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Communicable Disease Control Manual Chapter 4: Tuberculosis

Appendix A:
Tuberculin Skin Testing Procedure







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Appendix A: Tuberculin Skin Testing Procedure

PRODUCT

Tuberculin Purified Protein Derivative (Mantoux) Solution TUBERSOL® Supplier: Sanofi Pasteur (1)

INDICATION

Diagnostic antigen to aid in the detection of infection with M. tuberculosis

DOSE

0.1 mL test dose by intradermal injection Multi-dose vial with 10 test doses of 0.1 mL

COMPONENTS

Active: 5 Tuberculin units (TU) 0.1 mL test dose (Purified protein derivative-standard (PPD-S) of *M. tuberculosis.*)

Other: Polysorbate 80 and Phenol (preservative).

Contraindications and Precautions

CONTRAINDICATIONS

TUBERSOL® should not be administered to clients with a:

- Prior acute allergic reactions, including anaphylaxis to TUBERSOL® or to any components of the formulation or container.
- Severe reaction to a previous TST at the injection site (e.g., necrosis, blistering, or ulcerations)
- Documented TB Disease or a clear history of previous TB disease or TB Infection, whether treated or not.
- Documented previous positive result.

PRECAUTIONS

Use precaution if burns or eczema present at skin testing sites because of greater likelihood of adverse reactions or severe reactions.

- If localized, consider using alternate sites (see Figure A-1).
- If extensive, avoid administering TST and consult TB Services for guidance.

SPECIAL CONSIDERATIONS

Refer to Section 4(b) Table 5 Special Considerations for TST and IGRA.

Common Expected Reactions

INJECTION SITE REACTIONS

Common expected reactions are typically mild and self-limiting:

- Swelling, itching, bruising and discomfort at the injection site.
- A small number of people (2-3%) develop minor redness or rash at the injection site without induration in the first 12 hours after a TST (2,3).



Adverse Reactions

SIGNIFICANT INJECTION SITE REACTIONS

More significant injection site reactions may occur:

- persistent swelling
- hematoma (up to three days after test)
- blistering (which can occur in 3-4% of positive tests)
- injection site necrosis in highly sensitive persons (2,3)

Anaphylaxis

Severe allergic reactions related to the administration of Tubersol® are rare (reported at a rate of less than one per million doses in Canada) (2). Anaphylaxis is a life threatening allergic reaction therefore anaphylactic (epinephrine-containing) kits must be available at the time of TST administration and clients should remain in the clinic for 15 minutes after getting a TST. These reactions can occur in people with and without a history of a TST.

- This reaction may include hives, difficulty breathing or shortness of breath, or swelling of the throat, tongue or lips.
- Nurses administering TSTs must follow the BCCDC decision support tool <u>Management of Anaphylaxis in Non-Hospital Settings</u> (4).
- Document as per agency guidelines.

Adverse Reaction Reporting

An adverse reaction is a noxious and unintended effect to a health product. If an adverse reaction following receipt of a TST (e.g., anaphylaxis, necrosis) occurs, the health care provider who administered the test should report the event per agency guidelines.

A **serious** adverse reaction is harms from a drug that are severe enough to result in: Hospital admission, birth defects, long-lasting disability or incapacity, a life-threatening or urgent medical situation, or death (5).

Reporting **serious** adverse reactions is mandatory for hospitals; however, adverse reaction reporting is encouraged for all health care institutions and health care workers. In BC, reporting is done via the BC Patient Safety & Learning System (BCPSLS), which forwards reports to Health Canada on behalf of the health authorities. For more information, visit BCPSLS Central, Vanessa's Law (6).

Health care providers without BCPSLS should directly report any serious adverse drug reaction through <u>Health Canada's MedEffect Adverse Reaction Reporting</u> (5).



Limitations to Tuberculin Skin Testing

Certain medical conditions and treatments may alter the immune status of clients and may cause a false-negative reaction (outlined in **Table A-1**). Many of these medical factors listed are included in the TB risk assessment with some factors such as a recent major viral illness or live vaccine having implications for the timing of TB testing (1). Other factors may impact the clinical care plan and are important to document in your TB risk assessment.

