Laboratory Services

CONTENTS

Introduction

Purpose

Use this section to do the following:

- Obtain contact information for laboratories.
- Determine which tests are available and the tests' turnaround times.
- 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.

Available Laboratory Tests

The laboratory tests listed below in Table 1 are available where noted.

Table 1: AVAILABLE LABORATORY TESTS

Test	Laboratory	Turnaround Time
Diagnosis		
T-Spot	Available by contacting the Wyoming TB Program at 307-777-8939	
Acid-fast (AFB) bacilli smear	Wyoming Public Health Lab	Within 24 hours from receipt in laboratory[4] The TB Lab processes specimens only 2 times a week. Every effort is made to get smears out quickly as possible on high suspect cases.
Culture	Wyoming Public Health Lab	Mycobacterial growth detection by culture within 14 days from date of specimen collection Identification of cultured mycobacteria within 21 days from date of specimen collection[5,6]
Drug susceptibility	Wyoming Public Health Lab for referral to the California State Public Health Lab. (Referral is automatic)	Within 30 days from date of specimen collection[7,8]
Nucleic acid amplification (NAA) test	Wyoming Public Health Lab for referral to the Montana State Public Health Lab. (Referral is automatic)	Within 2 days from date of specimen collection[9,10] The Lab is not open to receive specimens on weekends and holidays

Treatment Monitoring		
Hepatic enzymes or up to 8 clinical, multichannel chem 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	Wyoming Public Health Lab for referral to the California State Public Health Lab. (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 Chapter 2 -- 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.[11]

For information on reporting, see the "Reporting Tuberculosis" topic in Chapter 2 -- Surveillance section.

To locate and contact a laboratory, refer to Table 6: **Roles, Responsibilities and Contact Information of Laboratories** in the "Roles, Responsibilities, and Contact Information" topic in the Introduction.

For laboratory services available in Wyoming, contact the WPHL at 307-777-7431

Specimen Collection

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; therefore, 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 refrigerated conditions to inhibit the growth of contaminating organisms, since most specimens will contain bacteria other than mycobacteria.[12]

Refer to Table 2 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]) at this hyperlink: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

Table 2: SPECIMEN COLLECTION METHODS AND TYPES FOR PULMONARY TUBERCULOSIS

Pulmonary Tuberculosis	
Collection Method	**Specimen Type**
Spontaneous sputum collection occurs when the patient can cough up sputum without extra assistance.	▪ 5–10 ml of sputum from deep in the lung
Induced sputum collection should be considered if a patient needs assistance in bringing up sputum.*	▪ 5–10 ml of sputum from deep in the lung
Gastric aspirates can be submitted for the diagnosis of pulmonary tuberculosis (TB) in young children who cannot produce sputum.	▪ 50 ml of gastric contents
Bronchoscopy can be used in the following situations: ▪ If a patient cannot produce sputum by the above three methods[13] or ▪ If a patient has a substantial risk of drug-resistant TB and has initial routine studies that are negative[14] or ▪ In a patient in whom there is suspicion of endobroncheal TB[15] or ▪ If a variety of clinical specimens for the diagnosis of pulmonary TB or other possible diseases need to be obtained	▪ Bronchial washings ▪ Bronchoalveolar lavage ▪ Transbronchial biopsy
* 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.	

Refer to Table 3 for collection methods and specimen types for extrapulmonary TB.

Table 3: 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)*** ▪ Lymph node ▪ Pleural ▪ Bone/joint ▪ Kidney ▪ Peritoneal ▪ Pericardial	**Examples of fluids** ▪ Pleural ▪ Cerebrospinal ▪ Blood (WPHL does not accept blood) ▪ Urine (40mL sample, same day shipped and refrigerated) ▪ Synovial ▪ Peritoneal ▪ Pericardial
*** Do not place specimens in formalin. Place specimens in sterile physiologic saline. ***		

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 Wyoming 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 in 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 delay sending specimens in order 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.
4. If specimen cannot be picked up the same day of collection, refrigerate 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 eight to ten hours and, preferably early morning while the patient is still in bed.
- Collect a specimen daily for three days.
- Due to high pH, gastric aspirates have to be neutralized with a buffer.

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* at this hyperlink: http://www.nationaltbcenter.ucsf.edu/products/product_details.cfm?productID=ONL-06 .

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

For transportation, there are two primary categories of infectious substances, and each category has different packaging requirements to provide increased levels of protection against leaks and contamination. Persons shipping Category A or Category B Infectious Substances must have packaging and shipping training that is recognized by the Dept. of Transportation in accordance with 49 CFR, Part 172, Subpart H regulations.

http://tsi.dot.gov

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 United States Postal Service (USPS).

Category B Infectious Substances (raw diagnostic specimens, such as sputum, blood, or tissue) can be mailed through the USPS, shipped by private carrier (e.g., Federal Express, Airborne Express, etc.), or transported by a medical courier.

Shipment of dangerous goods by the USPS is regulated by the United States Department of Transportation. Specific shipping instructions from the Centers for Disease Control and Prevention (CDC) can be found in the publication by the United States 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:

- Office of Health and Safety. "Interstate Shipment of Etiologic Agents" [Web page] (Centers for Disease Control and Prevention Website): http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
- United States Postal Service. Domestic Mail Manual: http://pe.usps.com/text/dmm300/dmm300_landing.htm
- United States Postal Service. 135 Mailable Dangerous Goods (International Mail Manual): http://pe.usps.gov/text/Imm/immc1_013.htm
- National Archives and Records Administration. Code of Federal Regulations Title 39—United States Postal Service (U.S. Government Printing Office Website): http://www.access.gpo.gov/nara/cfr/waisidx_03/39cfrv1_03.html
- National Archives and Records Administration. Code of Federal Regulations Title 49—Transportation (U.S. Government Printing Office Website): http://www.access.gpo.gov/nara/cfr/waisidx_04/49cfrv2_04.html
- U.S. Department of Labor, Occupational Safety & Health Administration (OSHA):Occupational Health and Safety Standards 29 CFR 1910.1030: http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910 [16]

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: http://oregonstate.edu/vetmed/pdf/iata_602.pdf . 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: http://www.iata.org/NR/ContentConnector/CS2000/SiteInterface/sites/whatwedo/cargo/file/PI650.pdf .[17]

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

For more information, contact the WPHL at **307-777-7431**

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

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]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5412.pdf .
- ATS, CDC, IDSA. "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" (*Am J Respir Crit Care Med* 2000;161[4 Pt 1]). Available at: http://www.cdc.gov/tb/pubs/PDF/1376.pdf .
- National Committee for Clinical Laboratory Standards. *Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard* [Document no. M24-A] (Wayne, PA; 2003).

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. Available at: http://www.aphl.org/docs/TBTaskForcewcover.pdf . Accessed November 1, 2006.

[4] 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; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology*1993:767–770.

[5] 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; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

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[7] 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; and Tenover, R., et al. The resurgence of tuberculosis: is your laboratory ready? *Journal of Clinical Microbiology* 1993:767–770.

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[10] CDC. National plan for reliable tuberculosis laboratory services using a systems approach - recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services. *MMWR* 2005;54(No. RR-6):3.

[11] CDC. Diagnostic microbiology. In: Chapter 5: diagnosis of TB. *Core Curriculum on Tuberculosis (2000)* [Division of Tuberculosis Elimination Web site]. Updated November 2001. Available at: http://www.cdc.gov/tb/pubs/corecurr/index.htm . Accessed November 1, 2006.

[12] ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med*. 2000;161:1376–1395.

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[16] National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:2.
[17] National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:5–7.