Prince Edward Island
CANADA

Health and Wellness

Prince Edward Island Latent Tuberculosis Infection (LTBI) Guidelines

September 2025

Department of Health and Wellness
Chief Public Health Office

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Definitions

Active tuberculosis disease (TBD) – Active clinical disease that is usually symptomatic and for which microbiologic tests are usually positive and radiologic tests usually abnormal.

Bacille Calmette-Guerin (BCG): A live vaccine derived from attenuated Mycobacterium bovis

CPHO- Chief Public Health Office/Officer for Prince Edward Island

HIV – human immunodeficiency virus (HIV) is a virus that attacks the body's immune system, making a person more vulnerable to other infections and diseases. If untreated, it can lead to AIDS (acquired immunodeficiency syndrome)

Interferon gamma release assay (IGRA) – In-vitro T-cell based assays that measure interferon-γ (IFN-γ) production and that have been developed as alternatives to tuberculin skin testing (TST) for the diagnosis of latent TB infection. IGRA can help to distinguish if the positive TST result is from exposure to TB or another organism or cause. On PEI this test is used if there is a positive TST and the client is very low risk or has had BCG vaccine in the past.

Latent tuberculosis infection (LTBI) or Tuberculosis infection (TBI) – The presence of latent or dormant infection with Mycobacterium tuberculosis. Patients with LTBI have no evidence of clinically active disease, meaning that they have no symptoms, no evidence of radiographic changes that suggest active disease and negative microbiologic tests; they are non-infectious.

PHN – Public Health Nurse

Tuberculin skin test (TST) – Skin test to identify whether a person has delayed-type hypersensitivity reaction to tuberculin antigens. The only internationally recommended method of tuberculin skin testing is the Mantoux technique, which consists of intradermal injection of tuberculin material on the inner surface of the forearm. An induration is measured on a second visit that occurs 48-72 hours after administration.

Introduction

In 2022 the 8th version of the Canadian Tuberculosis Standards was published. This Prince Edward Island (PEI) Latent Tuberculosis Infection (LTBI) guideline document is based on these updated standards.

Over the past 10 years we have seen an increase in the population of PEI. There are people coming to live on PEI from various countries across the globe. Some of these countries have a very high rate of tuberculosis disease (TBD) in the general population and unknowingly people may have become infected. Most people who have LTBI will not develop active TB disease; on average, 5%-10% of those who are infected will develop TB during their lifetime. Determining who that 5-10% will be remains a challenge, thus as Canada moves toward the elimination of TBD, the treatment of LTBI, is vital.

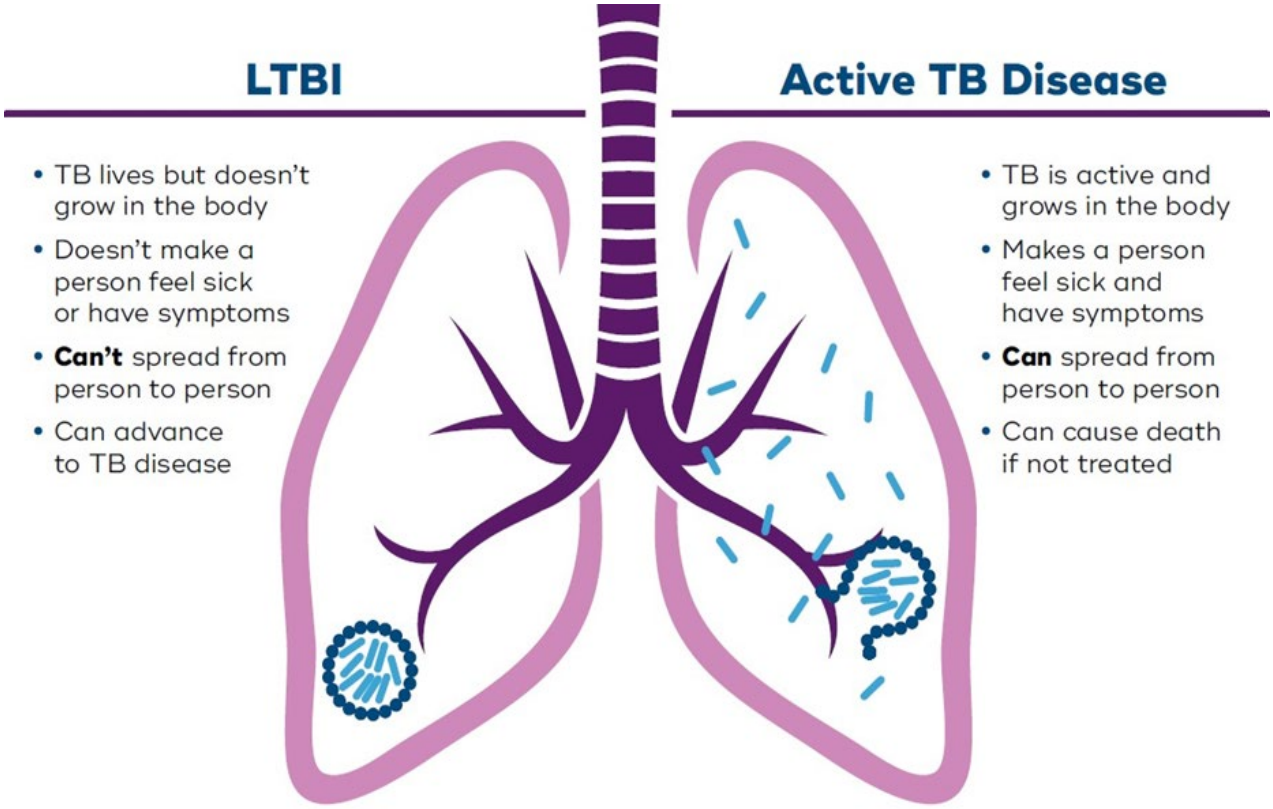
This guideline will outline the groups that should be considered for LTBI testing on PEI, the methods of testing as well as the treatment to be provided for those who are positive.

The treatment of LTBI can substantially reduce the risk of development of TBD and thus has the potential to protect the health of the individual from immediate and long-term health effects associated with TBD. By treating those with LTBI the public is also protected by reducing the number of potential sources of TBD and future transmission.

It is important to differentiate active TB disease (TBD) where a person is infectious to others and which causes illness, and latent TB infection (LTBI) which is not infectious and does not make a person sick (Figure 1.).

For all individuals being considered for LTBI treatment, it is essential to rule out active TBD prior to starting any LTBI treatment regimen.

Figure 1: LTBI vs. TBD



Source: [The time is now - Chief Public Health Officer spotlight on eliminating tuberculosis in Canada - Canada.ca](#) (2018)

Case Definition

LTBI

There is no national case definition for LTBI. The following criteria are used to diagnose LTBI in Prince Edward Island, consistent with the Canadian Tuberculosis Standards (8th Edition, 2022) and the reporting requirements under the Prince Edward Island Public Health Act.

