Introduction

CONTENTS

About the *Montana Tuberculosis Program Manual*

Purpose

This manual is designed to present the key steps and crucial information needed to perform tuberculosis (TB) control tasks in states in which TB occurs with a low incidence—defined by the Centers for Disease Control and Prevention (CDC) as less than 3.5 cases/100,000 population/year.[1] Where additional or more detailed information is available, hyperlinks to CDC guidelines and other resources are provided.

The *Montana Tuberculosis Program Manual* is based on a template created by an advisory group convened during CDC Task Order #6. The advisory group developed the template's format and created its content by reviewing other TB control manuals, current CDC guidelines, and needs in the four low-incidence states of Idaho, Montana, Utah, and Wyoming.

Audience

The audience for this manual includes city/county/regional public health nurses, outreach workers, physicians, and public health officers; Indian Health Services (IHS) staff; physician consultants; private sector physicians; infection control nurses in hospitals and other facilities; disease intervention specialists; state epidemiologists; and state TB program staff.

How to Use This Manual

Portable Document Format

This manual is available electronically as a portable document format (PDF) file. To view the PDF file, you will need the free Adobe Reader.

Hyperlinks

When viewing this manual online with an Internet connection, you can go directly to underlined Web addresses by clicking on them.

Cross-References

When viewing this manual electronically, you can go directly to other sections or topics in the manual by clicking on text next to this icon:

Forms

Required and recommended forms are available on the CDEpi Resource Page for Public Health. For more information on these forms, contact us at 406-444-0273.

