

Source:	Manager, TB Prevention and Control Saskatchewan
Cross Index:	
Date Approved:	January 22, 2016
Date Revised:	
Date Effective:	January 27, 2016
Date Reaffirmed:	
Scope:	TB Prevention and Control Saskatchewan and Partners
Authorization:	TB Prevention and Control Saskatchewan Leadership

Any PRINTED version of this document is only accurate up to the date of printing. TB Prevention and Control Saskatchewan (TBPC SK) cannot guarantee the currency or accuracy of any printed document. Always refer to the [TBPC SK](#) web page for the most current versions of documents in effect. TBPC SK accepts no responsibility for use of this material by any person or organization not associated with TBPC SK. No part of this document may be reproduced in any form for publication without permission of TBPC SK.

	<u>PAGE</u>
1. Overview and Purpose _____	3
2. Definitions _____	3
3. Indications _____	4
4. Contraindications _____	4
5. Who May Perform Tuberculin Skin Tests _____	5
6. Anaphylaxis _____	5
7. Tuberculin PPD Storage and Handling _____	5
8. TST Screening Assessment _____	6
9. Two-step Testing to Detect Boosting _____	7
10. Procedure _____	8
Preparation _____	8
Administration _____	9
Post Administration _____	10
Reading the TST Result _____	10
Documentation and Reporting _____	12
11. Management of a Positive TST _____	13
12. Roles and Responsibilities _____	14
Appendix A: Interpretation of TST Results _____	15
<i>Table 1: TST Size</i> _____	15
<i>Table 2: Factors Associated with False-Positive or False-Negative TST Reactions</i> _____	16

	<u>PAGE</u>
<i>Table 3: Risk Factors for the Development of Active TB among People with a Positive TST</i> _____	17
Appendix B: Tuberculin Skin Test Screening Record _____	18
Appendix C: Flowcharts for TST Screening Follow-up _____	19
Appendix D: Sample Primary Care Provider Letter Requesting Medical Evaluation for a Positive Tuberculin Skin Test _____	20
Appendix E: Recommended Management for Persons with a Positive TST _____	21
Appendix F: Tuberculosis Incidence Rate by Country _____	22
References _____	24

1. Overview and Purpose

The tuberculin skin test (TST) and interferon gamma release assay (IGRA) are the accepted tests for the identification of latent TB infection (LTBI) in Saskatchewan. The goal of screening for LTBI is to identify individuals at risk of progression to active tuberculosis (TB) and, therefore, would benefit from treatment of LTBI or scheduled clinical follow up by TB Prevention and Control Saskatchewan. The TST cannot distinguish between latent TB and active TB; accordingly, it is not recommended for use in the diagnosis of active TB.

The purpose of this policy and procedure is to

1. establish standards of practice for the administration, reading, interpretation, documentation and reporting of tuberculin skin tests and subsequent identification of persons at increased risk of developing active TB;
2. establish a common approach to the management of positive tuberculin skin tests;
3. ensure prompt reporting and management of adverse reactions; and
4. outline storage and handling practices for purified protein derivative (PPD) tuberculin.

2. Definitions

Booster phenomenon means an increase in tuberculin skin test reaction after an initial negative test when the test is repeated any time from one week to one year later and is performed in the absence of exposure or other evidence of new TB infection. The immune response to PPD tuberculin may wane over time when infection was acquired remotely resulting in failure to recall prior infection when the initial TST is administered. The initial TST may stimulate the immune system causing a positive or boosted reaction on the second test. Boosting reactions are usually seen many years after infection, especially in the elderly. This phenomenon has also been described in people with prior BCG vaccination or sensitivity to nontuberculous mycobacterial antigens. Also referred to as the booster effect or boosting.

Conversion means an increase in the size of a TST reaction on repeat testing that reflects new TB infection. A positive TST may develop three to eight weeks following exposure to an individual with infectious active TB. Conversion is considered to have occurred if the negative TST was within the previous two years before the positive TST was identified.

Induration means the area of localized soft tissue swelling which is measured to determine the result of a TST.

Mantoux technique means the recommended method for administering a TST that consists of an intradermal injection of 5 tuberculin units (0.1 mL) of PPD tuberculin in the inner forearm.

Purified Protein Derivative (PPD) Tuberculin means a standardized diagnostic antigen, derived from *Mycobacterium tuberculosis* bacteria, used in tuberculin skin testing to elicit an immune response and to identify persons infected with TB. May be referred to as PPD, tuberculin or Tubersol®.

Regular volunteer means a person volunteering in a health-care, long term care, or correctional facility who expects to work 150 hours or more during the next year; meaning approximately a half day per week.

TBIS means TB Information System; the electronic data management system maintained by TB Prevention and Control Saskatchewan.

TBPC SK means TB Prevention and Control Saskatchewan.

Tuberculin skin test (TST) means a test administered to identify if a person has a delayed-type hypersensitivity reaction to PPD tuberculin. May also be referred to as a Mantoux, tuberculin or TB skin test.

Two-step TST means serial tuberculin skin testing, ideally performed one to three weeks after an initial negative result, to distinguish a boosting reaction from true TST conversion caused by recent infection.

3. Indications

The TST is most useful when clearly indicated for specific populations and programs. In Saskatchewan, the indications for screening for LTBI include:

- Exposure to persons with infectious active TB (contact screening)
- Human Immunodeficiency Virus (HIV) infection
- Pediatric screening (childhood/school screening), within defined areas of the province
- Immigration screening and surveillance
- Prior to starting tumour necrosis factor-alpha inhibitors
- Prior to transplantation
- Pre/post travel for some individuals travelling to specific countries
- Admission to a correctional facility for one year or longer
- Occupational screening for all health-care, correctional and long term care employees and regular volunteers at the time of hire and at regular intervals (e.g., annually) as recommended based on the facility risk and risk categories for activities performed by health care workers.

Note: Screening students enrolled in post-secondary health service programs is recommended at the time of program entry. The decision to screen students may depend on program and/or institution resources. When the capacity for screening is limited then screening should focus on health-care students at greatest risk of exposure to active TB during their educational program such as those that will knowingly work in areas with infectious TB patients and those that will perform aerosol-generating medical procedures.

4. Contraindications

TST is not recommended for:

- Those with documented active TB or a well-documented history of adequate treatment for latent or active TB;
- Those with a major viral illness at the time of testing (e.g., measles, mumps, varicella);
- Those with a severe reaction to a previous TST such as blistering, ulceration, or necrosis;
- Those with a known allergy or anaphylaxis to any component of the PPD or anaphylaxis to a past TST (anaphylaxis is an absolute contraindication);
- Those with extensive eczema or burns over administration sites;
- Those who have received the following vaccines within the past four weeks – measles, mumps, rubella, varicella, yellow fever, and/or live attenuated influenza vaccines such

as Flumist. Testing should be deferred as a false-negative TST result could occur. However, if the opportunity to perform the TST might be missed, the TST should be given.