1. Prior to Testing for LTBI

To rule out active tuberculosis disease (TBD), the following must be confirmed:

a) **Negative Clinical Assessment:** Absence of symptoms and physical findings suggestive of active TBD, including but not limited to:
   - Cough lasting longer than 3 weeks
   - Hemoptysis (bloody sputum)
   - Unexplained weight loss
   - Fever

- Night sweats
- Fatigue or malaise
- Physical examination findings, such as skin lesions (e.g., cutaneous TB) or lymphadenopathy (e.g., scrofula)

b) **Negative Microbiologic Testing:** If sputum testing for Mycobacterium tuberculosis is performed (e.g., in the presence of symptoms or abnormal chest x-ray), results must be negative (e.g., smear microscopy, culture, or nucleic acid amplification testing).

2. Diagnostic Criteria for LTBI

An LTBI diagnosis is confirmed by either of the following, in the absence of active TBD:

a. **Positive Tuberculin Skin Test (TST):** A positive TST result, defined per Canadian Tuberculosis Standards:

Notes on Diagnostic Testing:

- ≥5 mm induration in high-risk groups (e.g., close contacts of active TB cases, HIV-positive individuals, those with immunosuppression).
- ≥10 mm induration in moderate-risk groups (e.g., health care workers, immigrants from high-TB-burden countries).

b. **Positive Interferon Gamma Release Assay (IGRA):** A positive IGRA result (e.g., QuantiFERON- TB Gold Plus or T-SPOT.TB), indicating immune sensitization to Mycobacterium tuberculosis.

- Either a positive TST or a positive IGRA is sufficient to diagnose LTBI in the appropriate clinical context (e.g., high risk of TB reactivation, such as recent TB exposure, HIV infection, anti-TNF therapy, dialysis, organ transplant candidates, or silicosis).
- In individuals with a history of Bacille Calmette-Guérin (BCG) vaccination or exposure to non-tuberculous mycobacteria (NTM), IGRA is preferred to confirm a positive TST due to the risk of false-positive TST results. However, a negative IGRA following a positive TST does not automatically rule out LTBI, particularly in high-risk individuals (e.g., recent TB contacts, immunocompromised patients). Clinical judgment, risk assessment, or specialist consultation should guide the diagnosis.
- Negative TST and IGRA results generally rule out LTBI, but false negatives may occur in cases of immunosuppression, recent TB exposure (<8 weeks), or anergy. Repeat testing or specialist consultation may be warranted in high-risk cases.

3. Radiographic Evaluation

A normal chest x-ray or a chest x-ray with no evidence of active TBD (e.g., no cavitary lesions, consolidations, or other signs of active disease) is required to support an LTBI diagnosis.

Suspect LTBI

- A "suspect LTBI" designation may be used temporarily for individuals with a positive TST who meet the pre-testing assessment criteria (negative clinical, microbiologic, and radiographic findings) but have not undergone IGRA testing (e.g., due to unavailability or pending results). These individuals should undergo further evaluation, such as IGRA testing (especially if BCG-vaccinated or low-risk) or consultation with a TB specialist. LTBI treatment may be considered based on risk factors and clinical judgment, per the Canadian Tuberculosis Standards.

Reporting

Latent Tuberculosis Infection (LTBI) is reportable under the Prince Edward Island *Public Health Act.*

The Positive LTBI Report Form (Appendix 1) must be filled out for all clients who have a positive TST or IGRA result and sent to the Chief Public Health Office along with a recent chest x-ray result.

Laboratories

The Provincial Laboratory shall, in accordance with the Prince Edward Island *Public Health Act,* report all positive laboratory results (IGRA) by mail, fax, or electronic transfer to the Chief Public Health Officer (CPHO) (or designate).

Health Care Providers

Any positive TST/IGRA results must be reported to the CPHO by the performing health care provider by completing the Positive LTBI Report Form (Appendix 1) and sending it by mail, fax or electronic transfer once the result is known. It is not necessary to report LTBI on the weekends/holidays.

National notification

LTBI is not nationally notifiable at this time. However, there is a movement for provinces and territories to make LTBI notifiable in order to understand the rates and potential increase in cases of TBD related to increases in LTBI rates. PEI is one of the first provinces to make LTBI reportable. It is possible that it will become nationally notifiable in the future as more provinces and territories have the information available.

Etiology

In most individuals, Mycobacterium tuberculosis (*M. tuberculosis*) infection is contained initially by host defenses, and infection remains silent (latent). However, LTBI has the potential to develop into TBD at any time. Several risk factors, such as time since tuberculosis exposure, medical conditions, treatments or personal habits that affect host immunity can affect an individual's risk for progression from LTBI to TBD.

Clinical presentation

In the classical concept of LTBI, *M. tuberculosis* bacteria are believed to survive for years at the site of the original infection in the lung and draining lymph nodes and in the small granulomas or solid caseous

material of lympho-hematogenously seeded foci. Granuloma formation, with its oxygen-depleted environment, is a defining characteristic of TB. It is this stage of infection that is termed LTBI and is usually identified by a positive TST or IGRA in the absence of TBD

Epidemiology

About a quarter of the global population is estimated to have been infected with TB bacteria (LTBI). About 5–10% of people infected with TB will eventually have symptoms and develop TBD.

In 2024 on PEI there were 81 confirmed cases of LTBI and 57 suspect LTBI cases.

Transmission

With few exceptions, infection with Mycobacterium tuberculosis is acquired by inhalation of small droplet nuclei (1-5 microns in diameter) that contain just a few mycobacteria and can reach the alveoli. Through innate immune mechanisms, alveolar macrophages eradicate the bacteria in some individuals; in others, the bacteria can replicate and establish LTBI. Bacterial factors and host genetic factors that promote or limit acquisition of infection are not well understood.

Incubation

LTBI, by definition, is without symptoms. However, after exposure to someone with TBD, it takes up to 8 weeks before someone will show a positive result on a TST or IGRA .

Period of communicability

LTBI is not contagious.

Host susceptibility

It is now increasingly understood that host defense strategies against infectious diseases comprise both host resistance and disease tolerance. Host resistance is the ability of the host to prevent invasion or to eliminate the pathogen, while disease tolerance is defined as limiting the tissue damage caused by the pathogen and/or the immune response. Since the discovery of *M. tuberculosis* more than a century ago, great progress has been made in defining the mechanisms of host resistance to this respiratory pathogen. By contrast, our understanding of natural immunity in the 90 to 95% of infected individuals who remain disease-free is extremely limited. The inability of both the innate and adaptive immune system to eliminate the bacteria forces the host to develop a cellular barrier, referred to as a granuloma, around infected cells. Granuloma formation appears to be the point at which host immunity “switches” from resistance to tolerance.