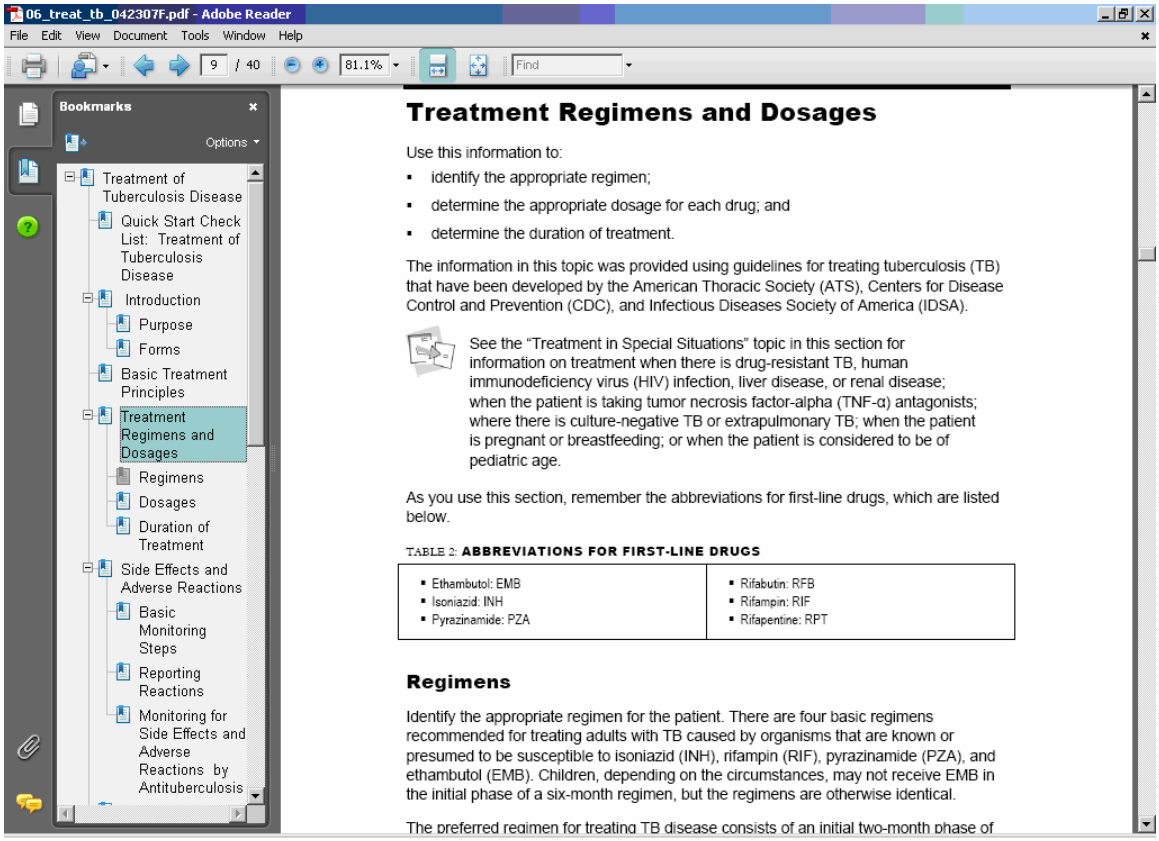
Bookmarks

In PDF files, you can use bookmarks to go quickly to a section or topic. If the bookmarks are not visible on the left, click the Bookmarks icon or tab on the left of the window.

To view sections and topics in the bookmarks list:

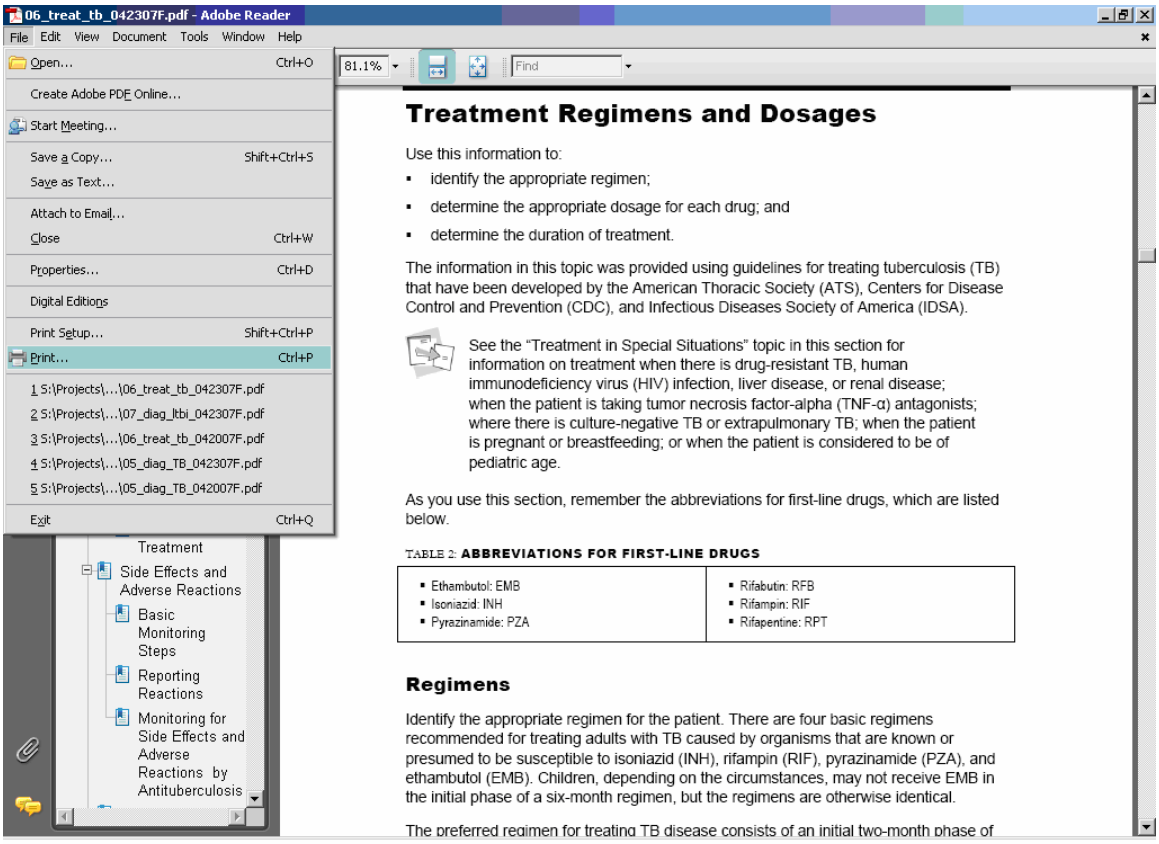
- Click + to see a more detailed list.
- Click – to hide the more detailed list.

