

Laboratory Services

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Forms Used in this Section

- [MTD Request Form](#)
- [Nucleic Acid Amplification \(NAA\) and Mycobacterium Tuberculosis Direct Test \(MTD\) Recommendations](#)
- [OFT: TB Control Guidelines for Public Health Staff](#) (Thurston County)
- [Sputum Collection](#) (Chelan/Douglas County)
- [Tuberculosis Screening Guidelines](#)

Introduction

Purpose

Use this section to do the following:

- Obtain contact information for laboratories
- Determine which tests are available and the turnaround times
- Identify which laboratory performs 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



In the WAC, see Chapter 246-101 (Notifiable Conditions) in the Title 246 (Department of Health) at <http://apps.leg.wa.gov/wac/default.aspx?cite=246-101>

Also, see the Notifiable Conditions Guidelines at, <http://www.doh.wa.gov/notify/guidelines/pdf/tuberculosis.pdf>

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 from CoreLabs for identification and susceptibility testing of <i>Mycobacterium tuberculosis</i>. Statewide coordination of genotyping for positive cultures. Serves as a consultant for questions involving mycobacterium laboratory testing. Open Monday – Friday 8am – 5 pm. Closed on national holidays.</p>	<p>Washington State Department of Health Public Health Laboratories 1610 NE 150th St. Shoreline, WA 98155 (King County) http://www.doh.wa.gov/EHSPHL/PHL/ Supervisor: 206-418-5474 TB Lab Lead: 206-418-5473</p>
<p>Private and Local Public Health Laboratories Laboratories on the following list provide primary specimen smear and culture testing for mycobacteria. Most refer isolates either to a CoreLab (reference Lab) or to the Washington State Department of Health Public Health Laboratories for identification and susceptibility testing.</p>	<p>Children’s Hospital and Regional Medical Center (Hospital) 4800 Sand Point Way NE Seattle, WA 98105 (King County) Ph: 206-987-2589 Fax: 206-987-3840</p> <p>Deaconess Medical Center – Spokane (Hospital) W 800 Fifth Ave Spokane, WA 99210 (Spokane County) Ph: 509-473-7410 Fax: 509-473-2700</p> <p>Dynacare Northwest, Inc (Clinic) 550 17th Ave Ste 310 Seattle, WA 98122 (King County) Ph: 206-861-7235 Fax: 206-861-7367</p>

Roles and Responsibilities**Contact Information****Private and Local Public Health Laboratories**

Laboratories on the following list provide primary specimen smear and culture testing for mycobacteria. Most refer isolates either to a CoreLab (reference Lab) or to the Washington State Department of Health Public Health Laboratories for identification and susceptibility testing.

Group Health ACC Lab
(HMO)
12400 E. Marginal Way S.
Tukwila, WA 98168
(King County)
Ph: 206-901-4500
Fax: 206-901-4501

Harborview Medical Center
(Hospital)
325 9th Ave
Box 259743
Seattle, WA 98104
(King County)
Ph: 206-731-3451
Fax: 206-731-8556

Molecular Epidemiology, Inc.
15300 Bothell Way N.E.
Lake Forest Park, WA 98155
206-522-0362

Multicare Medical Center Laboratories NW
(Hospital)
315 S. MLK Jr. Way
Tacoma, WA 98415
(Pierce County)
Ph: 253-403-1370
Fax: 253-403-1357

Oregon Medical Laboratory
PO Box 77003
Eugene, Oregon 97401
Ph: 541-334-8010 or
1-800-342-2971

PAML-Pathology Associates Medical Laboratories
110 W. Cliff Ave
Spokane, WA 99204
(Statewide)
Ph: PAML Client Services 800-541-7891
Bellevue/Seattle Client Services 888-472-2522
Olympia Client Services 888-910-6156
Fax: 509-924-0002

Roles and Responsibilities**Contact Information****Private and Local Public Health Laboratories**

Laboratories on the following list provide primary specimen smear and culture testing for mycobacteria. Most refer isolates either to a CoreLab (reference Lab) or to the Washington State Department of Health Public Health Laboratories for identification and susceptibility testing.