Diagnosis

Diagnosis of LTBI can be made by using the tuberculin skin test (TST) or Interferon-gamma release assay (IGRA) blood test. If either are positive, a chest x-ray and assessment for active TB disease symptoms should be done to rule out active TB before moving forward with treatment.

The following patients should be systematically tested and treated for LTBI:

- initiating anti-TNF treatment
- patients receiving dialysis

- patients preparing for an organ or haematological transplant
- patients with silicosis
- people infected with HIV

In countries with a low TB incidence like Canada, depending on local epidemiology, testing for and treatment of LTBI may be considered for:

- people who are incarcerated who have migrated from countries with a high TB burden
- people who are homeless
- people who use illicit drugs
- health workers

In PEI, health care workers are to be screened for LTBI per the Canadian TB Standards (2022) which recommends:

- **All** health care workers should have a baseline LTBI/TBD screening, including:
  - an individual risk assessment that identifies risks for TBD/LTBI (temporary or permanent residence in a high-incidence country, prior TBD, current or planned immune suppression or close contact with someone who has had TBD since the last tuberculin skin test);
  - a symptom evaluation; and
  - a tuberculin skin test for those without documented prior TBD or LTBI.
- The tuberculin skin test is the preferred diagnostic test for pre-employment and periodic testing (if indicated) for LTBI infection among health care workers.
- The procedure for and information about performing a TST can be found in Appendix 2
- A baseline 2-step tuberculin skin test (Appendix 3) should be done unless there is documentation of a prior negative 2-step test, in which case a single-step test should be done, and all results entered into the health care worker's health record.
- It is not recommended to do routine periodic TB testing of all health care workers with negative baseline tuberculin skin test. Repeat testing should be done when an exposure has occurred or is suspected.
- While volunteers should be screened for risk factors or LTBI, consideration could be given to performing a TST only in those who expect to volunteer at least one-half day/week or who have risk factors for LTBI.
- All health care workers with a positive TST should be assessed for active TB disease, including chest x-ray and a medical evaluation, including consideration for treatment of LTBI by a physician/NP experienced in management of LTBI; they should also be educated on the signs and symptoms of TBD.
- A TST should not be performed on a health care worker who has a documented previous TST-positive or has prior documented TBD.
- Treatment of health care workers with LTBI is encouraged in the absence of contraindications to the recommended medications.
- Symptom evaluation for all health care workers should be performed by Occupational Health Safety and Wellness when an exposure is recognized and referral for medical assessment be made as required.

- The health care worker who has been exposed to a person with TBD with a baseline negative tuberculin skin test should have another such test 8 weeks after exposure. (see PEI TB disease guideline)
- A positive TST is generally considered to be >= 10mm induration. However, if the client is high risk or a recent contact of a TB case >= 5mm. See Appendix 4 Interpretation of TST results and cutoff thresholds in various populations

How to obtain Tuberculin fluid for the TST

Purified protein derivative (PPD) tuberculin is a preparation of purified protein derived from culture filtrate of Mycobacterium tuberculosis. This solution is used to perform the tuberculin skin test and can be purchased through pharmaceutical distribution companies, for those who are doing TSTs for the general public at a cost.

Those testing employees of the health system (PHN, employee health, public and private long term care facilities, and all other HPEI sites) as well as UPEI and Holland College health clinics can source their PPD solution from the provincial pharmacy.

Medical Surveillance

Immigration, Refugees and Citizenship Canada (IRCC)

- People applying for temporary visa such as students, visitors and workers who have resided in certain countries for the 6 months prior to application, or those who will be caring for certain populations, require an immigration medical exam before coming to Canada. Also, those applying for permanent residency require an immigration medical exam at their point of application.
- Those applying from outside of Canada, with evidence of active TBD during their immigration medical exam, are denied entry until treatment has been completed.
- Individuals who do not have active TBD but have a history of TBD or those who have evidence of past TBD on their chest x-ray are reported to CPHO for medical surveillance.
- As a condition of entry, these individuals are required to report to or be contacted by a public health authority within 30 days of their arrival in Canada.
- All medical surveillance clients on PEI are seen in the public health clinic by a physician and further testing with IGRA and Chest x-ray or a schedule of x-ray monitoring is initiated.
- Clients are followed by the CPHO until treatment for LTBI is complete or, if treatment is not indicated, until chest x-ray schedule to determine stability is complete (usually completed over 2 years).

Management of a case of LTBI

As Canada moves toward the elimination of tuberculosis (TB), the treatment of latent tuberculosis infection (LTBI), also called tuberculosis preventive treatment (TPT), is paramount. Identification and

treatment of LTBI can substantially reduce the risk of development of TBD and thus has the potential to protect the health of the individual from immediate and long-term health effects associated with TBD, as well as protecting the public by reducing the number of potential sources of future transmission.

Pretreatment evaluation

It is critical to exclude active TBD prior to initiation of tuberculosis preventive treatment (TPT) to avoid undertreatment of TBD, with subsequent development of drug resistance. The initial assessment should include:

- pregnancy evaluation
- a clinical assessment to ensure the patient is not having the following symptoms of TBD:
    - Chronic cough of at least 2-3 wks duration
    - Fever and night sweats
    - Hemoptysis
    - Anorexia
    - Weight loss
    - Chest pain and other symptoms that are manifestations of more advanced disease
- chest x-ray
- baseline medications evaluated for potential drug-drug interactions with proposed TPT regimens
- baseline testing for all patients undergoing TPT, including:
    - complete blood count
    - alanine aminotransferase
    - bilirubin
    - hepatitis B and C serology
    - HIV serology

Treatment

Medications

In PEI, 4 months of rifampin is the treatment that is generally prescribed due to availability of the medication and the shorter duration of treatment. However, the choice between regimens should be tailored to the patient's specific circumstances, considering factors such as patient preference, pill burden/number of doses and potential for adverse effects, see Table 1 for treatment regimens.

Prior to starting TPT (all regimens), patients should be counseled regarding the following:

- an average 5-10% of those who are infected will develop TBD during their lifetime and that half of those people will develop TB within the first two years of infection
- taking all doses of the TPT will reduce this risk significantly, thus preventing the development of TBD
- possible side effects such as changes in color of urine (see Rifampin Fact Sheet Appendix 5)
- possible adverse events associated with TPT can occur but are rare
- contact ordering health care provider should they develop possible adverse events

- if prompt evaluation of such events by a health care provider is not possible or if symptoms are severe then the patient should stop their treatment medication

Table 1: Summary of recommended treatment regimens for latent TB infection.