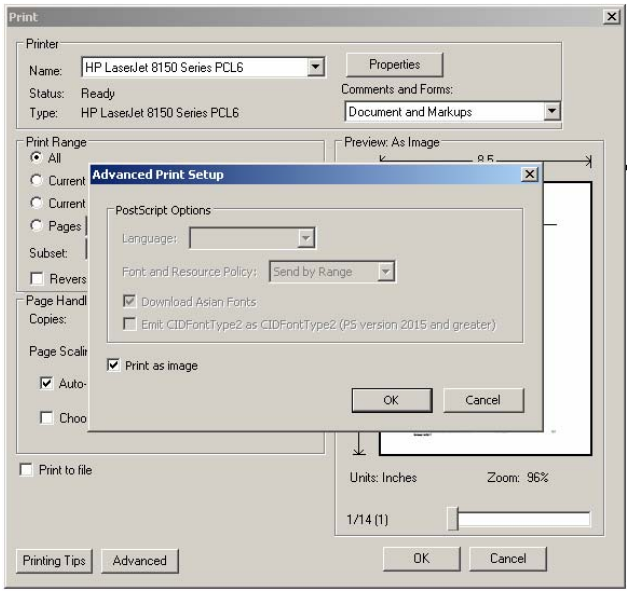
To go to a section or topic in the bookmarks list, point to its name and left-click.



Printing

To access the print dialog box, click the File drop-down menu, click Print, and then make your selections in the Print dialog box.





Some printers have older printer drivers that cause spaces to appear in the middle of words. To avoid this problem, click File/Print, click the Advanced button, check Print as Image, and then click OK. If you need further assistance with printing, call the Francis J. Curry National Tuberculosis Center's IT staff at 415-502-5810.

Icons

Throughout the manual, these icons quickly cue you about important information and other resources:

This warns about high-consequence information you must understand when performing the task.

This signals when you should call to report or to consult on the task.

This highlights special considerations for pediatric patients.

This suggests another relevant area in the manual or another resource that you may want to review.

This alerts you that a form is available for the task.

Abbreviations

Refer to the list below for abbreviations used in the manual.

ACET	Advisory Council for the Elimination of Tuberculosis
ACH	air changes per hour
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
AII	airborne infection isolation
ALT	alanine aminotransferase
ARPE	*Aggregate Report for Program Evaluation*
ART	antiretroviral therapy
AST	aspartate aminotransferase
ATS	American Thoracic Society
BAMT	blood assay for *Mycobacterium tuberculosis*
BCG	Bacille Calmette-Guérin
CDC	Centers for Disease Control and Prevention
CT	computed tomography
CXR	chest radiograph
DNA	deoxyribonucleic acid
DOT	directly observed therapy
DTBE	Division of Tuberculosis Elimination
DTH	delayed-type hypersensitivity
ED	emergency department
EMB	ethambutol
EMS	emergency medical service
ESRD	end-stage renal disease