Note: A TST may be administered before or on the same day as the immunization but at a different site. Immunization may be given any time after a TST has been performed and/or read.

Individuals may receive a TST if:

- They have a mild viral illness at the time of testing such as the common cold;
- They are pregnant or breastfeeding;
- They have been immunized with any vaccine on the day of the TST;
- They were immunized within the previous four weeks with vaccines other than the ones listed earlier;
- They have an undocumented history of a positive TST reaction (other than a severe reaction such as blistering);
- They have previously received the BCG vaccination.
- They are taking low doses of systemic corticosteroids defined as less than 15 mg prednisone (or equivalent) once a day. A dose of 15 mg or more daily for two to four weeks may suppress tuberculin reactivity.

Note: PPD does not contain live bacteria so cannot cause infection or conversion to a positive TST when testing is repeated in uninfected individuals.

5. Who May Perform Tuberculin Skin Tests

Regional Health Authorities, First Nations Health Services and other agencies are responsible for determining who may perform TST procedures within their organization, under what circumstances, and in keeping with the requirements of the individual's regulatory body.

6. Anaphylaxis

Epinephrine 1:1000, for intramuscular injection, must be available, as well as additional medications or supplies, in order to respond to an acute allergic reaction such as anaphylaxis. All persons administering skin tests must be able to identify and initially manage acute allergic reactions in accordance with their agency policies and procedures.

Note: While very rare, acute allergic reactions, including anaphylaxis, dyspnea, urticaria, and angioedema, have occurred in individuals following TST administration and have occurred in individuals without any prior history of testing. More information on anaphylaxis in non-hospital settings can be found in the [Saskatchewan Immunization Manual](#) and the [Canadian Immunization Guide](#).

7. Tuberculin PPD Storage and Handling

PPD vials shall:

- be stored between 2 to 8 °C;
- be stored in the dark when not in actual use;
- not be exposed to freezing temperatures or be allowed to freeze;

- only be opened at the time of use and following product verification; and
- be dated when first opened and used within 30 days of first entry.

Note: As noted in [chapter 9](#) of the Saskatchewan Immunization Manual, PPD vials that are wasted must be reported to the Saskatchewan Disease Control Lab using the Vaccine Wastage Report Form (CS 04). Completed forms must be faxed to the Vaccine Management Program, Ministry of Health at 306.798.0071.

PPD shall not be used when:

- the manufacturer's expiry date has been reached or 30 days after the vial has been opened;
- sterility of the vial is compromised or questionable; or
- visual inspection of the vial and solution shows evidence of particulate matter, discolouration, turbidity, damage to the vial septum, cracks, seepage or any other abnormality. PPD should be clear and colourless;
- storage and handling requirements have not been met:
 - a cold chain interruption has occurred (exposure to freezing temperatures or left at room temperature for an undetermined length of time);
 - the vial has been exposed to light for an undetermined length of time.

The guidelines and recommendations outlined in the [Saskatchewan Immunization Manual](#) shall be followed for all remaining storage and handling procedures including management of cold chain interruptions and expired product. Additional information may also be found in the [Tubersol® product monograph](#).

8. TST Screening Assessment

A TST screening assessment should be completed prior to TST administration. The assessment must include screening for allergies or anaphylaxis to any component within the PPD and adverse reactions to previous tests.

The following are suggested questions to ask prior to performing a TST in order to determine a client's eligibility, the appropriateness of testing, and to assist with interpretation of test results. The health professional responsible for the TST must appropriately individualize the assessment for each client. A physician should be consulted prior to administering the TST if concerns exist.

Use the [Tuberculin Skin Test Screening Record](#), available on the [TBPC SK](#) web page, to document the reason for the screen and to guide the assessment.

1. Have you had a TB skin test in the past? If yes, what was the result? Did you have an adverse or anaphylactic reaction to the test?
2. Have you been exposed to TB recently or in the distant past?
3. Have you received treatment for TB in the past?
4. Have you received a BCG vaccination? If yes, at what age? BCG scar present?

Note: Information on recognizing BCG scars may be found at www.phac-aspc.gc.ca/tbpc-latb/pdf/recognition-bcg-scars_e.ppt.

5. Do you have a medical condition that weakens the immune system such as HIV infection, chronic kidney failure requiring dialysis, diabetes, cancer of the head and neck, leukemia, lymphoma or silicosis?
6. Are you taking medication that weakens the immune system, such as prednisone, chemotherapy for cancer, immune suppressing drugs for organ transplantation or tumour necrosis factor-alpha inhibitor (anti-TNF) medications for the treatment of an inflammatory condition?
7. Do you have life-threatening allergies?
8. Are you allergic to polysorbate 80 (tween 80) or phenol?
9. Have you been immunized for measles, mumps, rubella, varicella, yellow fever or received the Flumist® vaccine for influenza in the last four weeks?
10. Are you well today?
11. Do you have any questions regarding the test?

9. Two-step Testing to Detect Boosting

1. Once a baseline two-step TST has been completed all subsequent tests need only be single step provided the two-step was documented.
2. The second TST shall be performed one to three weeks after the first test.

Exception: A documented negative TST within the past 12 months may serve as the first TST of a two-step test to detect boosting as the booster effect can be seen up to one year after an initial negative TST.

3. Two-step testing to detect boosting is not recommended in the context of a contact investigation nor is it required if there is a documented negative TST within the past 12 months.
4. Two-step testing is recommended:
 - As a baseline test when testing is planned at regular intervals (e.g., annual screening);
 - For all health-care, correctional, and long term care employees and regular volunteers at the time of hire;
 - For inmates at the time of admission to a correctional facility for one year or longer;
 - In persons 50 years of age or older in whom TST is indicated.

Note: The decision to perform two-step testing may depend on program resources, practicality, and the individual risk associated with remote latent TB that remains undiagnosed. Programs unable to implement the recommendations for two-step testing should, at a minimum and as resources permit, perform two-step testing in those aged 50 years or older.