Regimen	Duration	Dose	Frequency	Common adverse effects
First-line regimens				
Rifapentine and isoniazid (3HP)	3 months (12 doses)	Isoniazid: 15 mg/kg Maximum: 900 mg Rifapentine: 10-14.0 kg: 300 mg 14.1-25.0 kg: 450 mg 25.1-32.0 kg: 600 mg 32.1-49.9 kg: 750 mg ≥50.0 kg: 900 mg Maximum: 900 mg	Once weekly	Flu-like reactions, drug interactions
Rifampin (4 R)	4 months (120 doses)	10mg/kg Maximum: 600 mg	Daily	Rash, drug interactions
Second-line regimen				
Isoniazid (9H)	9 months (270 doses)	5mg/kg Maximum: 300 mg	Daily	Hepatoxicity, peripheral neuropathy
Alternative regimens				
Isoniazid (6H)	6 months (180 doses)	5mg/kg Maximum: 300 mg	Daily	Hepatoxicity, peripheral neuropathy
Intermittent isoniazid for 9 months	9 months (78 doses)	15mg/kg Maximum: 900 mg	Twice weekly	Hepatoxicity, peripheral neuropathy
Isoniazid and rifampin (3HR)	3 months (90 doses)	Isoniazid: 5mg/kg Maximum: 300 mg Rifampin: 10mg/kg Maximum: 600 mg	Daily	Hepatoxicity, peripheral neuropathy, drug interactions

NOTE: Rifapentine is not approved for use in Canada and only available through the Special Access Program from the Federal Government.

Evaluation During Tuberculosis Preventative Treatment

Clients should be evaluated at the end of the first month of treatment for medication tolerance and for a recheck of blood work including ALT, bilirubin and CBC. After the baseline and first month bloodwork, no additional blood work is required with the exception noted below.

- Monthly clinical assessments should be continued for the duration of treatment.
- In patients at low risk of adverse events and likely to complete treatment, the interval between visits may be extended.
- Patients taking 4 months of rifampin (4R) or 3 months of INH/Rifapentine (3HP) do not require further laboratory monitoring during treatment unless the patient has an abnormal test result, develops symptoms suggesting an adverse event or has risk factors for hepatotoxicity (history of previous drug-induced hepatitis, current cirrhosis or chronic active hepatitis of any cause, hepatitis C, hepatitis B with abnormal transaminases).
- For patients on regimens other than 3HP or 4R, monthly monitoring of ALT and bilirubin should also be performed among patients with risk factors for hepatoxicity.

Arrangement and Payment for TPT on PEI

TPT is **provided at no cost** for people living in PEI**.**

When prescribing TPT it is important to determine the visa status of the client so that the prescription can be sent to the correct pharmacy. Residents of PEI who are on a temporary work, student or visitor visa (even if they have a health card) do not qualify for pharmacare and cannot receive their medication through the provincial pharmacy and the pharmacare program.

For residents on temporary visas that do not qualify for pharmacare, arrangements for coverage of medication can be made by contacting the CPHO. In such circumstances the prescription can be sent to and dispensed by a community pharmacy and invoiced to the CPHO.

For residents who qualify for pharmacare. Clients must be "enrolled" in the TB program. This is achieved by contacting the CPHO and providing the client information and drug(s) that is being prescribed for the treatment of LTBI. The CPHO then provides the Provincial Pharmacy with the documentation required for enrollment. Prescriptions for TPT should be sent to the Provincial Pharmacy and will be dispensed in Charlottetown. For those living in other parts of the province who would like the medication delivered to them, a courier can be arranged with the pharmacy for a fee (if the fee is cost prohibitive to the client contact the CPHO).

If the person with LTBI chooses not to take TPT or treatment cannot be tolerated, the patient should be advised of the symptoms of active TBD to watch for and told to seek medical attention if these occur. A period of formal observation can be considered for high-risk patients who decline treatment.

Completion of Treatment

There is no test of cure for LTBI. No testing is required at the end of TPT, however, confirming treatment completion with the client is recommended.

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Appendix 1

Positive LTBI reporting form

All Health care providers who are administering TST/ordering IGRA will fill out the following form when a positive result is received and send it to the CPHO to fulfill the legal reporting requirement of the PEI Public Health Act.

Public Health Nursing will report a positive LTBI using the LTBI report form in the CD 2.0 database.

Prince Edward Island Health and Wellness
CANADA

Positive Latent Tuberculosis Infection (LTBI) Report Form

Case ID:

1. CLIENT INFORMATION:			
PHN	Sex ☐ Male ☐ Female	Date of birth	
Last name	First name		
Email			
Parent/Guardian (if applicable)			
Address	City/town	Postal Code	
Tel / Alt Tel	Family Dr	Tel	
Ethnicity / Employer		Tel	
Country of birth	Year of immigration		

2. REASON FOR TESTING:	
☐ 65 years of age and under at a LTC facility	☐ Diagnosis of Medical Condition
☐ Entry into Educational Program	☐ Working in TB Endemic Area
☐ Health Care Worker Screening	☐ Other, Specify

3. HAS CLIENT RECEIVED BCG:	
☐ No ☐ Yes	If yes, At what age

4. HAS CLIENT BEEN EXPOSED TO TB IN THE PAST:		
☐ No ☐ Yes	If yes, when (year)	Where (country)
Circumstances of Exposure:		
Was the client treated ☐ No ☐ Yes	If yes, describe	

5. TEST RESULTS			
IGRA completed	☐ No ☐ Yes	Result	☐ Positive ☐ Negative

Initial TST	**Second TST (If needed)**
Date planted	Date planted
Date read	Date read
Result (induration only, not redness) mm	Result (induration only, not redness) mm

6. RISK FACTORS FOR REACTIVATION	
☐ HIV Infection	☐ Abnormal Chest X-ray: granuloma
☐ AIDS	☐ Abnormal Chest X-ray: fibronodular disease
☐ Diabetes Mellitus	☐ Carcinoma of Head or Neck
☐ Cigarette smoker (> 1 pack/day)	☐ Recent TB infection (TST conversion ≤ 2 years ago)
☐ Transplantation (requiring immune-suppressant therapy)	☐ Tumor Necrosis Factor (TNF) alpha inhibitors (infliximab/Etanercept)
☐ Treatment with glucocorticoids	☐ Silicosis
☐ Underweight (< 90% ideal body weight or a body mass index (BMI) ≤ 20)	☐ Young age when infected with TB (i.e. 0 - 4 years)
☐ Chronic renal failure requiring hemodialysis	☐ Other

7. REFERRED FOR CHEST X-RAY AND REQUISITION GIVEN TO CLIENT
☐ No ☐ Yes If no, comment
NOTE: IT IS RECOMMENDED THAT ANY CLIENT WITH A POSITIVE TST HAVE A CHEST X-RAY IF ONE HAS NOT BEEN DONE IN THE PAST 6 MONTHS
ADDITIONAL COMMENTS:
HCP COMPLETING FORM:

PLEASE RETURN COMPLETED FORM TO THE CPHO – FAX: 902-620-3354,
MAIL: 16 FITZROY ST. 2ND FL SULLIVAN, PO BOX 2000 CHARLOTTETOWN, PE, C1A 7N8
EMAIL: slburns@ihis.org

Appendix 2

Tuberculin skin test (TST) administration and interpretation

Appendix 1

A.1. Tuberculin skin test (TST) administration and interpretation

A.1.1. Administration of TST

The only internationally recommended method of tuberculin skin testing is the Mantoux technique, which consists of intradermal injection of tuberculin material on the inner surface of the forearm. The instructions on how to perform this technique have been reproduced and adapted,[7,17] with supporting videos available.[18]

A.1.1.1. Handling the solution

- The purified protein derivative (PPD) should be stored between 2° and 8 °C and never frozen. Discard the solution if it freezes.
- Remove the tuberculin solution from the vial under aseptic conditions. A little more than 0.1 mL of PPD solution should be drawn into the TB syringe. Hold the syringe upright and lightly tap out the air, then expel one drop. Check that a full 0.1 mL remains in the syringe.
- Do not transfer the solution from one container to another, as the potency of the PPD may be diminished.
- Draw up the solution just before injecting it. Do not preload syringes for later use as the potency of the PPD may be diminished.
- The solution can be adversely affected by exposure to light. PPD should be stored in the dark except when doses are actually being withdrawn from the vial.
- Use the solution within one month after opening, as the potency of the solution may be diminished. Label each bottle with the discard date when it is opened.

A.1.1.2. Preparing the person to be tested

- Seat the person comfortably and explain the procedure.
- Use the inner aspect of the forearm, preferably the nondominant arm (where administration and reading of the reaction is easiest), about 10 cm (4 inches) below the elbow; avoid areas with abrasions, swelling, visible veins or lesions. If there is a localized rash, a burn or localized eczema, avoid this area.
- If neither forearm is suitable, use the outside of the forearm or the upper arm. In this case mark the location clearly in the record.
- Cleanse the area to be injected with an alcohol swab and let the area dry.
- Do not use EMLA® cream (or similar local anesthetic cream), as application of this cream has been reported to cause localized edema, which could easily be confused with a positive TST result.

A.1.1.3. Injecting the PPD tuberculin solution

- Use a 0.6 to 1.3 cm (¼ to ½ inch), 26- or 27-gauge needle with a disposable plastic tuberculin syringe.
- Position the bevel of the needle so that it opens facing up.
- While holding the skin of the inner aspect of the forearm taut, insert the needle at a 5°-15° angle to the skin without aspirating. The tip of the needle will be visible just below the surface of the skin. The needle is inserted until the entire bevel is covered (see Appendix Figure A1).
- Administer the PPD by the slow intradermal injection of 0.1 mL (5 tuberculin units).
- A discrete, pale elevation of the skin (a wheal) 6-10 mm in diameter should appear. The wheal will typically disappear in 10-15 minutes. The size of the wheal is not completely reliable, but if a lot of liquid runs out at the time of injection and there is no wheal, then repeat the injection on the opposite forearm, or on the same forearm as before, but at least 5 cm from the previous injection site.
- A drop of blood may be seen — this is normal. The person tested should be offered gauze to remove the blood but should be advised not to massage the site in order to avoid squeezing out the PPD and disrupting the test.
- Do not cover the site with a bandage.
- Tell the patient that they should not scratch the site but may perform all normal activities, including showering or bathing.
- Place uncapped disposable needles and syringes in appropriate puncture-resistant containers immediately after use.
- If the TST is accidentally given as a subcutaneous or an intramuscular injection, this should not pose a serious risk of harm. It is possible that tuberculin-sensitive persons may have localized inflammation, which should be self-limited. It would not be possible to take a measurement of, or clinically interpret, any such reaction, so the TST should be administered again immediately *using proper intradermal technique* on the volar surface of the forearm.
- After administration, record the following:
  - Date of injection
  - Dose of PPD (5 tuberculin units, 0.1 mL)
  - PPD manufacturer
  - PPD lot number
  - Expiration date of the PPD reagent
  - Site of injection
  - Person administering the TST.
- In settings where TST administration may be unsupervised or performed by persons with minimal experience, the quality of TST administration may be assessed by following mobile TST (mTST) protocols,[17,18] whereby photos of the wheal created after administration are taken and evaluated by an experienced reviewer.

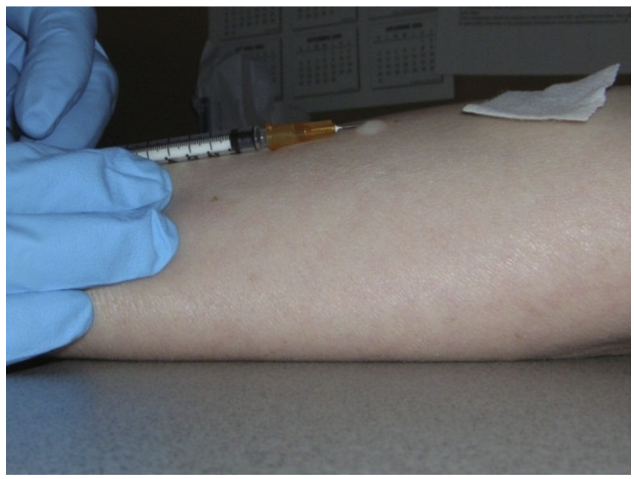

Figure A1. Technique of TST administration.

A.1.2. Precautions

- Acute allergic reactions, including anaphylaxis, angioedema, urticaria and/or dyspnea, have been rarely reported as temporally (not necessarily causally) associated with administration of Tubersol®.[108] The events have been reported in Canada at a rate of less than 1 per million doses; some were reported in persons without a prior history of TST.
- Epinephrine hydrochloride solution (1:1000) and other appropriate agents should be routinely available for immediate use in case an anaphylactic or other acute hypersensitivity reaction occurs. Health care providers should be familiar with the current recommendations of the National Advisory Committee on Immunization for monitoring of the patient for immediate reactions over a period of at least 15 minutes after inoculation and with the initial management of anaphylaxis in non-hospital settings.