FDA	U.S. Food and Drug Administration
HAART	highly active antiretroviral therapy
HCW	healthcare worker
HEPA	high-efficiency particulate air
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
IDSA	Infectious Diseases Society of America
IGRA	interferon gamma release assay
INH	isoniazid
LTBI	latent tuberculosis infection
M. tuberculosis	*Mycobacterium tuberculosis*
MDR-TB	multidrug-resistant tuberculosis
MIRU	mycobacterial interspersed repetitive units
MOTT	mycobacterium other than tuberculosis
NAA	nucleic acid amplification
NIOSH	National Institute for Occupational Safety and Health
NNRTI	nonnucleoside reverse transcriptase inhibitors
NTCA	National Tuberculosis Controllers Association
NTNC	National Tuberculosis Nurse Coalition
NTM	nontuberculous mycobacteria
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
PCR	polymerase chain reaction
PI	protease inhibitor
PPD	purified protein derivative
PZA	pyrazinamide
QA	quality assurance

QFT	QuantiFERON®-TB test
QFT-G	QuantiFERON®-TB Gold test
RFB	rifabutin
RFLP	restriction fragment length polymorphism
RIF	rifampin
RNA	ribonucleic acid
RPT	rifapentine
RVCT	*Report of Verified Case of Tuberculosis*
RZ	rifampin and pyrazinamide
TB	tuberculosis
TIMS	Tuberculosis Information Management System
TNF-α	tumor necrosis factor-alpha
TST	tuberculin skin test
TU	tuberculin units
USCIS	U.S. Citizenship and Immigration Services
UVGI	ultraviolet germicidal irradiation

Purpose of Tuberculosis Control

Tuberculosis (TB) is caused by a bacterial organism named *Mycobacterium tuberculosis.* (These organisms are sometimes called tubercle bacilli.) Mycobacteria can cause a variety of diseases. Some mycobacteria are called tuberculous mycobacteria because they cause TB or diseases similar to TB. These mycobacteria are *M. tuberculosis, M. bovis,* and *M. africanum.* Other mycobacteria are called nontuberculous mycobacteria (NTM) because they do not cause TB. One common type of nontuberculous mycobacteria is *M. avium* complex. Tuberculous mycobacteria readily spread from person to person; nontuberculous mycobacteria do not usually spread from person to person.

The goal of TB control in the United States is to reduce TB morbidity and mortality by

- preventing transmission of *M. tuberculosis* from persons with contagious forms of the disease to uninfected persons, and
- preventing progression from latent TB infection (LTBI) to active TB disease among persons who have contracted *M. tuberculosis* infection.[2]

For information on the transmission of *M. tuberculosis* and on how LTBI progresses to TB disease, see the Centers for Disease Control and Prevention's (CDC's) online course *Interactive Core Curriculum on Tuberculosis* (2004).

The four fundamental strategies to reduce TB morbidity and mortality are

1. early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment;
2. identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen;
3. identification of other persons with latent TB infection at risk for progression to TB disease, and treatment of those persons with an effective drug regimen; and
4. identification of settings in which a high risk exists for transmission of *M. tuberculosis* and application of effective infection control measures.[3]

For more information on these strategies and the thinking behind them, see "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (*MMWR* 2005;54[No. RR-12]).

Montana Laws and Rules on Tuberculosis Control

Montana laws and rules on tuberculosis (TB) are located in the Montana Code Annotated (MCA) and the Administrative Rules of Montana (ARM).

In the MCA, see Chapter 17 (Tuberculosis Control) in Title 50 (Health and Safety) found in Part 1-Tuberculosis Control.

In the ARM, see Subchapter 10 (Tuberculosis Control) in 37.114.1001–37.114.1016 found at this link.

Contact the Montana TB Program at 406-444-0273 for assistance with interpreting Montana laws and rules regarding TB control.

Montana and National Objectives

Montana Tuberculosis Program Objectives—2009

Below are state tuberculosis (TB) program objectives. Each objective is targeted by the Montana TB Program for 2009, based on Montana's epidemiology and recent program performance.