Providence Everett Medical Center – Pacific
(Hospital)
916 Pacific Ave.
Everett, WA 98201
(Snohomish County)
Ph: 425-258-7701
Fax: 425-258-7024

Quest Diagnostics-Seattle
1737 Airport Way S
Suite 200
Seattle, WA 98134-1636
Ph: 206-623-8100
Fax: 206-224-8370

Sacred Heart Medical Center
(Hospital)
W 101 Eighth Ave.
Spokane, WA 99204
(Spokane County)
Ph: 509-474-3065
Fax: 509-474-2052

Seattle-King County Department of Public Health
Laboratory
(Health Department)
325 Ninth Ave, #359973
Seattle, WA 98104
(King County)
Ph: 206-731-8950
Fax: 206-731-8693

Roles and Responsibilities**Contact Information****Private and Local Public Health Laboratories**

Laboratories on the following list provide primary specimen smear and culture testing for mycobacteria. Most refer isolates either to a CoreLab (reference Lab) or to the Washington State Department of Health Public Health Laboratories for identification and susceptibility testing.

Spokane Regional Health District Laboratory
(Health Department)
1101 W. College Ave #210
Spokane, WA 99201
(Spokane County)
Ph: 509-324-1440
Fax: 509-324-1492

St. John's Medical Center
(Hospital)
1615 Delaware St.
Longview, WA 98632
(Cowlitz County)
Ph: 360-636-4868
Fax: 360-636-4916

St. Mary Medical Center
(Hospital)
401 W. Poplar
Walla Walla, WA 99362
(Walla Walla County)
Ph: 509-525-3320
Fax: 509-522-5724

Roles and Responsibilities

Contact Information

Private and Local Public Health Laboratories

Laboratories on the following list provide primary specimen smear and culture testing for mycobacteria. Most refer isolates either to a CoreLab (reference Lab) or to the Washington State Department of Health Public Health Laboratories for identification and susceptibility testing.

Stevens Hospital Laboratory
(Hospital)
21601 76th Ave. W
Edmonds, WA 98026
(Snohomish County)
Ph: 425-640-4120
Fax: 425-640-4426

University of Washington Medical Center
(Hospital)
LAB MED BOX 357110
1959 NE Pacific St.
Seattle, WA 98195
(King County)
Ph: 206-616-8872
Fax: 206-616-8980

Virginia Mason Medical Center
(Hospital)
1100 9th Ave – C6LAB
Seattle, WA 98111
(King County)
Ph: 206-223-6850
Fax: 206-223-7540

Yakima Regional Medical Center
(Hospital)
110 S. 9th Ave
Yakima, WA 98902
(Yakima County)
Ph: 509-575-5035
Fax: 509-454-6193

Yakima Valley Memorial Hospital Laboratory
(Hospital)
2811 Tieton Dr.
Yakima, WA 98902
(Yakima County)
Ph: 509-575-8000
Fax: 509-575-8816

Available Laboratory Tests

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

When performing tests for the diagnosis of mycobacterial infection, acid-fast bacilli smear and culture **and** sensitivities must be ordered.

At the Washington State Department of Health Public Health Laboratory, 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 (MTD) testing is done on first time smear positive specimens and on initially smear-negative sputum specimens by special request from the local health jurisdiction health officer.

TABLE 2: AVAILABLE LABORATORY TESTS

Test	Laboratory	Turnaround Time
Diagnosis		
Interferon gamma release assay (IGRAs) for diagnosis latent TB infection (LTBI) (blood test)	Evergreen PACLAB 4 locations: 1. Evergreen Hospital 12040 NE 128 th St Kirkland, WA 98034 Ph: 425-899-3900 Fax: 425-899-3901 2. PACLAB Redmond Patient Service Center 8301 161 st St. NE, Suite 104 Redmond, WA 98052 Ph: 425-869-4840 Fax: 425-869-4841 3. PACLAB Woodinville Patient Service Center 17000 140 th Ave NE Suite E102 Woodinville, WA 98072 Ph: 425-488-4900 Fax: 425-488-4902 4. PACLAB Canyon Park Patient Service Center 1909 214 th St SE, Suite 120 Bothell, WA 98021 Ph: 425-488-4950 Fax: None	Within a week of laboratory receipt of blood