The following persons can receive a TST:

- Those with a history of receiving BCG vaccination(s).
- Those with a common cold.
- Those who are pregnant or are breast-feeding.
- Those immunized within the previous four weeks with vaccines other than those listed below (live-virus vaccines).
- Those with a previous positive TST.
- Those taking low doses of systemic corticosteroids. A steroid dose equivalent to ≥15 mg prednisone daily for 2-4 weeks is required to suppress tuberculin reactivity.[109,110]

The following persons should **NOT** receive a TST:

- Those with positive, severe blistering TST reactions in the past or with extensive burns or eczema present over TST testing sites, because of the greater likelihood of adverse or severe reactions.
- Those with documented TB disease or a well-documented history of adequate treatment for TB infection or disease in the past. In such patients, the test is of no clinical utility.
- Those with current major viral infections (eg, measles, mumps, varicella).
- Those who have received live virus immunization within the past 4 weeks, as this has been shown to increase the likelihood of false-negative TST results.[111] Note that only measles vaccination has been shown to cause false-negative TST results, but it would seem prudent to follow the same 4-week guideline for other live-virus immunizations, including mumps, rubella, varicella (chickenpox) and yellow fever. However, if the opportunity to perform the TST might be missed, the TST should not be delayed for live-virus vaccines since these are theoretical considerations.
  - Note: A TST may be administered before or on the same day as the immunizations but at a different site.

A.1.3. Measuring induration

- The TST should be read by a trained health professional. Individuals without experience in reading a TST may not feel slight induration, and the TST would be mistakenly recorded as 0 mm.
- Self-reading is very inaccurate and is strongly discouraged.[112]
- Reading should be performed 48 to 72 hours after administration, as maximum induration can take up to 48 hours to develop, but after 72 hours it is difficult to interpret a reaction. Reactions may persist for up to one week, but for as many as 21% of individuals with a positive reaction at 48 to 72 hours, the reaction will be negative after 1 week.[113] If the TST cannot be read within 72 hours, it should be repeated at a location far enough from the previous test that the reactions do not overlap. There is no minimum wait time and the test can be readministered immediately.
- The forearm should be supported on a firm surface and slightly flexed at the elbow. Induration is not always visible. Palpate with fingertips to check if induration is present. If there is induration, mark the border of induration by moving the tip of a pen at a 45° angle laterally toward the site of the injection (Appendix Figure A2). The tip will stop at the edge of the induration, if present. Repeat the process on the opposite side of the induration. This pen method has advantages of being as reliable as the traditional palpation method (which relies entirely on fingertips) among experienced readers, and of being easier for new readers to learn and use.[7]
- Using a caliper, measure the distance between the pen marks, which reflects the diameter of the induration at its widest transverse diameter (at a right angle to the long axis of the forearm). A caliper is recommended because readings will be more precise and setting the caliper may reduce rounding error. If a caliper cannot be found a flexible ruler could be used.
- Do not record erythema (redness). Approximately 2-3% of persons tested will have localized redness or rash (without induration) that occurs within the first 12 hours. These minor allergic reactions do not indicate TB infection and they are not a contraindication to future TSTs.[114]
- Blistering, which can occur in 3 to 4% of subjects with positive tests, should be recorded.
- Record the result in millimeters (mm). Record no induration as "0 mm." Recordings of positive, negative, doubtful, significant and non-significant are not recommended.
- Do not round off the diameter of the induration to the nearest 5 mm, as this can interfere with determining whether TST conversion has occurred in the event of a future TST. If the measurement falls between demarcations on the ruler, the smaller of the two numbers should be recorded.
- After measuring, record the following and provide a record of the result to the patient:
  - Date the induration was read
  - Measurement of the induration, if any, in mm
  - Any adverse reactions (eg, blistering)
  - Name of the individual reading the test

- In settings where TST measurement may be unsupervised or performed by persons with minimal experience, the quality of TST measurement may be assessed by following mTST protocols,[17,18] whereby photos of the induration are taken and evaluated by an experienced reviewer. This method is most accurate when applied to no or large indurations. In all settings, routine quality control and quality assessment measures of TST induration measurement should be employed to maximize accuracy.

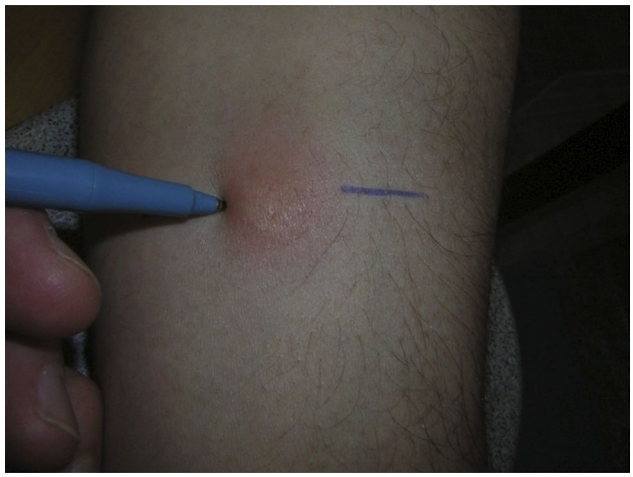

Figure A2. Ballpoint pen method for measuring the transverse diameter of the TST induration.

A.2. Reproducibility and causes of TST and IGRA variation

Table A1. Causes of variation with TST or IGRA.[88–90,92,115]

Common Causes of Variation	Causes of IGRA Variation	Causes of TST Variation
• **Pre-analytical errors**. For the TST, this includes possible issues with the PPD solution and administration (e.g., volume injected), while for IGRA these may include improper shaking of the tube after collection, delays in transport and/or incubation of samples, or errors in the actual time the sample is incubated. • **Within-person variations over time**. For the TST, responses may vary by up 5 mm in reaction size between tests. For the IGRA, a previous systematic review suggested there was a mean difference in two consecutive samples of 0.2 IU/mL between two QFT tests; similar data for T-SPOT.*TB* was not reported. • **Analytical errors**. For the TST, a mis-recording of TST measurements may lead to an incorrect conclusion of a change in induration on a second test. For the IGRA, if not recorded automatically, data-entry errors on quantitative values and interpretation may occur.	• **Test-retest variation**. While agreement is generally quite good when the same sample is tested in the same lab twice, there may be variation in the spots counted or IU/ml measured from the same sample. • **Inter-laboratory variation**. There may be different measurements when the same sample is tested in different labs. • **TST-induced variation**. A previous TST may "boost" a subsequent IGRA result. Conversions in a systematic review were uncommon but did occur with both T-SPOT.*TB* and QFT. Whether the risk of disease among persons with a boosted response is different than risk among those without a boosted response is unclear.	• **Variability associated with the reader** (eg, two different readers may measure the same induration differently).

A.3. Serial TST: Booster effect and conversions

A.3.1. TST booster effect

A single TST may elicit little response yet stimulate an anamnestic immune response, such that a second TST at any time from 1 week to one year later will elicit a much greater response.[89] This phenomenon is important to detect, as it represents a false positive, not a new TB infection. The booster effect was first described in older persons in whom it was felt to show TB infection acquired many years before (remotely) with subsequent waning of immunity.[95] It has also been described in persons with prior BCG vaccination or sensitivity to nontuberculous mycobacterial antigens.[94,116]

A two-step TST should be performed if subsequent TSTs will be conducted at regular intervals (eg, among health care or correctional workers).[89] This is to reduce the chance of a false-positive TST conversion when the TST is repeated. Please refer to Chapter 13: Tuberculosis Surveillance and Tuberculosis Infection Testing and Treatment in Migrants for recommendations on use of two-step TST in specific travelers.