TABLE 1: MONTANA TUBERCULOSIS PROGRAM OBJECTIVES

Treatment and Case Management
By 2009 **1.** At least 95% of patients with newly diagnosed tuberculosis (TB), for whom therapy for 12 months or less is indicated, will complete therapy within 12 months. **2.** Drug susceptibility results will be reported for all newly reported, culture-positive TB cases. **3.** Human immunodeficiency virus (HIV) status will be reported for at least 85% of all newly reported TB cases age 25–44.
Contact Investigation
By 2009 **1.** Contacts will be identified, for at least 95% of newly reported sputum acid-fast bacilli (AFB) smear-positive TB cases. **2.** At least 95% of contacts to sputum AFB smear-positive TB cases will be evaluated for infection and disease. **3.** At least 80% of contacts who are infected with latent TB infection (LTBI) will start therapy. **4.** At least 80% of infected contacts who are started on treatment for LTBI will complete therapy.
Surveillance
By 2009 **1.** All newly diagnosed cases of TB will be reported to Centers for Disease Control and Prevention (CDC) using the system developed by CDC. There will be at least 98% completeness for the key variables in the expanded *Report of Verified Case of Tuberculosis* (*RVCT*). **2.** At least 90% of all locatable immigrants and refugees designated as B1 or B2 will be appropriately evaluated within 45 days of notification of arrival by the CDC Division of Quarantine.

National Program Objectives

Below are the Centers for Disease Control and Prevention (CDC) program objectives, current as of December 2006.[4]

TABLE 2: NATIONAL PROGRAM OBJECTIVES AND PERFORMANCE TARGETS[5]

Indicator		National TB Program Objectives and Performance Targets
1	Percent completion of treatment	Increase timely completion of treatment National Objective: At least 93% of patients with newly diagnosed tuberculosis (TB), for whom therapy for 12 months or less is indicated, will complete treatment within 12 months by 2015.
2	TB case rate	Decline in TB rates a. National Objective: The average yearly decline in TB rates in US-born will be >11%. b. National Objective: The average yearly decline in TB rates in foreign-born will be >4%. c. National Objective: The TB rate in US-born will be <0.7 cases/100,000 by 2015. d. National Objective: The TB rate in foreign-born will be <14 cases/100,000 by 2015. e. National Objective: The TB rate in US-born black non-Hispanics will be <1.3 cases/100,000 by 2015. f. National Objective: The TB rate in children <5 years of age will be <0.4/100,000 by 2015.
3	Thorough contact investigations	Improve contact identification, evaluation, and treatment a. National Objective: All sputum-AFB-smear-positive TB cases will have at least one contact listed by 2015. b. National Objective: At least 93% of contacts to sputum-AFB-smear-positive TB cases will be evaluated for infection and disease by 2015. c. National Objective: At least 88% of infected contacts will start treatment by 2015. d. National Objective: At least 79% of contacts who start treatment will complete treatment.

Indicator		National TB Program Objectives and Performance Targets
4	Timely laboratory reporting	Ensure timely laboratory reporting a. National Objective: State public health labs will report 100% of results of culture identification of *M. tuberculosis* complex to submitter and state TB program within 21 days of receipt of specimen by 2015. b. National Objective: Increase the percentage of TB patients with initial positive cultures who also are tested for and receive drug susceptibility results to 100% by 2015.

Source: National TB Indicators Project. *Initial Indicators and Performance Targets.* Atlanta, GA: CDC Division of Tuberculosis Elimination; November 1, 2006. [Cleared by CDC but unpublished as of December 2006.]

In addition to the national program objectives listed above, the CDC has two goals (listed below) that do not have national program objectives established at this time. Specific objectives relating to these two goals will be established in the future.

1. National Goal: Increase the percentage of immigrants and refugees designated as Class A, B1, or B2 who are appropriately evaluated and treated.
2. National Goal: For jurisdictions with greater than 50 reported cases of TB occurring annually in U.S.-born African Americans, decrease the case rate.