BCG implications on TST

Some factors, such as a Bacille Calmette-Guérin (BCG) vaccine, may cause a false-positive Tuberculin Skin Test (TST) reaction. The BCG is not considered the cause of a positive TST greater than 10 to 15 mm **IF:**

- The vaccination was given in infancy and the person tested is now 10 years of age or older; or
- There is a high probability of TB infection (e.g., TB contacts, individuals from high TB incidence regions); or
- There is a high risk of progression from TB infection to TB disease (e.g. child under five years of age or recent contact or severe immune suppression).



Table A-1: Factors associated with false-negative and false-positive TST* (2,7)

Condition	False-Negative	False-Positive
Infections	 Viral Illness (e.g., HIV, measles, varicella) Bacterial illnesses (typhoid fever, pertussis, brucellosis, typhus, leprosy) Early TB infection (less than 8 weeks) Severe TB disease (meningitis, disseminated) Fungal disease 	Exposure to NTM
Vaccines	 Measles, mumps, rubella Polio Varicella Smallpox and monkeypox Yellow fever 	BCG vaccine (depending on timing and clinical context)
Concurrent clinical and/or demographic factors	 Metabolic abnormalities Chronic renal failure Primary immune deficiencies Malignancies (e.g., lymphomas, leukemia) Sarcoidosis Poor nutrition Very young or elderly age Protein deficiency 	Transfusion with whole blood from donors with known positive TST
Drugs	 Corticosteroids, TNF-α blockers, JAK inhibitors Interleukin receptor antagonists, or other immunosuppressive medications Chemotherapy 	
Technical factors	 Material—poor quality, inadequate dose, improper storage (exposure to heat/light) Administration—not an intradermal injection 	
Reader factors or Analytical variation	Reading—inexperienced reader, recording error, read too early/late	Inaccurate recording of TST measurements may lead to incorrect conclusion of a change in the induration on a second test

^{*} For information about IGRAs, see <u>Section 4(b) Table 5 Special Considerations for TSTs and IGRAs.</u>



Informed Consent for Tuberculin Skin Testing

According to the British Columbia College of Nurses and Midwives (BCCNM) Consent Practice Standard (8), it is the ethical obligations of nurses to recognize, respect, and promote the client's right to be informed and make informed choices, including refusing or revoking permission for health care.

Valid, informed consent generally requires that:

- The consent is given voluntarily.
- There is no fraud or misrepresentation used to obtain consent.
- The client is capable to give or refuse consent, or consent is obtained from a substitute decision maker
- The client or substitute decision maker has the information needed to make a decision about the proposed care, service, treatment or research, including: the condition for which the health care is proposed, the nature of the proposed health care, the potential risks and benefits, alternative courses of health care, and the opportunity to ask questions and receive answers.
- This informed consent guidance is congruent with provincial legislation, regulations, and BCCNM standards of professional nursing practice.

Obtaining TST informed consent

- The <u>HealthLinkBC Healthfile 51d Tuberculosis Skin Test</u> supports TST informed consent discussions and is available in eight languages.
- Document TST consent or refusal on the provincial TB screening form and/or agency documentation system.
- For further learning on informed consent, refer to the <u>BCCDC CDC Manual, Chapter 2-Immunization Program, Appendix A</u> (4).

Client Education and After Care

Education

When administering and reading a TST, client education and aftercare are essential to informed consent and high-quality patient care.

- As part of the informed consent process, provide clients with standard information about TB screening. Follow agency policies, relevant BCCDC guidelines and BCCNM Standards of Practice.¹
- Health care providers can use this appendix; the <u>HealthLinkBC Healthfile 51d TB Skin Test</u> and agency-specific resources support TST discussions with clients.
- Explain the TST procedure to clients; including that, it is a two-part test, who should not get a TST, possible reactions and when to contact a health care provider.

¹ BCCDC Communicable Disease Control Manual, Chapter 2, <u>Appendix A: Informed Consent</u> and BC College of Nurses & Midwives <u>Standard of Practice, Consent.</u>



Examples of standard information include:

- Wait in the clinic for 15 minutes after the injection and return for the TST read within 48 to 72 hours.
- The injection site may be itchy, but they must not scratch or cover the test site with a bandage.
 Indurations (swelling under the forearm) may last for up to one week
- People with a positive reaction should not have a repeat TB skin test.