10. Procedure

Preparation

1. Obtain informed consent from the client, parent, legal guardian or substitute decision maker ensuring the following is included in the process:
 - Explain the test purpose, procedure and post administration care. Provide educational materials as required and document teaching in the health record, if available. Instructions should include:
 - Wait 15 minutes, or longer as clinically indicated, before leaving the test centre to allow for monitoring of immediate adverse reactions. Individuals refusing to wait 15 minutes should receive instruction regarding the signs and symptoms of anaphylaxis and the need to seek immediate medical attention should they occur.
 - Pain/discomfort, pruritus, bruising or localized redness or rash may occur at the injection site. Severe blistering reactions may occur in up to 3-4 percent of those with positive tests. Application of a cold compress may provide relief from pain/discomfort and pruritus.
 - The wheal will disappear approximately 10-15 minutes after injection.
 - Report any adverse reactions and seek medical care as required.
 - Return within 48 to 72 hours for reading, as arranged.
 - Do not scratch or massage the site.
 - Refrain from placing a bandage, dressing, or cotton ball with tape over the site.
 - Continue normal activities such as bathing/showering.
2. Determine eligibility for testing and complete a TST screening assessment.
3. Ensure a fully charged cellular phone or land line is available in the event of an emergency such as anaphylaxis.
4. Perform hand hygiene and gather supplies:
 - PPD, supplied as a 1 mL multi-dose vial (ensure it has met storage and handling requirements and is not expired)
 - Gloves, in accordance with agency policy
 - Sterile, single use, disposable tuberculin syringe with safety needle (¼ - ½ inch long, 26 - 27 gauge needle recommended)
 - Alcohol swab(s)
 - Cotton swab or gauze
 - Sharps disposal container
 - [Tuberculin Skin Test Screening Record](#), health record
 - Educational material, as required
 - Epinephrine 1:1000 and related supplies

Administration

1. All TST shall be performed using the Mantoux technique.
2. Ensure proper storage and handling requirements have been met and the vial is in date.
3. Swab the vial septum with alcohol and allow it to dry. Using aseptic technique, draw a little more than 0.1 ml (5 tuberculin units) of PPD into the tuberculin syringe. Hold the syringe upright, lightly tap out the air then expel one drop. Check that 0.1 mL remains in the syringe.

Note: Avoid injecting air into the vial prior to withdrawing the PPD as this may increase the vial pressure and cause leakage at the puncture site.

Note: Do not preload syringes; draw up the PPD just before injecting it.

4. Rest the arm on a firm surface, palm up and elbow slightly flexed. Swab the administration site with alcohol and allow it to dry. Do not use topical anaesthetic creams, such as Emla[®], as localized edema can occur at the injection site which may be confused with a positive result.

Note: The inner aspect of the non-dominant forearm is recommended. In adults, the injection site should be approximately 10 cm from the antecubital fossa. Avoid areas with visible veins, scarring, abrasions, lesions, inflammation, burns, rash, or localized eczema. The outer aspect of the forearm or upper arm may be used when the inner forearms are not acceptable.

5. Hold the syringe almost parallel (5-15° angle) to the forearm and with bevel up insert the needle intradermally while holding the skin taut with the non-dominant hand. The bevel should be fully inserted and the tip of the needle visible under the skin.



Photo credit: Greg Knoblock. Content provider(s): CDC/Gabrielle Benenson.
Retrieved January 25, 2012 from <http://phil.cdc.gov/Phil/details.asp>

6. Inject the PPD slowly. Do not aspirate before injecting. A 6-10 mm wheal will develop. If a wheal at least 6 mm in size does not develop the test should be repeated on the opposite forearm or on the same forearm at least 5 cm from the initial injection site.
7. Withdraw the needle, activate the safety feature and place in designated sharps disposal container. Use a cotton swab or gauze to gently remove any drops of blood. Ensure pressure is not applied and the site is not massaged.

Post Administration

1. Assess for adverse reactions and provide necessary interventions as per agency policy. Ensure the individual waits a minimum of 15 minutes before leaving the test centre.
2. Document the administration (see page 11, *Documentation and Reporting*, for more information).

Reading the TST Result

1. Consultation with another professional should occur when uncertain of the result. Self-reading is inaccurate and results will not be accepted by TBPC SK.
2. TST results shall be read 48 to 72 hours after administration of PPD. A TST that cannot be read within 72 hours should be repeated as soon as possible at an injection site far enough from the previous test so the reactions do not overlap. A TST read after 72 hours and interpreted as positive need not be repeated.
3. Perform hand hygiene and gather supplies:
 - Flexible ruler or caliper
 - Soft ballpoint pen
 - TST record, health record

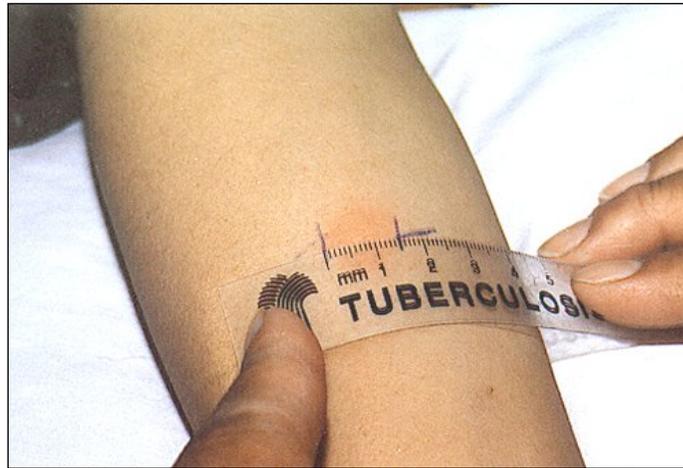
Note: Within Saskatoon Health Region, flexible rulers may be ordered through Main Stores or SPD/Dynamed (sku #203364). For all other health regions and agencies, flexible rulers are available from TB Prevention and Control Saskatchewan. Contact the Office Coordinator at (306) 655-1740 or 1-866-780-6482 to order.

4. Rest the arm on a firm surface with palm up and elbow slightly flexed. The area should be well lit. Inspect the site for blistering, breakdown or any other abnormality. Gently palpate to determine if induration is present.
5. Induration is measured along the transverse diameter (width) of the long axis of the forearm. Mark the borders of induration with a pen by holding the pen at a 45 degree angle and moving it laterally toward the injection site; if present, the pen will stop at the margin of induration. Measurements should not be recorded along any other diameter (e.g., 8 x 10 mm).



Photo credit: Greg Knoblock. Content provider(s): CDC/Gabrielle Benenson. Retrieved January 25, 2012 from <http://phil.cdc.gov/Phil/details.asp>

6. Using a flexible ruler or caliper, measure the distance between the pen marks. If the measurement falls between demarcation points on the ruler, the lesser of the two numbers shall be documented. Erythema is not measured.



7. Document test result in millimetres (see *Documentation and Reporting* section below for more information). Decide if the size of the reaction is positive (see Appendix A, table 1).
8. As applicable, inform the client of the need to forward results to TBPC SK. A [Tuberculin Skin Test Screening Record](#) is available for download from the [TBPC SK](#) web page.
9. Provide the client with a personal record of the test and result.

Note: [Tuberculin skin test result cards](#) may be ordered directly from TBPC SK or printed from the [TBPC SK](#) web page. To order, contact the Office Coordinator at (306) 655-1740 or 1-866-780-6482.

10. Make arrangements for a second TST if two-step testing is indicated. If the first TST is negative, the second TST should be performed one to three weeks later at a different injection site; one week is ideal.
11. If the TST was not requested by a physician (e.g., the TST is a requirement of employment, education, travel or was a self-referral) and the size of the reaction is considered positive, then refer the client to their primary care physician or nurse practitioner for medical evaluation (see section 11, Appendix A, and Appendix C for additional information). Clients that do not have a primary care provider should be directed to the nearest walk-in medical clinic for evaluation and should be given a copy of the most current list of doctors taking patients within the respective health region.