Standards

Program standards are what the stakeholders of the TB program would consider to be "reasonable expectations" for the program. For TB, standards have been established by nationally accepted authorities, such as the American Thoracic Society (ATS), the Infectious Diseases Society of America (IDSA), and the CDC, and generally recognized TB control experts, such as the National Tuberculosis Nurse Coalition (NTNC) and the National Tuberculosis Controllers Association (NTCA). Many state programs, and some local TB control programs, have established their own standards and objectives for case management.[6]

The standards of care for the medical treatment and control of TB are published jointly by the ATS, IDSA, and CDC. These standards should be available for reference by each TB staff member.

The standards are included in the following guidelines:

- ATS, CDC, IDSA. "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (*MMWR* 2005;54[No. RR-12]).
- ATS, CDC, IDSA. "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" (*Am J Respir Crit Care Med* 2000;161[4 Pt 1]).
- ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]).
- CDC, NTCA. "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC" (*MMWR* 2005;54 [No. RR-15]).
- CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]).
- CDC. "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection" (*MMWR* 2000;49[No. RR-6]).

For additional guidelines, see the Division of Tuberculosis Elimination's "TB Guidelines" Web page (Division of Tuberculosis Elimination Web site; accessed November 25, 2006).

Montana Evaluation Plan 2006–2007

The evaluation goal is to evaluate the success in increasing the documentation of culture conversion for pulmonary TB cases to 80%.

The target population includes all culture-positive, pulmonary TB cases reported in the state of Montana. Those excluded from the data evaluation will include cases in which there is documented evidence that an adequate effort was made to collect sputum and the patient was unable to do so.

The objective of the program is to increase the documentation of culture conversion of pulmonary TB cases from 60% to 80%. Included in the evaluation will be AFB smear negative and AFB smear positive pulmonary TB cases whose initial diagnosis was determined through culture confirmation. Excluded from the evaluation will be nonpulmonary cases and pulmonary cases in whom the inability to produce a satisfactory sputum specimen is documented.

The evaluation findings will be used by the Montana TB Program manager, the laboratory technical supervisor, local health department public health nurses (tribal, county, and Indian Health Service), and private providers to measure statewide success in increasing the documentation of culture conversion for pulmonary TB cases. The findings will provide feedback on case management and follow-up of cases, along with directions for improvement. The results will be published and presented at statewide training/educational workshops.

The evaluation program findings will be instrumental in improving the rate of collection and documentation of culture conversion for pulmonary TB cases. The findings will help the Montana TB Program identify the most effective strategies for improving rates of culture conversion and will help public health nurses focus their limited time, money, and energy on strategies that work.

The Montana TB Program will share the lessons learned and the evaluation findings with stakeholders.

Roles, Responsibilities, and Contact Information

Montana Tuberculosis Program Staff

TABLE 3: MONTANA TUBERCULOSIS PROGRAM STAFF ROLES, RESPONSIBILITIES, AND CONTACT INFORMATION

Roles and Responsibilities	Contact Information
Role and Responsibilities of Montana Tuberculosis Program Staff The Montana Tuberculosis Program manager ensures compliance with applicable public health laws and regulations related to tuberculosis (TB) reporting and control. The Montana TB Program conducts statewide TB surveillance, data evaluation, and development of policies and guidelines for the control and/or elimination of TB in the state. The Montana TB Program coordinates between local and other state jurisdictions and consults on all aspects of TB prevention and control, including case management, contact investigation, and outbreak investigation. In addition, the Montana TB program provides training and education and maintains programs for providing drug treatment, latent TB infection treatment, and incentives/enablers.	Position Vacant Montana Tuberculosis Program Manager Department of Public Health & Human Services Cogswell Building, Room C216 1400 Broadway Street, Helena, MT 59620 Tel: 406-444-0273 Fax:406-444-0272