Test	Laboratory	Turnaround Time
	<p>Providence St. Peter Hospital Clinical Laboratory 413 Lilly Road NE Olympia, WA 98506 Contact: Chemistry Lab Supervisor 360-493-5181</p> <p>Spokane Regional Health District Laboratory 1101 W. College Ave Spokane, WA 99201 Contact: SRHD Lab Director 509-324-1450</p> <p>Tacoma General Hospital 315 Martin Luther King, Jr Way Tacoma, WA 98405 Ph: 253-403-1398 (ask for Immunology Supervisor)</p> <p>TriCities Laboratory (Kennewick, WA) 7131 West Grandridge Blvd. Kennewick, WA 99336 Contact: Technical Operations Manager 509-736-0105</p>	<p>Within a week of laboratory receipt of blood</p> <p>Within a week of laboratory receipt of blood</p> <p>Within 4-7 days of laboratory receipt of blood</p>
Acid-fast bacilli (AFB) smear	<p>Washington State Department of Health Public Health Laboratories</p> <p>Refer to list of private labs that provide testing for mycobacteria (Table 1)</p>	<p>Within 24 hours from receipt of specimen in the laboratory</p> <ul style="list-style-type: none"> • Monday through Friday • See (10.14) for sending specimens
Culture	<p>Washington State Department of Health Public Health Laboratories</p> <p>Refer to list of private and local public</p>	<p>Cultures are incubated for up to 8 weeks before reported as negative. Time to detection of mycobacterial growth is dependent on growth rate. Ideally, mycobacterial growth should be detected within 14 days</p>

Test	Laboratory	Turnaround Time
	health labs that provide testing for mycobacteria (Table 1)	of culture set up, although this is dependent upon many factors, including overgrowth by other organisms, etc.
Culture identification	Washington State Department of Health Public Health Laboratories: Refer to list of private and local public health labs that provide testing for mycobacteria (Table 1)	The goal for <i>M.tuberculosis</i> complex identification should be within 21 days of culture set up. Time to <i>M. tuberculosis</i> complex identification is dependent upon growth rate.
Drug susceptibility	First line drugs: Isoniazid, Rifampin, ethambutol, Streptomycin Washington State Department of Health Public Health Laboratories, Harborview Medical Center, Sacred Heart Medical Center PZA: PHL and Sacred Heart Medical Center Second line drugs: PHL	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 and presence of other organisms which must be eliminated to provide a pure culture for testing). An additional 3-4 weeks is needed for the confirmation of resistance and testing for the second line anti-TB drugs.
Nucleic acid amplification (NAA) test (MTD) Manufactured by GenProbe	Washington State Department of Health Public Health Laboratories MTD Request Form	Within 2-3 working days from receipt of specimen in the laboratory. <ul style="list-style-type: none">Tuesday and Thursday
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)	Refer to list of private labs that provide testing for mycobacteria (Table 1) or use a local lab of your choice	Check with Lab

Test	Laboratory	Turnaround Time
Uric acid	Refer to list of private labs that provide testing for mycobacteria (Table 1) or use a local lab of your choice	Check with Lab
Complete blood count (CBC) and platelets	Refer to list of private labs that provide testing for mycobacteria (Table 1) or use a local lab of your choice	Check with Lab
Kidney function	Refer to list of private labs that provide testing for mycobacteria (Table 1) or use a local lab of your choice	Check with Lab
PCR	UW, see link http://depts.washington.edu/molmicd/mdx/available_tests.shtml	Check with Lab
Epidemiologic Monitoring		
<p>Genotyping of positive cultures for MTB.</p> <p>For information on Restriction Fragment Length Polymorphism (RFLP) see: http://www.cdc.gov/tb/genotyping/Chap5/5_Developing_3c_RFLP.htm</p>	Washington State Department of Health Public Health Laboratories for referral to the Berkeley testing site (Referral is automatic)	<p>Ideally 2 to 4 weeks from receipt of specimen at the Berkeley Laboratory</p> <p>Results reported to LHJ by WA State TB Services</p>



See Notifiable conditions and the health care provider ([WAC 246-101-101](#))

And Notifiable conditions and laboratories ([WAC 246-101-201](#))