Note: A letter requesting a medical evaluation may be provided to the client to take to their primary care provider or may be faxed directly to the provider (refer to Appendix D for a sample letter). A copy of the Recommended Management for a Positive Tuberculin Skin Test should also be provided for the primary care provider (refer to Appendix E).

Documentation and Reporting

1. Document the following:

- client identifiers (a minimum of three should be included such as full name, date of birth and provincial health number);
- product name, dose, and lot number;
- reason for screen;
- site of injection;
- date and time the TST was given and read; test result in millimetres.

Note: Absence of a reaction shall be recorded as 0 mm. Results must be recorded as whole numbers rather than terms or symbols such as positive, significant, negative, nil or the null sign (∅).

- person administering and reading the test;
- adverse reactions, associated care and follow up.

2. Report all positive and negative TST results to TBPC SK with the exception of testing performed off-reserve for the purposes of travel, employment/occupational health or post-secondary education requirements. If applicable, clients should be informed that results will be forwarded to TBPC SK and entered in TBIS.

Note: A [Tuberculin Skin Test Screening Record](#) is available for download from the [TBPC SK web page](#). Results forwarded to TBPC SK do not constitute a referral.

3. All TST records forwarded to TBPC SK will be entered in the TBIS in accordance with standard protocol.
4. TST results shall be entered in Panorama (the Pan-Canadian Public Health Surveillance System) for those agencies with access.
5. Serious adverse events or reactions, such as acute allergic reactions, must be reported to TBPC SK using the [Canada Vigilance Adverse Reaction Reporting Form](#) in addition to being documented and reported in accordance with agency policy. The form should also be submitted to Health Canada.

If the event or reaction followed administration of an active immunizing agent that was administered at the same visit as the TST, an [Adverse Event Following Immunization](#) (AEFI) form should be completed instead of the Canada Vigilance Adverse Reaction Reporting form. The AEFI should be submitted to the local Medical Health Officer, Ministry of Health and TBPC SK.

11. Management of a Positive TST

1. Persons with a positive TST require a medical evaluation to assess for current or past active TB. Those diagnosed with latent TB should be counseled regarding the symptoms of active TB and their risk of developing it.

Practitioner responsible for medical evaluation	Indication for screening
TBPC SK physician	<ul style="list-style-type: none"> • Exposure to infectious TB (contacts) • Immigration screening and surveillance • Pediatric (childhood/school) screening
Physician requesting TST <i>(consult and/or refer to TBPC SK as needed)</i>	<ul style="list-style-type: none"> • HIV infection • Prior to anti-TNF therapy • Prior to transplantation • Admission to correctional facility (≥ 1 year)
Primary care physician or nurse practitioner <i>(consult and/or refer to TBPC SK as needed)</i>	<ul style="list-style-type: none"> • Employment/occupational requirement • Post-secondary education requirement • Travel

2. Medical evaluations should include:
 - Medical history and physical examination
 - Assessment of symptoms
 - Assessment of risk factors for progression to active TB
 - Chest x-ray (CXR), unless contraindicated
 - HIV testing for those 13 years of age or older or at the discretion of the physician for those under 13 years of age
 - Sputum collection for acid-fast bacteria if symptomatic or CXR abnormal

Note: Individuals with HIV infection may have atypical or absent clinical or radiographic findings with active TB. Even when the CXR is normal, sputum collection for smear and culture should be considered in individuals with HIV infection.

 - Assessment for treatment of latent TB

12. Roles and Responsibilities

TB Prevention and Control Saskatchewan

1. Provide support and consultation to partners performing TST.
2. Maintain all reported TST results in TBIS.
3. Complete medical evaluations as required and prescribe treatment for LTBI as necessary.
4. Review individuals referred to the program.
5. Request TST for screening and surveillance purposes as needed.
6. Perform skin tests as required.

Physician Performing Medical Evaluation

1. Complete medical evaluation and referral to TBPC SK as required.

Regional Medical Health Officer

1. Provide local medical directive(s) for TST administration and adverse reaction protocols as required and in accordance with Regional policy.
2. Advise on issues related to TST policy and procedure.

Health-care Professionals Responsible for TST Procedures

1. Follow organizational and professional standards for safe medication/biological product administration.
2. Maintain competence in TST procedures and seek further education or training as needed.
3. Assess appropriateness of testing and determine if contraindications exist. Provide education as required.
4. Maintain a record of the administration and result in the client's health record and report to TBPC SK as required.
5. Take appropriate action in response to adverse reactions as per agency policy and procedure.
6. Seek consultation with another trained professional if uncertain of induration measurement.

APPENDIX A: Interpretation of TST Results

Accurate interpretation of TST results depends on three factors:

1. The size of induration;
2. The positive predictive value; that is, the probability that a positive result reliably indicates true infection with *Mycobacterium tuberculosis*. False positive and negative TST reactions can occur as a result of technical or biologic circumstances and may alter the validity of test results; and
3. The risk of developing active TB disease if the individual is truly infected with *Mycobacterium tuberculosis*.

Additional information regarding TST interpretation can be found in the [Canadian Tuberculosis Standards](#), 7th edition. Refer to [chapter 4](#) for information regarding interpretation of a positive TST and [chapter 6](#) for information regarding TST cut-points for treatment of latent TB infection. An online [TST/IGRA Interpreter](#) is available at www.tstin3d.com.

Table 1: TST Size

TST Reaction Size (mm induration)	Situation in which the reaction is considered positive
0 – 4 mm	In general, considered negative and treatment not indicated
	Child under 5 years of age and high risk of TB infection
≥ 5 mm	HIV Infection
	Contact with a person with infectious TB within the past 2 years
	Presence of fibronodular TB on CXR (healed TB and not previously treated)
	Organ transplantation (related to immune suppressant therapy)
	Tumour necrosis factor-alpha inhibitors (anti-TNF drugs)
	Other immunosuppressive drugs (e.g., corticosteroids – equivalent of ≥ 15 mg/day prednisone for one month or more; risk of TB disease increases with higher dose and longer duration)
≥ 10 mm	End-stage renal disease
	All others, including the following specific situations: <ul style="list-style-type: none"> – TST conversion (within 2 years) – Diabetes, malnutrition (less than 90 % ideal body weight), cigarette smoking, daily alcohol consumption (greater than 3 drinks per day) – Silicosis – Hematologic malignancies (leukemia, lymphoma) and certain carcinomas (e.g., head and neck)

Adapted from: Public Health Agency of Canada, Canadian Thoracic Society & Canadian Lung Association. (2013) *Canadian Tuberculosis Standards*, 7th edition. Retrieved October 25, 2015 from <http://www.respiratoryguidelines.ca/tb-standards-2013>.