Local Public Health Agencies and Private Medical Providers

TABLE 4: LOCAL PUBLIC HEALTH AGENCIES' AND PRIVATE MEDICAL PROVIDERS' ROLES AND RESPONSIBILITIES

Local Public Health Agencies	Private Medical Providers
Role and Responsibilities of Local Public Health Agencies Local public health agencies are responsible for receiving reports of suspected or confirmed cases of tuberculosis (TB) within their jurisdictions and reporting these to the Montana TB Program. Local public health departments are required through the Montana Code Annotated (MCA) to ensure that TB cases within their jurisdictions are appropriately isolated (if necessary) and treated until cured. In addition, local public health departments must perform contact investigations surrounding infectious/potentially infectious TB cases. Regular reporting of case management findings and contact investigation results must be submitted to the Montana TB Program. Local public health agencies also conduct targeted testing and treatment of high-risk populations and individuals.	Role and Responsibilities of Private Medical Providers Medical providers in Montana are required to report suspected or confirmed TB cases to their local public health departments. In addition, providers need to coordinate care and treatment of patients with the local health department jurisdictions, who by Montana law are required to ensure that TB cases are appropriately managed for public health reasons. Private providers must provide all information related to or important to the diagnosis and treatment of TB to the local public health department. Together with the local public health department, the private provider assumes responsibility for the successful completion of therapy of the TB patient.

State Laboratory

TABLE 5: ROLE, RESPONSIBILITIES, AND CONTACT INFORMATION OF THE STATE LABORATORY

Role and Responsibilities	Contact Information
State Laboratory The Montana Public Health Laboratory (MTPHL) provides tuberculosis diagnostic services that are a vital part of the Montana Tuberculosis Program. The MTPHL is the only facility in the state providing full diagnostic tuberculosis services, including AFB smear; culture isolation, identification, and susceptibility testing; and TB direct detection by nucleic acid probe. In addition, the MTPHL provides consultation, training, and referral services to other laboratories performing TB diagnostic services within the state.	**Deborah Gibson** Laboratory Manager Microbiology and Molecular Diagnostics Montana Public Health Laboratory Department of Public Health & Human Services Street address: Cogswell Building 1400 Broadway Street Helena, MT 59620 Mailing address: P.O. Box 6489 Helena, MT 59604 Tel: 800-821-7284 and 406-444-3444 Fax: 406-444-1802

Resources and References

Resources

- CDC. “Framework for Program Evaluation in Public Health” (*MMWR* 1999;48[No. RR-11]).
- Division of Tuberculosis Elimination. *A Guide to Developing a TB Program Evaluation Plan* (Division of Tuberculosis Elimination Web site; accessed November 1, 2006).
- Division of Tuberculosis Elimination. *Understanding the TB Cohort Review Process: Instruction Guide* (Division of Tuberculosis Elimination Web site; accessed November 1, 2006).
- Francis J. Curry National Tuberculosis Center. *Quality Improvement for TB Case Management: An Online Course* (Francis J. Curry National Tuberculosis Center Web site; accessed November 1, 2006).
- New Jersey Medical School National Tuberculosis Center. *Planning & Implementing the TB Case Management Conference: A Unique Opportunity for Networking, Peer Support and Ongoing Training* (Newark, NJ; 2004).

References

[1] CDC. Progressing toward tuberculosis elimination in low-incidence areas of the United States: recommendations of the Advisory Council for the Elimination of Tuberculosis. *MMWR* 2005;51(No. RR-5):1.

[2] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):14.

[3] ATS, CDC, IDSA. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54(No. RR-12):15.

[4] National TB Indicators Project. *Initial Indicators and Performance Targets.* Atlanta, GA: CDC Division of Tuberculosis Elimination; November 1, 2006. [Cleared by CDC but unpublished as of December 2006.]

[5] National TB Indicators Project. *Initial Indicators and Performance Targets.* Atlanta, GA: CDC Division of Tuberculosis Elimination; November 1, 2006. [Cleared by CDC but unpublished as of December 2006.]

[6] Division of Tuberculosis Elimination. National Center for HIV, AIDS and Tuberculosis Prevention, Centers for Disease Control and Prevention. *A Guide to Writing a TB Program Evaluation Plan* [Division of Tuberculosis Elimination Web site]:24. Accessed November 1, 2006.