Also, see Notifiable Conditions Guidelines, at
<http://www.doh.wa.gov/notify/guidelines/pdf/tuberculosis.pdf>

Table 3: Laboratory Turn Around Times for PHL

Test	Type	Results Available	Results sent to clinician and LHJ
Direct tests	Positive smear	24-48 hours	Phoned and faxed within 24 hours by PHL
	Negative smear	24-48 hours	Faxed within 24 hours by PHL
	Amplified Mycobacterium Tuberculosis Direct test (MTD) Note: Only the Public Health Laboratory performs this test	Tuesday and Thursday	Positives and negatives phoned and faxed within 24 hours by PHL,
Culture results	AFB Positive Cultures	1-4 weeks, ideally within 14 days of culture set up	Result phoned, all results faxed within 24 hours by PHL.
	AFB Negative Cultures	Up to 8 weeks	Faxed within 24 hours by PHL.
	Genetic Probe Test for MTB, MAC, M. gordonae and M. kansasii	Done weekly on AFB positive cultures, usually within 21 days of culture set up.	Phoned and faxed within 24 hours by PHL.
	Biochemical analysis for mycobacteria other than those listed above (considered atypical or MOTT Mycobacteria Other Than Tuberculosis)	2-3 months	Faxed by PHL.
Drug Susceptibility	Performed on confirmed MTBC cultures:		
	Bactec* (primary drugs)	7-10 days	Faxed within 24 hours by PHL.
	Plate method ** (second line drugs and confirmation of resistance to primary drugs)	Up to 4 weeks	Faxed within 24 hours by PHL.

* Bactec method: Streptomycin, Isoniazid, Rifampin, Ethambutol, Pyrazinamide

** Plate method: Streptomycin, Isoniazid, Rifampin, Ethambutol, Ethionamide, P-aminosalicylic acid, Ofloxacin and Amikacin.

Note: Reports on specimens from Harborview Medical Center will be sent to DOH TB Services. TB Services will ascertain the patients' county of residence and fax to the appropriate county LHJ.



To understand the evaluation process in diagnosing TB disease and LTBI, view the "Tuberculosis Screening Guidelines" provided on page [4.6](#).

Specimen Collection



For an explanation of proper specimen collection and submission, see instructions at the Washington State Department of Health Public Health Laboratory Website: www.doh.wa.gov/ehspl/phl

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 conditions (refrigeration) that inhibit the growth of contaminating organisms, since most specimens will contain bacteria other than mycobacteria.⁴

Washington State Department of Health Public Health Laboratories (PHL)

At Washington State Department of Health Public Health Laboratories, culture identification is automatically performed on all isolates, and first-line susceptibility testing is automatically performed on all initial *Mycobacterium tuberculosis* complex isolates. Nucleic Acid Amplification (MTD) testing is done on first time smear positive sputum specimens and on initially smear-negative sputum specimens by special request from the local health jurisdiction health officer.

(Refer to Washington State Specific References (10.26) at the end of this section for information regarding MTD testing)

Sputum specimen kits are available from the Washington State Department of Health Public Health Laboratories (WSPHL) by calling the PHL mailroom **206-418-5579**.

Washington State Department of Health
Public Health Laboratories
Mailroom Services
1610 N.E. 150th St.
Shoreline, WA 98155

Ph: 206-418-5579
Fax: 206-418-5405

When sending the sample to WSPHL use only the unique Washington State Department of Health Public Health Laboratories (WSPHL) sputum specimen kits distributed by WSPHL. Keep the kits intact until used, as all necessary items are contained in the kit. Do not use urine cups. Follow the packing instructions exactly. If the specimen leaks, it cannot be tested and the lab area must be decontaminated. If using another lab (Table 1) contact them for collection supplies.

If the patient or someone helping the patient will be shipping the specimen, assure that he/she understands all of the specific steps to follow in collecting and preparing the specimen for shipping.



Information regarding the TB Specimen Collection kits can be found at: <http://www.doh.wa.gov/ehsphi/phl/Brochures/flyerTBship.pdf> (TB Specimen Collection Kit)



For more information regarding sputum collection, please see [Sputum Collection](#), located in the **FORMS** section of the manual.