For individuals that are **healthy** and **not** known to have been exposed to an active TB source:

- A TST of 10 mm or more is considered positive when an earlier TST was less than 5 mm.
- When a prior TST result was 5-9 mm (and not previously considered positive), then an increase of 6 mm or more from the prior result is considered positive. Example: When the previous TST was 6 mm then the subsequent TST would need to be 12 mm or more to be considered positive.
- A TST of 10 mm or more on the second TST of a two-step TST is considered positive regardless of a previous TST result.

For individuals that are **healthy and contacts** to an active TB source:

- A positive TST result is 5 mm or more on initial or repeat testing unless a previous TST was 5-9 mm, then an increase of at least 6 mm from the previous TST would be considered positive.

Refer to table 1 for individuals that are immune compromised, whether known to have been in contact with an active TB source and regardless of whether two-step testing is being performed.

Table 2: Factors Associated with False-Positive or False-Negative TST Reactions

False-positive reaction may be caused by:

Infection with nontuberculous mycobacteria

Reading or recording error (e.g., erythema measured rather than induration)

‡ BCG vaccination

False-negative reaction may be caused by:

Reading or recording error

Incorrect administration such as injection too deep, incorrect dose, injection given more than 20 minutes after drawing PPD into syringe

Improper storage and/or handling of PPD

Active TB, especially if advanced (20-30% of persons with active TB will have a false negative result at the time of diagnosis)

Other bacterial infections such as typhoid fever, pertussis, leprosy, brucellosis

HIV infection especially if CD4 less than 200 cells/mm³

Other viral infections such as measles, mumps, varicella

Fungal infection (South American blastomycosis)

Immunosuppressive drugs such as corticosteroids, TNF alpha inhibitors, and others

Live virus vaccination within the past 4 weeks

Metabolic disease such as chronic renal failure, severe malnutrition, stress (surgery, burns)

Diseases of lymphoid organs such as lymphoma, chronic lymphocytic leukemia, sarcoidosis

Age (infants less than six months old or those over 65)

Adapted from: Public Health Agency of Canada, Canadian Thoracic Society & Canadian Lung Association. (2013) *Canadian Tuberculosis Standards, 7th edition*. Retrieved October 25, 2015 from <http://www.respiratoryguidelines.ca/tb-standards-2013>.

‡ Ignore BCG as cause of a positive TST if:

- given in infancy and the person tested is now 10 years of age or older;
- latent TB infection is highly probable – close contacts of a person with infectious TB, Canadian-born people residing in communities with high TB incidence, immigrants or visitors from countries with high TB incidence;
- the risk of progression from latent TB to active TB is high.

BCG may be the cause of a positive TST if given after 12 months of age AND there has been no known exposure to active TB or other risk factors.

Note: High TB-incidence communities/countries/territories are defined as those with a three year average of 30 cases per 100,000 population for all forms of active TB.

Refer to *appendix D* and the following websites for additional information on international TB incidence rates and BCG vaccination policies:

[BCG World Atlas](http://www.bcgatlas.org/index.php) found at <http://www.bcgatlas.org/index.php>

[World Health Organization Tuberculosis Country Profiles](http://www.who.int/tb/country/data/profiles/en/) found at <http://www.who.int/tb/country/data/profiles/en/>

Table 3: Risk Factors for the Development of Active TB among People with a Positive TST

RISK FACTOR	Estimated risk of TB relative to people with no known risk factor
HIGH RISK	
Acquired immunodeficiency syndrome (AIDS)	110-170
HIV infection	50-110
Transplantation (related to immunosuppressant therapy)	20-74
Silicosis	30
Chronic renal failure requiring hemodialysis	10-25
Carcinoma of head and neck	11.6
Recent TB infection (≤ 2 years)	15
Abnormal CXR (fibronodular disease)	6-19
MODERATE RISK	
Treatment with TNF alpha inhibitors	1.5-5.8
Diabetes mellitus (all types)	2-3.6
Treatment with glucocorticoids (≥ 15 mg/day prednisone)	4.9-7.7
Infected at a young age (< 5 years)	2.2-5
SLIGHTLY INCREASED RISK	
Heavy alcohol consumption (≥ 3 drinks/day)	3-4
Underweight ($< 90\%$ ideal body weight, body mass index ≤ 20)	2-3
Cigarette smoker (1 pack/day)	1.8-3.5
Abnormal CXR (granuloma)	2
LOW RISK	
Person with positive TST, no known risk factor and normal CXR ("low risk reactor")	1
VERY LOW RISK	
Person with positive two-step TST (booster), no other known risk factor and normal CXR	0.5

Adapted from: Public Health Agency of Canada, Canadian Thoracic Society & Canadian Lung Association. (2013) Canadian Tuberculosis Standards, 7th edition. Retrieved October 25, 2015 from <http://www.respiratoryguidelines.ca/tb-standards-2013>.

APPENDIX B: [Tuberculin Skin Test Screening Record](#)