The two-step protocol needs to be performed and documented ONCE. Any subsequent TST should be 1 step, regardless of how long it has been since the last TST.[7]

The same material and techniques of administration and reading should be used as with any other TST. The second test should be performed one to 4 weeks later. Less than one week does not allow enough time to elicit the booster phenomenon, while more than 4 weeks increases the possibility of a true TST conversion. Both tests should be read and recorded at 48 to 72 hours after administration. Expanding the interval to read the first TST after 1 week (and therefore immediately before a second TST) is less accurate and is not recommended.

Longitudinal studies of the risk of TB following a booster reaction defined the reaction simply as a second TST result of 10 mm or more induration.[85,117–119] Therefore, a second TST result of 10 mm or more should be considered significant and the patient referred for medical evaluation and chest radiography. [7,89]

All subjects with a reaction of 10 mm or more on the second TST of a two-step TST do not need a TST in the future. There is no clinical utility.[7] They should be referred for medical evaluation, as performed for those with a positive first TST. In longitudinal studies of the elderly, subjects with a second TST response of 10 mm or more had a risk of TB that was approximately half that of subjects whose first TST response was 10 mm or more. Similar findings were shown in a small cohort of hemodialysis patients. Since the risk of TB is about half that of patients from the same population group whose initial TST result is positive, the decision to provide TPT should be individualized.

A common question is how to manage a person whose first TST measured 5-9 mm and the second test measured 10 + mm but increased by less than 6 mm from the first test. As previously mentioned, this should be managed as a "positive TST," meaning referral for medical evaluation and no further TSTs. While appropriate epidemiologic data are lacking, it seems reasonable to suggest that the risk of TB disease would be lower than in persons whose second TST increased by at least 6 mm. The decision to provide TPT should be individualized.

A.3.2. TST conversions

If there has been recent exposure, such as close contact with a person with TB disease or occupational TB disease exposure, then TST conversion will be more likely than when there has been no exposure. Conversion is defined as a TST of 10 mm or greater when an earlier test resulted in a reaction of less than 5 mm. If the earlier result was between 5 and 9 mm, the definition of conversion is more controversial. Increases of 6 or 10 mm have been proposed, but there is weak evidence supporting both.[89] In general, the larger the increase, the more likely it is due to a true conversion. However, like consideration of a "booster," any second TST result of 10 mm or greater should be considered a "positive" and the patient evaluated for possible TPT.

All available experimental and epidemiologic evidence consistently shows that TST conversion occurs within 3-8 weeks of exposure.[89] Therefore, to identify a true conversion (ie, new infection), a single TST should be performed as soon as possible after an exposure to tuberculosis is recognized and the contact is identified. If the first TST is negative and performed less than 8 weeks after contact with the index patient, then a second TST should be scheduled no sooner than 8 weeks after the contact was broken. This also means for contacts that are identified more than 8 weeks after contact with an index patient is broken (eg, casual contacts), a single TST can be performed, and the result acted upon.[7]

A.4. Dimensions to consider when interpreting TB infection diagnostic test results

A.4.1. Pretest probability of TB infection and predictive value

The pretest probability of TB infection refers to the probability a person truly has infection. The positive predictive value therefore reflects the likelihood that a positive result truly represents infection and the negative predictive value the likelihood a negative result truly represents absence of infection. The positive predictive value of the TST may be significantly reduced by BCG vaccination in populations with low pretest probability of infection; similarly, in populations with significant immune impairment, the negative predictive value of both TST and IGRA may be significantly impacted in populations with high pretest probability of infection.

A.4.2. Discriminatory ability of the test to identify individuals at increased risk of TB disease

The discriminatory ability of the test to identify individuals who will develop TB disease refers to the IRR, that is, the likelihood of developing disease among persons testing positive vs. negative. In populations where false negatives with a TST or IGRA are expected to be common (eg, due to immune impairment or other biologic reasons), the IRR of a test may fall substantially, even with very high specificity. Similarly, in populations where false positives are expected to be common, the IRR of a test may be substantially impacted, even if sensitivity is very high. Therefore, the discriminatory ability of a test is likely to be severely impacted in populations where sensitivity and/or specificity are expected to be reduced.

A.4.3. Risk of TB disease

The risk of TB disease is elevated among persons with medical conditions that affect immunity, recent infection or certain habits, and is described for various populations among persons with a positive test in Table 2 of the main text. Using estimates of IRR, risk of TB disease can be estimated among persons with a negative test. Risk of disease is the most paramount consideration when faced with a test result, as TB disease may result in long-term patient morbidity or even death. Risk of disease at the time the test is done should not be the only consideration; it is important to also consider future risk of disease. This is especially important among certain persons, such as those tested prior to initiating immunosuppressants, prior to transplantation, or early in chronic kidney disease, as risk of disease is likely to increase in the future.

Appendix 3

Two Step TST

A two-step TST is required for anyone who will need ongoing TSTs such as health care and corrections workers. The two step TST establishes a baseline so that the response will not be confused with conversion for subsequent exposures.

If the first step is negative (appendix 4), the second step TST should be completed no sooner than one week and no later than twelve months after the first TST. The ideal time frame for the second step is one to four weeks after the first. If performed less than one week after the first TST there is not enough time to elicit the booster reaction and greater than four weeks allows the possibility of a conversion from an exposure. A two-step TST is required only once if done properly and documented. All subsequent TST can be single step, regardless of how long it has been since the previous test.

If the first step of the two step TST is positive, the second step is not required.

Appendix 4

Interpretation of TST results and cutoff thresholds in various populations

TST Result	Situation in which reaction is considered positive
<5 mm	In general, this is considered negative
≥5 mm	People living with HIV Known recent (<2 years) contact with a patient with infectious TB disease Fibronodular disease on chest x-ray (evidence of healed, untreated TB) Prior to organ transplantation and receipt of immunosuppressive therapy Prior to receipt of biologic drugs, such as tumor necrosis factor alpha inhibitors, or disease-modifying antirheumatic drugs Prior to receipt of other immunosuppressive drugs, such as corticosteroids (equivalent of ≥15 mg per day of prednisone for at least one month) Stage 4 or 5 chronic kidney disease (with or without dialysis)
≥10 mm	Recent (<2 years) conversion of TST from negative to positive Diabetes (controlled or uncontrolled) Malnutrition (<90% of ideal body weight) Current tobacco smoker (any amount) Daily consumption of >3 alcoholic drinks Silicosis Hematologic malignancies (lymphomas and leukemia) and certain carcinomas (such as cancers of head, neck, lung and/or gastrointestinal tract) Any population considered at low risk of disease.