Instructions for collecting and sending specimens to PHL

1. Instruct the patient to collect the sputum specimen first thing in the morning (if possible) after rinsing the mouth with water and spitting the water out into the sink.
2. Instruct the patient to cough deeply and spit the coughed up material into the specimen tube.
3. Screw the cap down tightly so the specimen tube doesn't leak.
4. Wash the outside of the specimen tube with soap and water, then dry.
5. Be sure that the specimen tube is labeled with the patient's name and the date (and the time the specimen was collected, if more than one specimen is collected on the same day) .
6. Wrap absorbent material around the specimen tube.
7. Place the wrapped specimen tube in the specimen bag.
8. Seal the specimen bag with the attached "twist-tie."
9. Place cotton or other cushioning material in the bottom of the small mailing container.
10. Place the specimen tube (in its bag) into the small mailing container and screw the cap on tightly.
11. Assure that **all** information including the patient's address is provided on the phl requisition form.
12. Wrap the completed laboratory requisition form around the outside of the small mailing container and secure with a rubber band.
13. Place the small mailing container into the large mailing container and screw the cap on tightly.
14. Ship the appropriately packaged container to the public health lab. (The address is on the container)

Med Ex now delivering packages from Greyhound Bus on Saturdays

PHL mailroom has made arrangements with Greyhound and Med Ex for an automatic 10:00am pickup on Saturdays. Med Ex should arrive at the lab between 10:00am-12:00 noon along with other courier deliveries.

Please encourage shippers to have their packages at the Seattle bus station no later than 9:30am on Saturday. This will help us ensure that their packages will be delivered to the PHL in a timely manner.

Refer to Table 4 on the following page 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 <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>

Other useful links:

- [WAC 246-101 Notifiable Conditions](#)
 - Also, see Notifiable Conditions Guidelines, at <http://www.doh.wa.gov/notify/guidelines/pdf/tuberculosis.pdf>
- [WAC 246-320-265 Hospital Infection Control Program](#)
- [WAC 296-800-160 Personal Protective Equipment](#)
- [WAC 296-842-100 through 300 Respirators](#)
- [WAC 388-97—140,147, 155 Infection Control Nursing Homes](#)
- [WRD 11.35 Tuberculosis Control in Health Care Settings](#)
- [WRD 11.36 Tuberculosis Control in Correctional Facilities](#)
- [DOC 670-030 Offender Tuberculosis Program](#)
- [DOC 670.000 Communicable Disease and Infection Control Program \(employees\)](#)

TABLE 4: 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.	<ul style="list-style-type: none"> • 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.*	<ul style="list-style-type: none"> • 5–10 ml of sputum from deep in the lung
Gastric aspirates can be submitted for the diagnosis of pulmonary tuberculosis (TB) in persons who cannot produce sputum. (This applies primarily to young children.)	<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 methods⁵ or • If a patient has a substantial risk of drug-resistant TB and has initial routine studies that are negative⁶ or • In a patient in whom there is suspicion of endobroncheal TB⁷ 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 5 for collection methods and specimen types for extrapulmonary TB.

TABLE 5: 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 • Pleura • Bone/joint • Kidney • Peritoneum • Pericardium 	Examples of fluids <ul style="list-style-type: none"> • Pleural • Cerebrospinal • Blood • Urine • Synovial • Peritoneal • Pericardial
* <u>Do not place tissue specimens in formalin.</u>		

How to Perform Spontaneous Sputum Collection at a Healthcare Facility



Refer to the Washington State Department of Health Public Health Laboratories sub-section under “Specimen Collection” (10.13)

1. Collect the specimen in a specialized room or booth designed for cough-inducing procedures (negative air pressure.)
2. 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.)
3. Instruct the patient on how to collect the sputum sample (Refer to detailed instructions under Sputum Collection – PHL)
4. Before shipping, make sure the specimen container and laboratory requisition are filled out **completely, including the patient’s address**. On the specimen container, record the patient’s name and the date and time of collection. (Time of collection is especially important when more than one sputum sample is being collected in the same day.)

