaction. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. Testing is performed on all new acid-fast bacilli (AFB) smear-positive samples, as well as any smear-negative samples that are requested by the TTBEP. |
| DNA Probe | The GEN-PROBE® ACCUPROBE® identification test is a rapid DNA probe test that utilizes the technique of nucleic acid hybridization for culture identification of *M. tuberculosis* complex. This testing is only performed when a GeneXpert® positive sample occurs for fast tracking of drug-susceptibility testing (DST). |
| LiPA | LiPA is based on the reverse hybridization principle. Biotinylated DNA material is hybridized with specific oligonucleotide probes immobilized as parallel lines on membrane-based strips. After hybridization, streptavidin labeled with alkaline phosphatase is added and bound to any biotinylated hybrid previously formed. Incubation with 5-bromo-4-chloro-3-indolyl phosphate and nitroblue tetrazolium (BCIP/NBT) chromogen results in purple/brown precipitate. To perform the LiPA, amplification of the 16S-23S ribosomal rRNA spacer region should be carried out. Amplification products are subsequently hybridized using 1 typing strip onto which 22 parallel DNA probe lines and 2 control lines are fixed. This method is used to identify mixed or contaminated cultures only. |
| MALDI-TOF (matrix-assisted laser desorption/ionization) | MALDI-TOF is a mass spectrometry process that transforms the proteins and peptides of a microorganism into positively-charged ions. The samples are analyzed from a fresh culture and then transferred to a selected position onto the sample plate. Each sample will have matrix added which absorbs the laser energy and transfers protons to the intact proteins or peptides in the gas phase. These ions become electrostatically accelerated and travel through the flight tube. Each ion’s mass will determine the speed at which it travels through the flight tube to the detector. The system measures the time (nanosecond range) between the pulsed acceleration and the detector signal of ions. The time is then converted into an exact molecular mass. Each organism has a unique “molecular fingerprint” that identifies it. The acquired mass spectra is then transformed to a peak list and compared to the reference library. All suspect Mycobacterium samples will undergo the Mycobacterial Extract protocol requiring heat inactivation |



1. Work Plan

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| --- |
| **Laboratory Element 1: Ensure availability of high-quality and prompt core laboratory services for tuberculosis (TB)** |
| **Objectives** | **Measures of Success** |
| Reduce turnaround times (TAT) | * 65% of specimens will be received within one (1) day of collection
* Report drug-susceptibility testing results for 75% of all isolates within 17 days of identification
* Report NAAT results within 48 hours for 85% of specimens received
* Report smears within 24 hours of specimen receipt for 85% of specimens received
* Improve TAT to 65% of Mtbc isolates reported within 21 calendar days of specimen receipt
 |
| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** |
| Drug-susceptibility testing (DST) | Report DST results within 17 days of identification | Growth rate of organism | Natasha Lindahl, TB Lab Supervisor | December 2024 |
| NAAT |  |  |  |  |
| Improve reporting format to promptly transmit results electronically or via fax | Report AFB smear results within one (1) day of receipt | Current LIMS system does not generate reports in real-time; not all providers have the ability to receive results electronically or via fax | Natasha Lindahl, TB Lab Supervisor | December 2024 |
| Organism identification | Report Mtbc isolates within 21 calendar days of specimen receipt | Mixed or contaminated cultures | Natasha Lindahl, TB Lab Supervisor | December 2024 |
| Monitor batch specimens (≥2 specimens received on the same day from the same patient) from all public health departments | Receipt within one (1) day of collection | Weekends/holidays | Natasha Lindahl, TB Lab Supervisor | December 2024 |

**[RESERVED FOR LAB WORKLOAD PDF]**

**[RESERVE FOR LAB TAT PDF]**

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| **Laboratory Element 2: Promote continual advancement of laboratory efficiency and quality assurance through the use of local data (i.e., your laboratory-specific data)** |
| **Objectives** | **Measures of Success** |
| Reduce laboratory pre- or post-analytical error rates | * Implementation of cross-contamination protocol to guide lab staff and TTBEP staff
* Decrease transcription or documentation errors made by lab staff by 5%
 |
| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** |
| Develop a universal cross-contamination SOP for lab and TTBEP staff | Completion and implementation of cross-contamination procedure with approval from laboratory director and TTBEP leadership | None | Dorothy Baynham, TB Lab Manager | December 2020 |
| Reduce transcription and documentation errors by laboratory personnel | Reduce the number of transcription or data entry errors by laboratory personnel by 5%; perform various quality assurance monitors throughout the year to verify accuracy of test requests, specimen submission, and accuracy in test reporting formats | Equipment interfacing with current LIMS system | Natasha Lindahl, TB Lab Supervisor | December 2024 |

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| **Laboratory Element 3: Collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information** |
| **Objectives** | **Measures of Success** |
| Increase collaboration with internal and external partners | * Recorded sign-in sheets, agenda, and minutes from meetings with TTBEP leadership
* Distribution of unsatisfactory logs to TTBEP program manager and regional TB programs
* Ensuring laboratory module of TB Program Manual is revised to reflect up-to-date procedures and tests
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| **Activities** | **Measure of Success** | **Anticipated Obstacles** | **Responsible Laboratory Staff** | **Target Completion Date/Timeline** |
| Conduct a minimum of six (6) meetings (either in-person or by conference call) with TTBEP leadership | Have all meetings schedule by mid-year | Availability of staff; coordination of staff schedules; limitation of in-person meetings due to COVID | Dorothy Baynham, TB Lab Manager | December 2024 |
| Provide monthly communication logs for unsatisfactory smear and culture submissions and GeneXpert testing to TTBEP leadership | Distribution of the document to TTBEP leadership by the last working day of each month | None | Dorothy Baynham, TB Lab Manager | December 2024 |
| Provide a weekly drug-susceptibility testing (DST) log to TTBEP leadership for all pending and completed TB susceptibilities | Distribution of the document to TTBEP by the end of the month | None | Dorothy Baynham, TB Lab Manager | December 2024 |
| Attend or contribute to the annual TTBEP statewide meeting | Attendance and/or presentation at the meeting | Travel and meeting bans for state employees during COVID  | Dorothy Baynham, TB Lab Manager | December 2024 |
| Review and update lab module of TTBEP TB Manual | Submission of revisions | None | Dorothy Baynham, TB Lab Manager | December 2020 |