

Laboratory Services

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Introduction

Purpose

Use this section to

- get contact information for laboratories;
- determine which tests are available and the tests' turnaround times; and
- identify which laboratory can perform a specific test.

The diagnosis of tuberculosis (TB), management of patients with the disease, and public health TB control services rely on accurate laboratory tests. Laboratory services are an essential component of effective TB control, providing key information to clinicians (for patient care) and public health agencies (for control services).¹

Policy

Public health laboratories should ensure that clinicians and public health agencies within their jurisdictions have ready access to reliable laboratory tests for diagnosis and treatment of TB.²

Effective TB control requires timely, complete, and accurate communication among the laboratory system, TB control program, and healthcare provider.³



For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.

Laboratory Contact Information

To locate and contact a laboratory, refer to Table 1: **Laboratory Contact Information**. For the list of the tests performed at each laboratory, refer to Table 2: **Available Laboratory Tests**.

TABLE 1: LABORATORY CONTACT INFORMATION

Roles and Responsibilities	Contact Information
<p>State Laboratory Full-service mycobacteriology laboratory. Accepts primary specimens and referral isolates for identification and susceptibility testing of <i>Mycobacterium tuberculosis</i>. Serves as a consultant for questions involving mycobacterium laboratory testing.</p>	<p>Montana Public Health Laboratory Susanne Zanto, CLS (NCA), SM (NRM) Laboratory Manager Microbiology and Molecular Diagnostics Street address: 1400 Broadway, Helena, MT 59620 Mailing address: P.O. Box 6489, Helena, MT 59604 Tel: 800-821-7284 and 406-444-3444 Fax: 406-444-1802 Email: szanto@mt.gov</p>
<p>Private Laboratories Provide primary specimen smear and culture for mycobacterium. Refer isolates for identification and susceptibility testing.</p> <p>Benefis Healthcare Rich Luoma Microbiology Supervisor 1101 26th Street South, Great Falls, MT 59405 Tel: 406-455-5445 Fax: 406-455-4970 Email: luomricl@benefis.org</p>	<p>St. Patrick Hospital Dennis Grasseschi Microbiology Supervisor P.O. Box 4587, Missoula, MT 59806 Tel: 406-543-7271 ext 2207 Fax: 406-329-5676 Email: dgrasses@saintpatrick.org</p> <p>St. Vincent's Healthcare Lowell Temme Microbiology Supervisor 1233 North 30th Street, Billings, MT 59101 P.O. Box 35200, Billings, MT 59107 Tel: 406-237-8000 Fax: 406-237-8098 Email: lowell.temme@svh-mt.org</p>

Available Laboratory Tests

The laboratory tests listed below in Table 2 are available where noted.

When performing tests for the diagnosis of mycobacterial infection, both acid-fast bacilli smear and culture must be ordered. Culture identification is automatically performed on any isolate, and first-line susceptibility testing is automatically performed on all initial *Mycobacterium tuberculosis* complex isolates. Nucleic acid amplification testing is ordered on an individual basis.

TABLE 2: AVAILABLE LABORATORY TESTS

Test	Laboratory	Turnaround Time
Diagnosis		
QuantiFERON®-TB Gold (QFT-G)	Not currently available.	
Acid-fast bacilli (AFB) smear	Montana Public Health Laboratory, Benefis Healthcare, St. Patrick Hospital, St. Vincent's Healthcare	On site testing: within 24 hours from receipt in laboratory Off-site testing: within 24 hours from receipt of specimen in laboratory (time from specimen collection to laboratory receipt should be 24 hours or less)
Culture	Montana Public Health Laboratory, Benefis Healthcare, St. Patrick Hospital, St. Vincent's Healthcare	Cultures are incubated for up to 6 weeks before reporting as negative. Time to detection of mycobacterial growth is dependent on growth rate. Ideally, growth of <i>Mycobacterium tuberculosis</i> should be detected within 14 days of specimen inoculation, although this is dependent on many factors.
Culture identification	Montana Public Health Laboratory	Ideally, <i>M. tuberculosis</i> complex should be identified within 21 days of specimen inoculation.