5. Use the State of Washington Department of Health Public Health Laboratories Mycobacteriology Laboratory Requisition form (or other laboratory-specific requisition for other laboratories.) The PHL requisition is included in the sputum collection kits which can be ordered from the PHL. An example of the requisition can be found at <http://www.doh.wa.gov/EHSPHL/PHL/Forms/Mtblisolates.pdf>



Information regarding the kits can be found at:

<http://www.doh.wa.gov/ehsphi/phl/Brochures/flyerTBship.pdf>

(TB Specimen Collection Kit)



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.”

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



Refer to the “Specimen Collection” (10.11) topic and the “Specimen Shipment” (10.22) topic both in this section of the manual.



In the WAC, see Chapter 246-101 (Notifiable Conditions) in the Title 246 (Department of Health) at

<http://apps.leg.wa.gov/wac/default.aspx?cite=246-101>

Also, see Notifiable Conditions Guidelines, at

<http://www.doh.wa.gov/notify/guidelines/pdf/tuberculosis.pdf>

7. 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.
8. Do not save specimens to ship all three on the same day; instead, ship each one as soon as possible after collection.
9. Use the most rapid method of shipping the specimen(s) to PHL.



Make every effort to submit specimens to PHL or other laboratory within 24 hours of collection. Normal flora can overgrow any mycobacteria in the specimen and make it unusable. Most laboratories will not run a specimen over five days old. Know how long it takes the specimen to arrive at PHL or other laboratory from the time it leaves your facility, and submit specimens accordingly.

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: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>.

- [WAC 246-320-265 Hospital Infection Control Program](#)
- [WAC 296-800-160 Personal Protective Equipment](#)
- [WAC 296-842-100 through 300 Respirators](#)
- [WAC 388-97—140,147, 155 Infection Control Nursing Homes](#)
- [WRD 11.35 Tuberculosis Control in Health Care Settings](#)
- [WRD 11.36 Tuberculosis Control in Correctional Facilities](#)
- [DOC 670-030 Offender Tuberculosis Program](#)
- [DOC 670.000 Communicable Disease and Infection Control Program \(employees\)](#)

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 the sputum sample. (Refer to detailed instructions under Sputum Collection – Washington State Department of Health Public Health Laboratories)
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. If the patient or someone helping the patient will be shipping the specimen, assure that he/she understands all of the specific steps to follow in collecting and preparing the specimen for shipping.



Refer to the Washington State Department of Health Public Health Laboratories sub-section under "Specimen Collection" (**10.13**)

Induced Sputum Collection at a Healthcare Facility

If the patient cannot produce sputum spontaneously, 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. Collect the specimen in a specialized room or booth (negative air pressure) designed for cough-inducing procedures.

Facilities should have appropriate respiratory protection, environmental controls, and policies and procedures in place to prevent transmission of TB to other persons. For further information regarding infection control during sputum collection, refer to the Infection Control Section: environmental controls, respiratory protection and facility requirements for infection control policies and procedures.



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:

<http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>

- [WAC 246-320-265 Hospital Infection Control Program](#)
- [WAC 296-800-160 Personal Protective Equipment](#)
- [WAC 296-842-100 through 300 Respirators](#)



Use the State of Washington Department of Health Public Health Laboratories Mycobacteriology Laboratory Requisition form (or other laboratory-specific requisition for other laboratories.) The PHL requisition is included in the sputum collection kits which can be ordered from the PHL. An example of the requisition can be found at :

<http://www.doh.wa.gov/EHSPHL/PHL/Forms/MtbIsolates.pdf>

Information regarding the PHL sputum collection kits be found at:

<http://www.doh.wa.gov/ehsphil/phl/Brochures/flyerTBship.pdf>

(TB Specimen Collection Kit)

How to Collect Gastric Aspirates

Gastric aspirates are most commonly collected on children, however this procedure may also be used in adults.

The following are basic guidelines for collecting gastric aspirates:

Patient Preparation:

4. The patient is to have nothing by mouth after midnight.
5. The family (patient) should come to the clinic first thing in the morning.
6. Place a nasal gastric tube in the patient. Do not use surgilube as it is bacteriostatic. Use as large a bore NG tube as is comfortable (minimum 10 french). Avoid too deep a placement to prevent passage through the pylorus.