	TB Prevention and Control Saskatchewan Population and Public Health	SK Toll Free: 1-866-780-6482			
Sample					
Saskatoon Main Office Royal University Hospital 103 Hospital Drive Saskatoon SK S7N 0W8 Phone: 306-655-1740 Fax: 306-655-1495	Prince Albert Office Cooperative Health Centre 110 – 8 th Street East Prince Albert SK S6V 0V7 Phone: 306-765-4260 Fax: 306-765-4264	Regina Office Regina General Hospital 1440 – 14 th Avenue Regina SK S4P 0W5 Phone: 306-766-4311 Fax: 306-766-4710			
TUBERCULIN SKIN TEST SCREENING RECORD TBPC Use Only – TB File _____					
Last Name		First Name	Middle Initial	Other Name(s)	
Gender	Date of Birth (y/m/d)	Provincial Health Number		Treaty/Band Number	
Male <input type="checkbox"/> Female <input type="checkbox"/>					
Address (Street/PO Box)		City/Town/Community		Postal Code	Province
Phone (Home)		(Work)	(Cell)		
BCG (year)	Family Physician <input type="checkbox"/> None	Health-care Provider Requesting TST (if applicable)			
REASON FOR SCREEN (tick all that apply)					
<input type="checkbox"/> Contact Contact to (name or TB file #): _____ Last contact date (y/m/d) _____					
<input type="checkbox"/> Correctional facility resident <input type="checkbox"/> Employment <input type="checkbox"/> Immigration <input type="checkbox"/> High risk medical condition (specify) _____					
<input type="checkbox"/> Pre Anti-TNF therapy <input type="checkbox"/> Pre-school/School <input type="checkbox"/> Pre Transplant <input type="checkbox"/> Other (specify) _____					
ADMINISTRATION					
Initial TST					
Date given (y/m/d)	Time (hours)	Site of injection	Tubersol PPD 5 TU (0.1 mL) – Lot #	SYMPTOMS	
Given by			Title/Position	<input type="checkbox"/> None <input type="checkbox"/> Fever <input type="checkbox"/> Cough (productive) <input type="checkbox"/> Hemoptysis <input type="checkbox"/> Cough (non-productive) <input type="checkbox"/> Night sweats <input type="checkbox"/> Fatigue <input type="checkbox"/> Weight loss <input type="checkbox"/> Other (specify) _____	
Test Centre			Phone		
Result (mm)	Date read (y/m/d)	Time (hours)	Read by	Title/Position	Phone
Is the size of the reaction considered positive (refer to table on reverse side)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown					
Repeat TST (e.g., if two-step TST)					
Date given (y/m/d)	Time (hours)	Site of injection	Tubersol PPD 5 TU (0.1 mL) – Lot #	SYMPTOMS	
Given by			Title/Position	<input type="checkbox"/> None <input type="checkbox"/> Fever <input type="checkbox"/> Cough (productive) <input type="checkbox"/> Hemoptysis <input type="checkbox"/> Cough (non-productive) <input type="checkbox"/> Night sweats <input type="checkbox"/> Fatigue <input type="checkbox"/> Weight loss <input type="checkbox"/> Other (specify) _____	
Test Centre			Phone		
Result (mm)	Date read (y/m/d)	Time (hours)	Read by	Title/Position	Phone
Is the size of the reaction considered positive (refer to table on reverse side)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown					
Previous TST if known					
Result (mm)	Date (y/m/d)	Test Centre			
COMMENTS (if applicable include adverse reactions, allergies, if sputum sent, if referred to family physician)					
TBPC RN USE ONLY Date reviewed: <input type="checkbox"/> No follow up required <input type="checkbox"/> Physician order sent <input type="checkbox"/> Refer to family physician for evaluation <input type="checkbox"/> Letter sent to primary care provider <input type="checkbox"/> CXR required <input type="checkbox"/> Referral to TBPC required <input type="checkbox"/> Letter sent to client <input type="checkbox"/> Sputum required <input type="checkbox"/> Schedule TBPC clinic appointment					
Original: Health Record TBPC SK 2015-10-25		Copy: TB Prevention & Control SK		Entered in Panorama: _____ Entered in TBIS: _____	

APPENDIX C: Flowcharts for TST Screening Follow-up

The following flowcharts do not include processes for persons named as contacts to infectious TB nor do they apply to persons presumed to have active TB disease.

Figure 1: TST requested by physician

Example: prior to anti-TNF (biologic) therapy or transplant

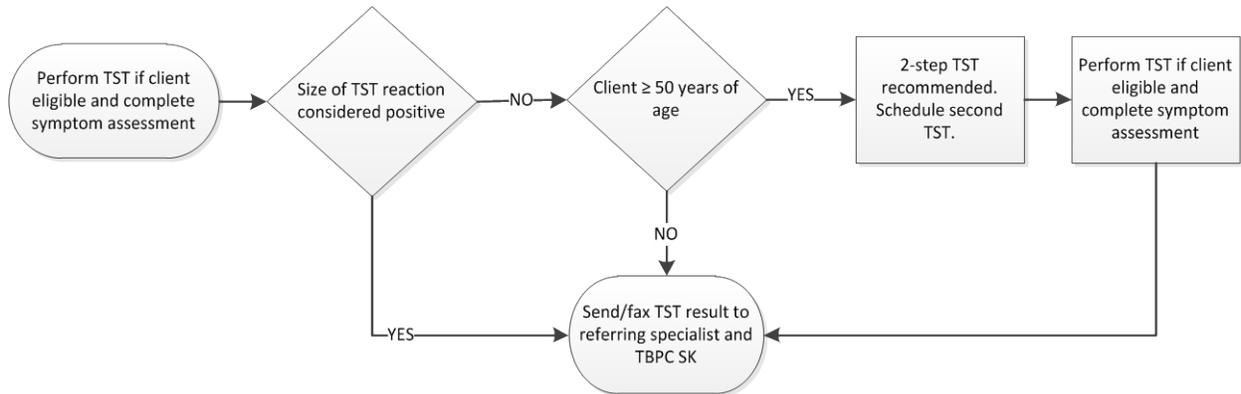
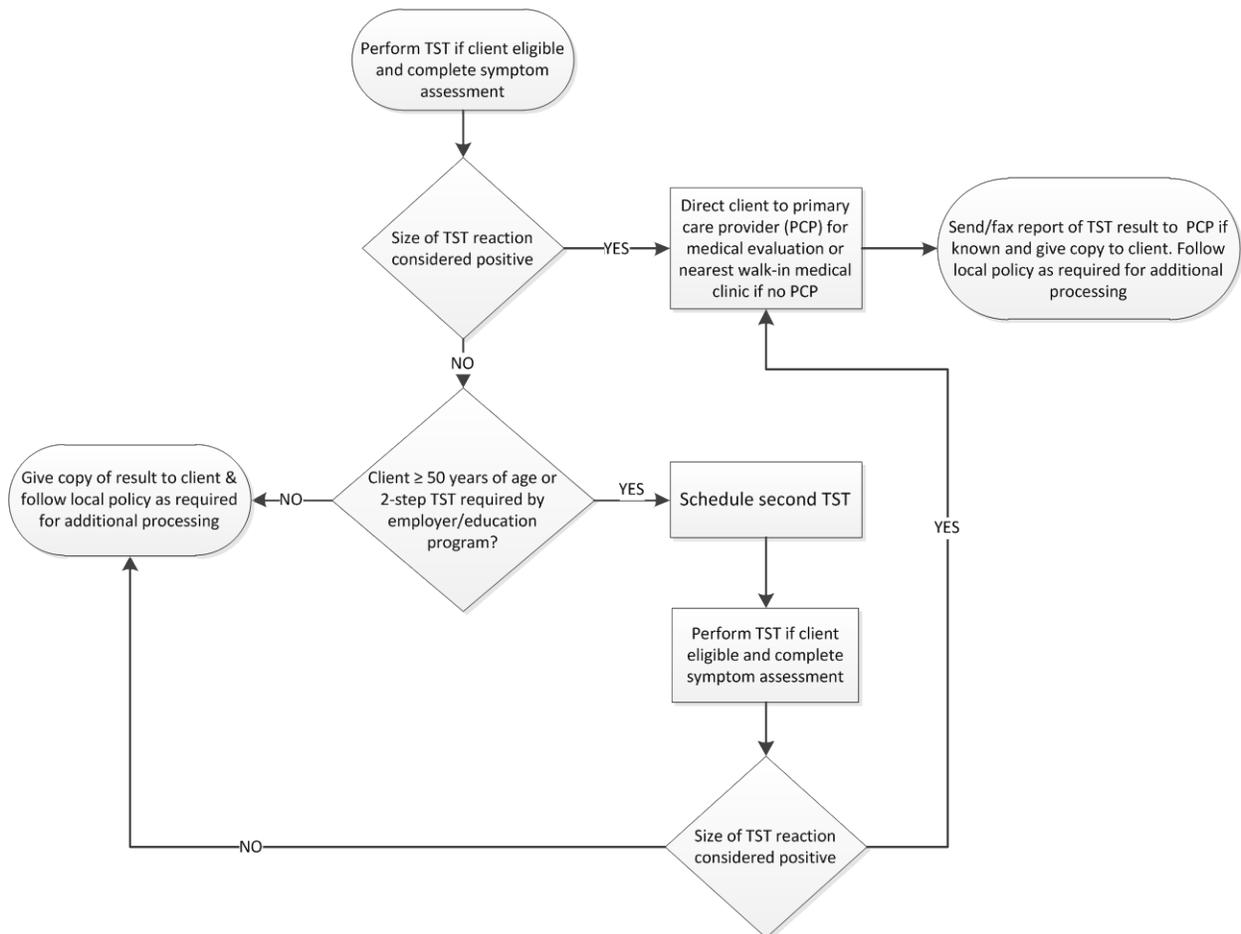