Aftercare

- Activities such as showering, bathing or swimming may continue as normal.
- Encourage the client to contact you or their primary care provider with any unexpected or unusual symptoms after the test.
- At home, apply a cold compress to minor reactions (e.g. rash, redness, itchiness) for comfort.
- Antihistamine (e.g., diphenhydramine) may be helpful for minor rashes or itchiness at the test site. Follow your agency policy when recommending over-the-counter medications.
- If blistering occurs, gently apply sterile dressings to any open areas.
- Refer the client to their primary health care provider for further medical follow-up as required and document as per agency guidelines.

Preparation of Tubersol® 2

- Store at +2°C to +8°C and protect from light.
- Do not freeze. Do not use the solution if frozen, and dispose of as per your agency policy.
- Store in the fridge in the original box or in the dark except when doses are actually being withdrawn from the vial as the solution can be adversely affected by exposure to light.
- Do not transfer the testing solution from one container to another (the potency could be diminished).
- Do not preload syringes for later use as the potency of the testing solution could be diminished; lot numbers and expiry dates may be lost; and post-puncture expiry may elapse or be unknown. Draw up the testing solution just before injecting it.
- Label the vial of testing solution with the date of first puncture.
- Follow your agency's policy to dispose of testing solution:
 - IF 1 month (30 days) from date of first puncture, or the vial expiry date if earlier than the post-puncture expiry (1).
 - o In use for an undetermined length of time (i.e. open vials without the date of first puncture)(9).

² Refer to the <u>BCCDC CDC Manual, Chapter 2-Immunization Program, Appendix E-Management of Biologicals</u> for information on biological products, cold chain management and forms.

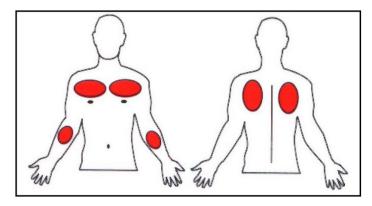


Administering the Tuberculin Skin Test

Prepare the Client for Testing

- Ensure the client is seated safely and comfortably.
- Identify the test site, preferably the inner aspect of a forearm, about 5-10 cm (2-4 inches) below the elbow. Clean the test site with an alcohol swab and let it dry.
- **Do not** apply EMLA® cream (or similar local anesthetic cream) to the test site. This may cause localized edema, which may be confused with a response to the testing solution.
- AVOID areas with abrasions or lesions, swelling, visible veins, localized edema, burns or rashes.
 Use an alternate test site if neither forearm is suitable (see Figure A-1). If extensive eczema, avoid administering TST and consult TB Services for guidance.

Figure A-1, Sites for tuberculin skin test administration



Prepare to Administer the Test

- Follow your facility's standard infection control precautions. Apply gloves if indicated.
- Prepare Tubersol[®] for administration:
 - Use an aseptic technique to maintain sterility when opening vial, and between doses.
 - Do not inject excess air into the vial.
 - Remove the testing solution from the vial under aseptic conditions, using a 0.6 to 1.3 cm (¼ to ½ inch), 26- or 27-gauge needle with a disposable plastic tuberculin syringe.
 - Withdraw a little more than 0.1 mL of testing solution into the syringe.
 - Hold the syringe upright and lightly tap out the air, then expel one drop.
 - o Ensure that a full 0.1 mL of testing solution remains in the syringe.



Inject the Testing Solution INTRADERMALLY

- Position the bevel of the needle so that it opens facing upward.
- While holding the skin at the test site taut, insert the needle at a 5° to 15° angle to the skin. The tip
 of the needle should be visible below the skin's surface. Insert the needle just to the point where the
 entire bevel (opening) is covered.
- Do NOT aspirate. Slowly depress the plunger of the syringe until the entire 0.1 mL of testing solution is injected.
- A discrete, pale elevation of the skin (a wheal) 6 to 10 mm in diameter should appear during the injection (see Figure A-2). The wheal will disappear within 15 minutes.