Sample Collection:

7. Aspirate the stomach contents. If less than 10 cc of mucus is aspirated, instill 20-30 cc of sterile water into the tube and quickly withdraw. (Note: the organism is most viable when not exposed to saline or preservatives; the kind of sterile water used for infant feeding is fine). Reposition the tube and/or the patient to maximize the yield of gastric contents.
8. Place the gastric aspirates in a special bicarbonate-containing gastric aspirate tube or regular specimen cup.
9. Transport the specimen to the microbiology lab. If a special bicarbonate-containing tube or cup is not available, the lab must neutralize the stomach acid with bicarbonate within ½ hour.



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:

http://www.nationaltbcenter.edu/products/product_details.cfm?productID=ONL-06

Detailed information on gastric aspirate collection is also available at the following website:

http://www.nationaltbcenter.edu/catalogue/epub/downloads/GAP/GA_Patient_Prep.pdf

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 and extrapulmonary specimens will be collected by the physician and facility performing the procedure.

Interferon Gamma Release Assay (IGRA) QuantiFERON[®]-TB- Gold In-Tube Testing (QFT-G)

The QuantiFERON[®]-TB Gold In-Tube Test (QFT-G) is an interferon gamma release assay (IGRA) which tests blood for the presence of *M. tuberculosis* infection. For patients with a previous positive TST reaction, an IGRA (QFT-G) can be done if there is suspicion that the TST result was a false positive. In addition, the IGRA (QFT-G) test is not affected by past bacille of Calmette-Guerin (BCG) vaccination and may eliminate the unnecessary treatment of patients with BCG-related-false-positive results on a TST.

The advantages of the IGRA (QFT-G), compared with the TST, are that results can be obtained after a single patient visit, and that, because it is a blood test performed in a qualified laboratory using standardized analysis methods, the variability in results associated with skin test reading can be eliminated.

However, the IGRA (QFT-G) test has practical limitations that include the need to draw blood and to ensure its receipt in a qualified laboratory within 16 hours.

CDC recommends that the IGRA (QFT-G) may be used in all circumstances in which the TST is currently used, including contact investigations, evaluation of recent immigrants, and sequential-testing surveillance programs for infection control (e.g., those for health-care workers). The use of IGRA (QFT-G) in pediatric populations is still being researched, but looks promising. The CDC guidelines can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm>

Guidelines for the use of the IGRA (QFT-G) test developed by Thurston County are available in the forms section of this manual. <http://www.doh.wa.gov/cfh/TB/Manual/Forms/TBControlGuidelines.pdf>

For a list of laboratories offering the IGRA (QFT-G) test in Washington State, see **Table 3**



A single IGRA test is used in place of (and not in addition to) the TST in screening of healthcare workers.



For more information regarding QFT healthcare worker guidelines see [QFT: TB Control Guidelines for Public Health Staff](#) (Forms Section)

Specimen Shipment

There are three main categories of transportation methods: medical couriers, ground transportation, and air transportation. Shipment of specimens is further categorized by their likelihood of causing infection if improperly handled. Each category requires different packaging requirements to provide increased levels of protection against leaks and contamination.

The following is for informational purposes:

Category A

Category A specimen handling applies only to laboratories because they deal with pure mycobacterial cultures which are classified as “dangerous goods.” Local Health Jurisdictions and other healthcare providers will not be handling these specimens.

Category A: Pure mycobacterial cultures (or culture isolates suspected of being mycobacteria) are classified as 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.

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: 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 at <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>
- 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 171–185 (August 14, 2002) at http://www.access.gpo.gov/nara/cfr/waisidx_04/49cfrv2_04.html
- The Department of Labor, Occupational Safety and Health Administration (OSHA): [29 CFR 1910.1030](#)⁸

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 650.⁹

Category B specimens are “raw” specimens which are handled by Local Health Jurisdictions and other healthcare providers.

Category B

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, taxi or private vehicle.

For information regarding requirements for shipping, refer to the Washington State Department of Health Public Health Laboratories website at:

<http://www.doh.wa.gov/EHSPHL/PHL/packaging.htm>

Shipping Training Requirements

Employers are responsible for assuring proper training for all employees with job responsibilities which include the packaging and shipping of diagnostic (clinical) specimens. This training may be conducted either at the job location or by sending employees to a course presented by the Washington State Department of Health Public Health Lab or other source for training. Documentation of training from a former employer is also acceptable. Only the employer can certify that the training is appropriate for each individual given their job responsibilities.