Figure 2: TST not requested by physician

Example: travel, employment or post-secondary education requirement or self-referral



APPENDIX D: Sample Primary Care Provider Letter Requesting Medical Evaluation for a Positive Tuberculin Skin Test



Occupational Health and Safety
Royal University Hospital
6th Floor Administration Offices
103 Hospital Drive
Saskatoon SK S7N 0W8
email@saskatoonhealthregion.ca

Tel: 306.655.1020
Fax: 306.655.1037

SAMPLE

To: *Dr. Smith*

From: *Jack Jones, Occupational Health Nurse*

Date: *February 1, 2015*

Re: Request for Medical Evaluation for Positive Tuberculin Skin Test

The following individual had a tuberculin skin test and the size of the reaction is considered positive.

Name: *Jane Doe*

PHN: *100 200 300*

Date of birth: *September 1, 1970*

Date of tuberculin skin test: *January 30, 2015*

Tuberculin skin test result 15 mm

Reason for test: *Employee screen (new hire)*

As recommended by *TB Prevention and Control Saskatchewan*, a medical evaluation is required for all persons with a positive tuberculin skin test to assess for current or past active TB. Please see attached information from *TB Prevention and Control Saskatchewan* regarding the recommended management for persons with a positive TST.

Thank you.

APPENDIX E: [Recommended Management for Persons with a Positive TST](#)

The following recommendations for medical evaluation and referral to TB Prevention and Control Saskatchewan are for persons found to have a positive tuberculin skin test (TST) on routine screening (e.g., travel, employment or post-secondary education requirements) and are not valid for interpretation of TST in known TB contacts.

STEP 1: Complete recommended medical evaluation.

STEP 2: Determine if the TST reaction is considered positive. Refer to table 1 on page 2. The Online TST/IGRA Interpreter is also available to assist with interpretation <http://www.tstin3d.com/>.

STEP 3: Refer to TB Prevention and Control Saskatchewan as required.

To speak with the TB physician on-call contact the Royal University Hospital switchboard 306.655.1000. For general inquires and referrals call SK toll-free 1-866-780-6482 or:

Saskatoon Main Office
Royal University Hospital
Phone: 306-655-1740
Fax: 306-655-1495

Prince Albert Office
Cooperative Health Centre
Phone: 306-765-4260
Fax: 306-765-4264

Regina Office
Regina General Hospital
Phone: 306-766-4311
Fax: 306-766-4710

MEDICAL EVALUATION**MEDICAL HISTORY AND PHYSICAL EXAMINATION**

- General health evaluation including height/weight
- Current medications
- Past medical history
- Social history
- Prior TB screening (TST, IGRA, CXR)
- Prior BCG vaccination
- Recent or past exposure to TB
- Previous diagnosis of active or latent TB
- Previous treatment for active or latent TB
- Country of birth &/or residence in a high TB incidence country

RECOMMENDATIONS

Refer to TB Prevention and Control SK if negative TST within the previous 2 years

SYMPTOMS

- Cough \geq 2 weeks
- Fever \geq 7 days
- Unexplained weight loss, anorexia, failure to thrive
- Fatigue, lethargy
- Hemoptysis
- Night sweats
- Chest pain, dyspnea
- Extrapulmonary signs such as lymphadenopathy

RECOMMENDATIONS

Sputum for AFB x 3 if symptomatic
Consult TB physician on-call as required

RISK FACTORS

- HIV infection
- Immunosuppressant therapy for organ transplantation
- Treatment with anti-TNF drugs
- Steroid therapy (\geq 15 mg/day for one month or more)
- Chronic renal failure requiring hemodialysis
- Cancer of the head and neck
- Hematologic malignancies
- Fibronodular disease on CXR (e.g., apical thickening, upper lobe volume loss, multiple nodules, fibrosis)
- TST conversion within the last 2 years (prior TST negative within 2 years)
- Diabetes
- Silicosis
- Less than 5 years of age

RECOMMENDATIONS

Refer to TB Prevention and Control SK if risk factors present

REQUIRED TESTS

- HIV test if \geq 13 years of age or at physician discretion if $<$ 13 years
- CXR

RECOMMENDATIONS

Sputum for AFB x 3 if CXR abnormal or HIV infection
Refer to TB Prevention and Control SK if HIV infection or abnormal CXR

APPENDIX F: Tuberculosis Incidence Rate by Country

High TB-incidence countries/territories are defined as those with a three year average of 30 or more cases per 100,000 population for all forms of active TB. The incidence per 100,000 population per year is identified in parenthesis following each country name below.

Last updated: December 1, 2015

Source: World Health Organization. (2015). Tuberculosis Country Profiles. Available at <http://www.who.int/tb/country/data/profiles/en/>