Figure A-2, Administration of a tuberculin skin test (2)



- Potential issues with intradermal administration where a repeat TST is indicated (2):
 - Accidental subcutaneous or intramuscular injection of Tubersol should not pose a serious risk of harm. Tuberculin-sensitive persons may have localized inflammation, which should be self-limited.
 - If no wheal appears or if a lot of testing solution leaks from the site during the injection.
 - Repeat TSTs immediately. Use proper intradermal technique and administer the TST on the opposite forearm, or the same forearm, at least 5 cm from the site of the previous TST.
- Remove the needle and lightly sponge the test site with dry gauze or a cotton ball. **Do not** press on or massage the test site. **Do not** cover the test site with a bandage.
- Place used needles and syringes in appropriate puncture-resistant containers immediately after use.
- Discard gloves if using, and wash hands.

Documenting the TST Plant

Include the date, dose, lot number and testing site in the client record as per agency guidelines.



Reading the Tuberculin Skin Test

Examine the TST site 48 to 72 hours after the TST plant. After 72 hours, the TST result is invalid and must be repeated, unless 10 mm or more induration is present.

A repeat TST can be done immediately. Use the opposite forearm, or the same forearm, at least 5 cm from the site of the previous TST.

Procedure:

- Read the TST site in an area with good lighting. Ensure the client is seated with their forearm supported on a firm surface and slightly flexed at the elbow.
- Palpate the test site with your fingertips to check for firmness or swelling (induration). If any
 induration is felt, ask the client if you may temporarily mark their arm with a pen. Using a pen to
 locate and mark the edges of the indurated area allows for a more accurate measurement.
- Mark the left border of the indurated area by moving the tip of a pen at a 45° angle laterally toward the test site (**see Figure A-3**). The tip will stop at the edge of the induration. Repeat the process on the right side of the induration.

Figure A-3, Pen method for locating and marking edges of induration

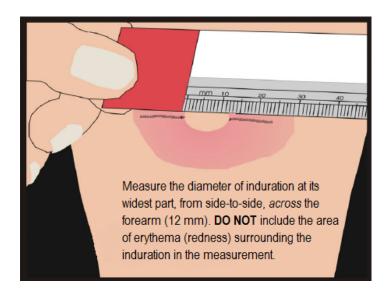


Measuring Induration

- Use a caliper ruler to measure the distance between the pen marks, which will reflect the induration
 at its widest point, from side-to-side, across the forearm (see Figure A-4 above). If a caliper ruler is
 not available, a flexible ruler may be used (shown).
- Remove pen marks from the client's arm by rubbing them lightly with an alcohol swab.



Figure A-4, Measurement of tuberculin skin test induration



Practitioner Alert!

Health care providers trained in this skill must read a TST in person. Self-reading, virtual reading and self-reporting of TST results, is **not** acceptable.

Documenting the TST Reading

On the client record, clearly document:

- Date the TST was read
- Print your name and sign in the 'read by' field (to identify the health care provider that read the TST)
- Size of induration in **millimetres** (mm): If no induration is noted, record the result as 0 mm.
- If the measurement falls between demarcations on the ruler, record the smaller of the two numbers.
- Any adverse reaction (e.g. blistering or rash).

Practitioner Alert!

DO NOT RECORD the size of induration:

- In decimal points, (e.g. document 12.2 mm as 12 mm).
- Measurements in centimetres (cm).
- TST results as positive, negative, significant, or non-significant.



Two-Step Tuberculin Skin Testing

Refer to Section 4(a) for background information and indications for two-step TST.

Practitioner Alert!

The two-step TST protocol is **not** equivalent to the standard initial and eight-week post-exposure TST assessment in contacts. **DO NOT** use in TB contact tracing.

Procedure:

- Complete a TST and document the results as per agency guidelines.
- If the result of the TST is less than 10 mm of induration, perform a second TST 1 to 4 weeks later.
- Administer the second TST on the opposite forearm, or the same forearm, at least 5 cm from the site of the previous TST. Use the same procedures for administering, reading and measuring twostep TST results as single TSTs.
- Document the results of the two-step TST as per agency guidelines.

NOTES:

- A documented TST result of less than 10 mm of induration within the prior 12 months may be accepted as the first result (first step) of a two-step TST.
- When live virus vaccines are required as well as two-step TSTs, administer them on the same day
 as the second TST.



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