Test	Laboratory	Turnaround Time
Drug susceptibility	Montana Public Health Laboratory	Ideally, results of first-line drugs should be available within 30 days from specimen receipt in the laboratory, but this is dependent on many factors (for example, growth rate, presence of a pure culture).
Nucleic acid amplification (NAA) test	Montana Public Health Laboratory	Within 48 hours from laboratory receipt of specimen
Treatment Monitoring		
Hepatic enzymes or up to 8 clinical, multichannel chemistry panel (that includes aspartate aminotransferase [AST], alanine aminotransferase [ALT], lactate dehydrogenase [LDH], total and direct bilirubin, alkaline phosphatase, uric acid, and calcium)	Available at most local clinical laboratories	Usually available same day
Uric acid	Available at most local clinical laboratories	Usually available same day
Complete blood count (CBC) and platelets	Available at most local clinical laboratories	Usually available same day
Kidney function	Available at most local clinical laboratories	Usually available same day
Epidemiologic Monitoring		
Genotyping	Montana Public Health Laboratory for referral to the California State Public Health Laboratory. (Referral is automatic.)	2 to 4 weeks from specimen receipt

Laboratories should report positive smears or positive cultures, and primary healthcare providers should report suspected or confirmed cases of TB to the health department, as specified in the “Reporting Tuberculosis” topic in the Surveillance section. Prompt reporting allows the health department to organize treatment and case management services and to initiate a contact investigation as quickly as possible.⁴



For information on reporting, see the “Reporting Tuberculosis” topic in the Surveillance section.



For a list of all of the services available, see the on-line version of the *MTPHL Laboratory Services Manual*.



For laboratory services available in Montana, contact Susanne Zanto, Laboratory Manager, Microbiology and Molecular Diagnostics, at the Montana Public Health Laboratory at 800-821-7284 or 406-444-3444.

Specimen Collection



For an explanation of proper specimen collection and submission, see the on-line version of the *MTPHL Laboratory Services Manual*.

Sputum is phlegm from deep in the lungs. The important characteristics needed in sputum specimens are freshness and actual sputum, rather than saliva. An early morning specimen is best, so when collecting a set of three sputum specimens, at least one of them should be an early morning specimen.

To isolate mycobacteria from clinical materials successfully, handle specimens carefully after collection. For optimal results, collect specimens in clean, sterile containers and keep them in conditions that inhibit the growth of contaminating organisms, since most specimens will contain bacteria other than mycobacteria.⁵

Refer to Table 3 to review the methods used to collect various specimens and the type of specimens obtained for pulmonary tuberculosis (TB).



During procedures in which aerosols may be produced, use appropriate respiratory protection and environmental controls. For more information, refer to the CDC's "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]).

TABLE 3: SPECIMEN COLLECTION METHODS AND TYPES FOR PULMONARY TUBERCULOSIS

Pulmonary Tuberculosis	
Collection Method	Specimen Type
<p>Spontaneous sputum collection occurs when the patient can cough up sputum without extra assistance.</p>	<ul style="list-style-type: none"> ▪ 5–10 ml of sputum from deep in the lung
<p>Induced sputum collection should be considered if a patient needs assistance in bringing up sputum.*</p>	<ul style="list-style-type: none"> ▪ 5–10 ml of sputum from deep in the lung
<p>Gastric aspirates can be submitted for the diagnosis of pulmonary tuberculosis (TB) in young children who cannot produce sputum.</p>	<ul style="list-style-type: none"> ▪ 50 ml of gastric contents
<p>Bronchoscopy can be used in the following situations:</p> <ul style="list-style-type: none"> ▪ If a patient cannot produce sputum by the above three methods⁶ or ▪ If a patient has a substantial risk of drug-resistant TB and has initial routine studies that are negative⁷ or ▪ In a patient in whom there is suspicion of endobroncheal TB⁸ or ▪ If a variety of clinical specimens for the diagnosis of pulmonary TB or other possible diseases need to be obtained 	<ul style="list-style-type: none"> ▪ Bronchial washings ▪ Bronchoalveolar lavage ▪ Transbronchial biopsy
<p>* It is important to specify if the sputum is induced or not, because induced sputum is “more watery” and appears to be just saliva. Some laboratories may throw out induced sputum and report it as an inadequate specimen.</p>	

Refer to Table 4 for collection methods and specimen types for extrapulmonary TB.

TABLE 4: SPECIMEN COLLECTION METHODS AND TYPES FOR EXTRAPULMONARY TUBERCULOSIS

Extrapulmonary Tuberculosis		
Collection Method	Specimen Type	
Extrapulmonary specimen collection from tissue and other body fluids can be submitted for the diagnosis of extrapulmonary tuberculosis.	Examples of tissues (biopsy)* <ul style="list-style-type: none"> ▪ Lymph node ▪ Pleural ▪ Bone/joint ▪ Kidney ▪ Peritoneal ▪ Pericardial 	Examples of fluids <ul style="list-style-type: none"> ▪ Pleural ▪ Cerebrospinal ▪ Blood ▪ Urine ▪ Synovial ▪ Peritoneal ▪ Pericardial
* Do not place specimens in formalin.		