Afghanistan (189)	China, Macao SAR (82)	India (167)
Albania (19)	Colombia (33)	Indonesia (399)
Algeria (78)	Comoros (35)	Iran, Islamic Republic of (22)
American Samoa (7)	Congo (381)	Iraq (43)
Andorra (9.2)	Congo, Democratic Republic of (325)	Ireland (7.4)
Angola (370)	Cook Islands (12)	Israel (5.8)
Anguilla (23)	Costa Rica (11)	Italy (6)
Antigua and Barbuda (7.6)	Cote d'Ivoire (165)	Jamaica (4.7)
Argentina (24)	Croatia (12)	Japan (18)
Armenia (45)	Cuba (9.4)	Jordan (5.5)
Aruba (11)	Curacao (3.7)	Kazakhstan (99)
Australia (6.4)	Cyprus (5.3)	Kenya (246)
Austria (7.8)	Czech Republic (4.6)	Kiribati (497)
Azerbaijan (77)	Denmark (7.1)	Korea, Democratic People's Republic (442)
Bahamas (12)	Djibouti (619)	Korea, Republic of (86)
Bahrain (14)	Dominica (0.71)	Kuwait (21)
Bangladesh (227)	Dominican Republic (60)	Kyrgyzstan (142)
Barbados (0.91)	Ecuador (54)	Laos, People's Democratic Republic (189)
Belarus (58)	Egypt (15)	Latvia (49)
Belgium (9)	El Salvador (41)	Lebanon (16)
Belize (37)	Equatorial Guinea (162)	Lesotho (852)
Benin (61)	Eritrea (78)	Liberia (308)
Bermuda (0)	Estonia (20)	Libya (40)
Bhutan (164)	Ethiopia (207)	Lithuania (62)
Bolivia, Plurinational State of (120)	Fiji (67)	Luxembourg (6.6)
Bonaire, Saint Eustatius and Saba (0)	Finland (5.6)	Macedonia, Former Yugoslav Republic (15)
Bosnia and Herzegovina (42)	France (8.7)	Madagascar (235)
Botswana (385)	French Polynesia (22)	Malawi (227)
Brazil (44)	Gabon (444)	Malaysia (103)
British Virgin Islands (1.7)	Gambia (174)	Maldives (41)
Brunei Darussalam (62)	Georgia (106)	Mali (58)
Bulgaria (27)	Germany (6.2)	Malta (12)
Burkina Faso (54)	Ghana (165)	Marshall Islands (335)
Burundi (126)	Greece (4.8)	Mauritania (111)
Cambodia (390)	Greenland (197)	Mauritius (22)
Cameroon (220)	Grenada (1.3)	Mexico (21)
Canada (5.2)	Guam (40)	Micronesia, Federated States of (195)
Cape Verde (138)	Guatemala (57)	Moldova, Republic of (153)
Caymen Islands (7)	Guinea (177)	Monaco (2.2)
Central African Republic (375)	Guinea-Bissau (369)	Mongolia (170)
Chad (159)	Guyana (103)	Montenegro (21)
Chile (16)	Haiti (200)	Montserrat (0)
China (68)	Honduras (43)	
China, Hong Kong SAR (74)	Hungary (12)	
	Iceland (3.3)	

Morocco (106)	Saint Lucia (9.1)	Timor-Leste (498)
Mozambique (551)	Saint Vincent and the Grenadines (24)	Togo (58)
Myanmar (Burma) (369)	Samoa (19)	Tokelau (0)
Nambia (561)	San Marino (1.6)	Tonga (14)
Nauru (73)	Sao Tome and Principe (97)	Trinidad and Tobago (22)
Nepal (158)	Saudi Arabia (12)	Tunisia (33)
Netherlands (5.8)	Senegal (138)	Turkey (18)
New Caledonia (15)	Serbia (24)	Turkmenistan (64)
New Zealand (7.4)	Seychelles (26)	Turks and Caicos Islands (10)
Nicaragua (58)	Sierra Leone (310)	Tuvalu (190)
Niger (98)	Singapore (49)	Uganda (161)
Nigeria (322)	Sint Maarten (Dutch) (0)	Ukraine (94)
Niue (0)	Slovakia (6.7)	United Arab Emirates (1.6)
Northern Mariana Islands (61)	Slovenia (7.7)	United Kingdom of Great Britain and Northern Ireland (12)
Norway (8.1)	Solomon Islands (86)	United States of America (3.1)
Oman (9.6)	Somalia (274)	Uruguay (30)
Pakistan (270)	South Africa (834)	US Virgin Islands (7.7)
Palau (42)	South Sudan (146)	Uzbekistan (82)
Panama (46)	Spain (12)	Vanuatu (63)
Papua New Guinea (417)	Sri Lanka (65)	Venezuela (Bolivarian Republic of) (24)
Paraguay (43)	Sudan (94)	Vietnam (140)
Peru (120)	Suriname (38)	Wallis and Futana Islands (3.7)
Philippines (288)	Swaziland (733)	West Bank and Gaza Strip (5.8)
Poland (21)	Sweden (7.5)	Yemen (48)
Portugal (25)	Switzerland (6.3)	Zambia (406)
Puerto Rico (1.4)	Syrian Arab Republic (17)	Zimbabwe (278)
Qatar (29)	Tajikistan (91)	
Romania (81)	Tanzania, United Republic of (327)	
Russian Federation (84)	Thailand (171)	
Rwanda (63)		
Saint Kitts and Nevis (7.2)		

References

- Health Canada: Health Products and Food Branch. (2005). Letter from Sanofi Pasteur, 19 May 2005, Risk of Serious Allergic Reactions Following Tubersol® [Tuberculin Purified protein Derivative (Mantoux)] Administration. Retrieved September 9, 2013 from <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2005/14373a-eng.php>
- Health Canada. (2012). Adverse Reaction and Medical Device Problem Reporting. Retrieved October 25, 2015 from <http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php#a2>
- Lieberman, P., Nicklas, R. A., Oppenheimer, J., Kemp, S. F., & Lang, D. M. (Ed.) (2010). The diagnosis and management of anaphylaxis practice parameter: 2010 Update. Retrieved October 25, 2015 from [http://www.jacionline.org/article/S0091-6749\(10\)01004-3/pdf](http://www.jacionline.org/article/S0091-6749(10)01004-3/pdf)
- Public Health Agency of Canada. (2014). Canadian Immunization Guide. Retrieved May 1, 2014 from <http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>
- Public Health Agency of Canada. (2011). Reporting Adverse Events Following Immunization (AEFI) in Canada: User Guide to Completion and Submission of the AEFI Reports. Retrieved October 25, 2015 from <http://www.phac-aspc.gc.ca/im/pdf/AEFI-ug-gu-eng.pdf>
- Public Health Agency of Canada, Canadian Thoracic Society & Canadian Lung Association. (2013) Canadian Tuberculosis Standards, 7th edition. Retrieved April 28, 2014 from <http://www.respiratoryguidelines.ca/tb-standards-2013>
- Saskatchewan Ministry of Health. (2012). Saskatchewan Immunization Manual. Retrieved October 25, 2015 from <http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx>
- Schaaf, H. S. & Zumla, A. (Ed.). (2009). Tuberculosis: A Comprehensive Clinical Reference. Europe: Elsevier.
- Thompson, N.J., Glassroth, J. L., Snider, D. E., & Farer, L. S. (1979). The Booster Phenomenon in Serial Tuberculin Testing. *American Review of Respiratory Disease*, 119, 587-597.
- Tubersol® Tuberculin Purified Protein Derivative (Mantoux) Product Monograph. (2012). Sanofi Pasteur: Toronto, Ontario. Retrieved October 25, 2015 from https://www.vaccineshoppecanada.com/document.cfm?file=tubersol_e.pdf
- World Health Organization. (2015). *Tuberculosis Country Profiles*. Retrieved December 1, 2015 from <http://www.who.int/tb/country/data/profiles/en/>