Training and certification should occur within 90 days of hire or assignment to a job where such knowledge is needed. Retraining should occur whenever regulatory changes indicate, or at least once every three years. Training should also be followed by demonstration of competency, either during the training course, or by the employer at the facility, which documents the validity of the training and the mastery of the content by the employee. Documentation of this training and the resulting certification must be kept throughout the entire time the individual is employed in the facility.

As part of the training process, the employer has several responsibilities:

- Training must be specific to the job duties performed by an individual.
- Retraining must be provided as needed, according to changing regulations.
- The employer must be in contact with the carrier to assure that most recent rules are met.
- The employer must keep records of the curriculum and content of each training session.

- The employer must certify that the individual has been properly trained in accordance with work responsibilities and has passed a test to assure competency.
- The employer must maintain the documentation throughout the entire course of employment of an individual.



For further information refer to:

- Washington State Department of Labor and Industries Enforcement Directive: [OSHA CPL 2-2.69](#)
- Requirements for Specimen containment: [WAC 296-823-14045](#)
- Requirements for labeling: [WAC 296-823-14025](#)
- For shipping training courses, contact the Washington State Department of Health Public Health Laboratories website at: <http://www.doh.wa.gov/ehsphl/phl/Training/train.htm>
- For shipping regulations, refer to “[Resources and References](#)” at the end of this section.



For more information regarding shipping requirements, contact the following staff at the Washington State Department of Health Public Health Laboratories:

- Training Program Advisor (PHL) ph: 206-418-5404 Fax: 206-418-5445
- Training Program Manager (PHL) ph: 206-418-5401 Fax: 206-418-5445
- Training Program (PHL) ph: 206-418-5402 Fax: 206-418-5445



To obtain specimen collection and transport supplies, see the topic on “Specimen Collection” and “Specimen Shipment” in this section of the manual.

Sputum specimen kits are available from the Washington State Department of Health Public Health Laboratories (PHL) by calling the PHL mailroom at **206-418-5579**.

Washington State Department of Health
Public Health Laboratories
Mailroom Services
1610 N.E. 150th St.
Shoreline, WA 98155

Ph: 206-418-5579
Fax: 206-418-5405

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]). 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).

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]). Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf> .
- CDC. *Public Health Mycobacteriology: A Guide for the Level III Laboratory* (Atlanta, GA; 1985).
- Francis J. Curry National Tuberculosis Center. *Pediatric TB: A Guide to the Gastric Aspirate (GA) Procedure* (Francis J. Curry National Tuberculosis Center Web site). Available at: http://www.nationaltbcenter.edu/products/product_details.cfm?productID=ONL-06 .
- International Air Transport Association (IATA). IATA Web site. Available at: <http://www.iata.org/index.htm> .
- 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).
- 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). Available at: <http://pe.usps.com/> .



In the WAC, see Chapter 246-101 (Notifiable Conditions) in the Title 246 (Department of Health) at <http://apps.leg.wa.gov/wac/default.asp?cite=246-101>

Also, see Notifiable Conditions Guidelines, at <http://www.doh.wa.gov/notify/guidelines/pdf/tuberculosis.pdf>

References

- ¹ 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):18.
- 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/Documents/Global_docs/tb_task_force_future.pdf
- ⁴ ATS, CDC, IDSA. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med.* 2000;161:1376–1395.
- ⁵ Iseman, MD. *A Clinician's Guide to Tuberculosis, 2000.* 1st ed. Philadelphia, PA: Williams & Wilkins; 2000:135–136.
- 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 National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:2.
- ⁹ National Jewish Medical and Research Center. *How to Mail Specimens and Cultures to the National Jewish Mycobacteriology Laboratory.* Denver, CO; March 2005:5–7.

Washington State Laboratory References

- [Nucleic Acid Amplification \(NAA\) and Mycobacterium Tuberculosis Direct Test \(MTD\) Recommendations](#)



For more information, see Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the diagnosis of Tuberculosis at

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?s_cid=mm5801a3_e

- [Tuberculosis Screening Guidelines](#)