How to Perform Spontaneous Sputum Collection at a Healthcare Facility

1. Collect the specimen in a specialized room or booth designed for cough-inducing procedures.
2. Instruct the patient on how to collect the sputum sample.
 - a. Put a mark at the 5 ml level on the sputum tube (if not already marked) to show the patient the minimum amount of sputum needed. (Most laboratories consider 5 to 10 ml an adequate amount.)
 - b. Review with the patient how to collect sputum.
3. Make sure the specimen container and laboratory requisition are filled out completely before shipping.
 - a. On the specimen container, record the patient name and the date and time of collection.
 - b. Use the blue “Montana Standard Laboratory Requisition” form.



It is especially important to **specify if the sputum is induced or not**, because an induced sputum generally is “more watery” and appears to be just saliva. Some private laboratories may throw out the specimen and report it as an “inadequate specimen.”

4. Make sure the specimen and laboratory requisition are packaged into appropriate shipping containers, per laboratory instructions.



Refer to the “Specimen Collection and Shipment Supplies” topic in the Supplies, Materials, and Services section, and see the “Specimen Shipment topic,” which follows.

5. If possible, send the specimen on the day it is collected. If this is not possible, refrigerate the specimen until it is sent on the next day.
6. Do not keep specimens to send all three on the same day.
7. Use the most rapid transport to the laboratory: yourself, courier, overnight carrier, or US mail.



Make every effort to submit specimens to the laboratory within 24 hours of collection. Normal flora can overgrow any mycobacteria in the specimen and make it unusable. If specimens cannot be submitted within 24 hours, keep in mind that most laboratories will not run a specimen over five days old. Know how long it takes the specimen to get to the laboratory from the time it leaves your hands, and submit specimens accordingly.

How to Direct a Patient to Perform Spontaneous Sputum Collection at Home

If a patient will be collecting sputum specimens at home, provide the following guidance.

1. Put a mark at the 5 ml level on the sputum tubes (if not already marked) to show the patient the minimum amount of sputum needed. (Most laboratories consider 5 to 10 ml an adequate amount.)
2. Review with the patient how to collect sputum.
3. Make arrangements for a healthcare worker to pick up the specimen or for the patient, a family member, or a friend to drop off the specimen.

Induced Sputum Collection at a Healthcare Facility

If the patient cannot produce sputum spontaneously, then make arrangements for an induced sputum to be collected at a facility. Facilities where sputum can be collected include the respiratory therapy department of a local hospital, TB clinic, or laboratory. Facilities should have appropriate respiratory protection, environmental controls, and policies and procedures.

How to Collect Gastric Aspirates

The following are basic guidelines for collecting gastric aspirates:

- Collect the specimen after the patient has fasted for 8 to 10 hours and, preferably, while the patient is still in bed.
- Collect a specimen daily for three days.



For additional information on how to collect a gastric aspirate and prepare the specimen for transport, see the guide and Francis J. Curry National Tuberculosis Center's online video *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure*.

Bronchoscopy or Collection of Extrapulmonary Specimens

If TB staff are consulting with physicians before the specimens are collected, the physician should be reminded to send part of the specimen (not in formalin) to the microbiology laboratory for acid-fast bacilli (AFB) smear and culture, in addition to any other tests or pathology examinations the physician plans to obtain. In addition, a post-bronchoscopy sputum specimen should be sent for AFB smear and culture.

- **Bronchoscopy:** Refer the patient to a local specialist.
- **Extrapulmonary specimens:** These specimens will be collected by the physician performing the diagnostic work-up.

Specimen Shipment

There are three main categories of transportation methods: medical couriers, ground transportation, and air transportation. Category B Infectious Substances (raw diagnostic specimens, such as sputum, blood, or tissue) can be mailed through the US Postal Service (USPS), shipped by private carrier (e.g., Federal Express, Airborne Express, etc.), or transported by a medical courier. Pure mycobacterial cultures (or culture isolates suspected of being mycobacteria) are Category A Infectious Substances and can be transported only by a medical courier or shipped by private carrier as dangerous goods. Category A Infectious Substances cannot be mailed through the US Postal Service. Each category requires different packaging requirements to provide increased levels of protection against leaks and contamination.