Abbreviations: TST, tuberculin skin test; HIV, human immunodeficiency virus; TB, tuberculosis.

Appendix 5

Fact Sheets

Prince Edward Island CANADA Health and Wellness

Health PEI

Latent TB Testing

What is Tuberculosis?
Tuberculosis (TB) is a disease caused by a germ called *Mycobacterium* (my-ko-bak-teer-i-um) *tuberculosis*. TB most often affects the lung, but TB germs can infect any part of the body. TB may be latent or active. "Latent" means that the germs are in the person's body but are not causing symptoms. Latent TB is not contagious (it cannot be spread). It is sometimes called "sleeping" TB. However, latent TB can become active. This can happen if a person's immune system is too weak to prevent the TB germs from growing and multiplying. If this happens, the TB changes from being latent infection to being an active disease.

The two phases of TB (latent/sleeping and active) can both be treated with medicine.

Latent TB Infection	Active TB Disease
TB germs are "asleep" in your body. This phase can last for a very long time – even many years.	TB germs are active and spreading. They are damaging tissue in your body.
You don't look or feel sick. Your chest x-ray is usually normal or stable.	You usually feel sick. Your doctor will do special tests to find where TB is harming your body.
You can't spread TB to other people.	If the TB germs are in your lungs, you can spread TB to other people by coughing, sneezing, talking, or singing.
Usually treated by taking one medicine for 4 months.	Treated by taking 3 or 4 TB medicines for at least 6 months.

What is a TB skin test (TST)?
Early diagnosis is very important in the control of tuberculosis (TB). A TST can assist in the diagnosis by showing whether someone has been exposed to *Mycobacterium tuberculosis* bacteria.
You may need a TST for employment, entry into an education program, travel or because you have been in contact with a person who has active TB.

How is a TST done?
The TST is a 2-part test:
Step 1: a very fine needle injects a small amount of liquid just under the skin on the inside of the forearm. Although there is very little risk, you will be asked to stay in the waiting room for 15 minutes after the test to ensure there is no allergic reaction. You may get a temporary raised area where the needle was given. This is normal. If this area becomes itchy, do not scratch it and leave it uncovered.

Step 2: after 48-72 hours you will go back to have your test read. The nurse will assess the reaction to the TST. The test results are measured in reaction size (mm of induration). If there is a reaction, this does not indicate the presence of active tuberculosis disease. A positive tuberculin test reaction will need further evaluation with other diagnostic procedures such as a chest x-ray.

A second (booster) test may be required depending on the circumstances for testing, the person's history of exposure to TB and the results of the initial TST. The nurse will advise you on the need for

further testing.

What is a TB Blood Test (IGRA)?
The tuberculosis (TB) blood test, also called an Interferon Gamma Release Assay or IGRA, is a way to find out if you have TB germs in your body. The TB blood test can be done instead of or along with a TB skin test (Mantoux).

You should have a TB blood (or TB skin test) if you:

- have had frequent close contact with someone who has active TB disease,
- have lived in a country where many people have TB,
- work or live in a nursing home, clinic, hospital, prison, or homeless shelter, or
- have HIV infection or your immune system is not very strong.

A "negative" TB blood test result usually means that you don't have TB germs in your body.

A "positive" TB blood test result means you probably have TB germs in your body. Most people with a positive TB blood test have latent TB infection. To be sure, a health care provider will examine you and do a chest x-ray. You may need other tests to see if you have latent TB infection or active TB disease.

What if I had the BCG Vaccine?
The BCG vaccine (TB vaccine) may help protect young children from getting very sick with TB. This protection goes away as people get older. People who have had BCG vaccine still can get latent TB infection and active TB disease.

If you had the BCG vaccine and you have a choice of having a TB blood test or a TB skin test, it is better for you to have the TB blood test. This is because the TB blood test is not affected by the BCG vaccine. This means that your TB blood test will be "positive" only if you have TB germs in your body. BCG vaccination may cause a false positive reaction

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Rifampin

What is Rifampin?

Rifampin is a medication taken when a person has been exposed to someone who has active pulmonary tuberculosis (TB of the lungs). Rifampin is used to treat both latent TB to prevent progression to active TB and, in combination with other medications, for the treatment of active TB.

Who should NOT take rifampin?

Rifampin should not be taken when a person:

1) Has had an allergic reaction to rifampin in the past
2) Has liver disease

When should rifampin be taken?

Rifampin should be taken with a full glass of water at least 1 hour before a meal or two hours after a meal. If you take antacids, take them at least 1 hour after taking rifampin.

What are precautions when taking rifampin?

- **AVOID** use of alcoholic beverages while taking rifampin
- Rifampin may decrease the effectiveness of oral contraceptives (birth control). Other methods of birth control should be used while you are taking rifampin
- Contact lenses should not be worn while taking rifampin as it will permanently discolour the lenses
- It is normal for rifampin to cause your urine, tears, and/or saliva to become orange-coloured
- If you are planning a pregnancy or become pregnant while taking rifampin, contact your doctor/nurse practitioner to determine whether to continue taking rifampin

What are the side effects of rifampin?

A person taking rifampin should watch for the following symptoms:

- Bone or joint pain
- Rash or itchiness
- Flu-Like symptoms - fever, chills, dizziness, sweating
- Nausea or upset stomach

If these symptoms are noted a person should be seen by a doctor.

If you have any of the following more serious adverse effects, call your doctor or nurse practitioner immediately:

- Fever for 3 days or more
- Yellowing of the skin or eyes
- Loss of appetite
- Vomiting
- Weakness or fatigue

An adult taking rifampin should have liver tests done by their doctor while taking rifampin.
For more information, please contact the Chief Public Health Office 902 368-4996.

Prince Edward Island CANADA Health and Wellness

Tuberculin Skin Test (TST)

Health PEI

What is Tuberculosis?

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A second (booster) test may be required depending on the circumstances for testing, the person's history of exposure to TB and the results of the initial TST. The nurse will advise you on the need for further testing.

Who should not receive a TST?

- Those with positive, severe blistering TST reactions in the past;
- Those with extensive burns or eczema over TST testing sites;
- Those with documented active TB or a well-documented history of adequate treatment for TB infection or disease in the past;
- Due to the decreasing utility of TST to diagnose Latent Tuberculosis Infection (LTBI) after age 65 and the increasing risk of adverse effects from LTBI treatment in this age group, screening with a posterior-anterior and lateral chest x-ray for active TB is preferred for those over 65.

  The TST should be delayed for:
  - Those with current major viral infections (e.g. measles, mumps, varicella);
  - Those who have received measles or other live virus immunization within the past 4 weeks.

If you have further questions about the TST or TB please contact your health care provider or local public health nursing office.