Shipment of dangerous goods by USPS is regulated by the US Department of Transportation. Specific shipping instructions from the Centers for Disease Control and Prevention (CDC) can be found in the publication by the US Department of Health and Human Services (DHHS) *Public Health Mycobacteriology: A Guide for the Level III Laboratory*. Packaging and shipment of specimens by USPS should meet the following regulations:

- Public Health Service/CDC: 42 CFR, Part 72—Interstate Shipment of Etiologic Agents
- USPS: 39 CFR and USPS Domestic Mail Manual C023.1.1, International Mail Manual 135, and USPS Publication 52
- US Department of Transportation: 49 CFR, Parts 171–180 (August 14, 2002)
- The Department of Labor, Occupational Safety and Health Administration (OSHA): 29 CFR 1910.1030⁹

For shipments by private carriers, follow International Air Transportation Association (IATA) instructions. *Mycobacterium tuberculosis* pure cultures are defined as infectious substances/etiologic agents when shipped by private carrier and must be shipped in packaging approved by the United Nations (UN), according to IATA Packing Instruction 602. Diagnostic specimens are defined as human or animal specimens, including excreta, secreta, blood and its components, tissue, tissue fluids, and cultures of nontuberculous mycobacteria being transported for diagnostic or investigational purposes. Diagnostic specimens must be packaged according to IATA Packing Instruction 650.¹⁰

The Montana Public Health Laboratory (MTPHL) has a contract with a medical courier to pick up specimens at various locations and deliver them to the MTPHL each weekday. Routes cover many of the major cities in Montana, and some locations serve as a central collection point for other facilities in that city.



For more information, contact Denise Higgins or Susanne Zanto, laboratory managers, at the Montana Public Health Laboratory at 800-821-7284.

Refer to the shipping regulations that are listed under “Resources and References” at the end of this section. Personnel who handle, package, and ship infectious materials must be trained in these procedures.



For packaging and shipping recommendations and training information, call Denise Higgins, laboratory manager, at the Montana Public Health Laboratory, at 800-821-7284 ext 3040 or directly at 406-444-3040.



To obtain specimen collection and transport supplies, see the topic on “Specimen Collection and Shipment Supplies” in the Supplies, Materials, and Services section.

Resources and References

Resources for Laboratory Services

Detailed descriptions of recommended laboratory tests; recommendations for their correct use; and methods for collecting, handling, and transporting specimens have been published.

For more information on laboratory testing for tuberculosis (TB), see the following:

- 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]).
- Montana Public Health Laboratory. *MTPHL Laboratory Services Manual*.
- National Committee for Clinical Laboratory Standards. *Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard* [Document no. M24-A] (Wayne, PA; 2003).

Resources for Specimen Collection and Shipment

- CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005" (*MMWR* 2005;54[No. RR-17]).
- CDC. *Public Health Mycobacteriology: A Guide for the Level III Laboratory*(Atlanta, GA; 1985).
- Francis J. Curry National Tuberculosis Center. *Conducting Sputum Induction Safely* (Francis J. Curry National Tuberculosis Center Web site).
- Francis J. Curry National Tuberculosis Center. *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure* (Francis J. Curry National Tuberculosis Center Web site).
- International Air Transport Association (IATA). IATA Web site.
- Montana Public Health Laboratory. *MTPHL Laboratory Services Manual*.

- National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory* (Denver, CO: March 2005).
- National Jewish Medical and Research Center. *Instructions (for Patients) for Collecting and Mailing Sputum Specimens* (Denver, CO: March 2005).
- National Tuberculosis Controllers Association—National Tuberculosis Nurse Consultant Coalition. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care* (Atlanta, GA; 1997):39–42.
- US Department of Transportation. Hazardous Materials: Revision to standards for infectious substances. Part III 49 CFR Part 171. Federal Register (August 14, 2002).
- USPS. *Mailing Standards of the United States Postal Service: Domestic Mail Manual* (USPS Web site).

References

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 - 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):19.
 - ³ Association of Public Health Laboratories. *The Future of TB Laboratory Services: A framework for integration/collaboration/leadership* [Association of Public Health Laboratories Web site]. 2004. Accessed November 1, 2006.
 - ⁴ CDC. Diagnostic microbiology. In: Chapter 5: diagnosis of TB. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. Accessed November 1, 2006
 - ⁵ ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med.* 2000;161:1376–1395.
 - ⁶ Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000.* 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.
 - ⁷ Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000.* 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.
 - ⁸ Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000.* 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.
 - ⁹ National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:2.
 - ¹⁰ National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:5–7.