BC Centre for Disease Control
Provincial Health Services Authority

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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

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 (1,2).

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 (1,2)

Anaphylaxis

Acute allergic reactions, including anaphylaxis, angioedema, urticaria and/or dyspnea, have been rarely reported as temporally (not necessarily causally) associated with administration of Tubersol® (reported at a rate of less than one per million doses in Canada) (1).

- Acute allergic reactions, including anaphylaxis, can occur in people without a prior history of a TST.
- Epinephrine-containing kits must be available at the time of TST administration.
- Clients should remain in the clinic for 15 minutes after getting a TST.
- Always report serious or unexpected reactions as per agency guidelines.

Anaphylaxis is a potentially life-threatening allergic reaction that is rapid in onset and progression of symptoms. Changes develop over several minutes and usually involve at least two body systems (affecting the skin, respiration, circulation). Urticaria and angioedema are the most common manifestations of anaphylaxis.

Note: There are two anaphylaxis Decision Support Tools (DST) for health professionals in BC and the clinical direction in both documents is identical.

- Anaphylaxis: Initial Emergency Treatment by Nurses (Adult & Pediatric) (3) is a Provincial Clinical DST for Acute, Community, Long Term Care sites and non-hospital settings. Exception: when an alternate practice standard/procedure, clinical decision support tool or medical order is in effect for initial emergency treatment of anaphylaxis.
- All nurses (RN, RPN and LPN) who immunize without an order must follow the BC Communicable Disease Control Manual, Chapter 2: Immunization; Part 3 Management of Anaphylaxis in Non-Hospital Settings (3) established by the BCCDC.

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 (4).

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 (5).

Health care providers without BCPSLS should directly report any serious adverse drug reaction through Health Canada's MedEffect Adverse Reaction Reporting (4).

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 (6). 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 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).

Tuberculin Skin Test (TST) Quick Reference Guide

The online TST Quick Reference Guide for Health Care Providers (7) can be printed and used alongside this Appendix as a visual summary of the TST procedures to follow:

- Before TST
- Administration
- After TST
- Reading TST
- Next steps

Table A-1: Factors associated with false-negative and false-positive TST* (1,8)

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 • Oral Polio • Varicella • 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 Section 4(b) Table 5 Special Considerations for TSTs and IGRAs.

♦ Smallpox and Mpox (IMVAMUNE®) is a non-replicating live attenuated vaccine that contains genetically modified *orthopoxvirus* that has lost its ability to replicate in human cells. IMVAMUNE® can be given any time before or after tuberculin skin testing (9).

Informed Consent for Tuberculin Skin Testing

According to the British Columbia College of Nurses and Midwives (BCCNM) Consent Practice Standard (10) 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 HealthLinkBC Healthfile 51d Tuberculosis Skin Test 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 BCCDC CDC Manual, Chapter 2-Immunization Program, Appendix A (11).

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 HealthLinkBC Healthfile 51d TB Skin Test 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, Appendix A: Informed Consent and BC College of Nurses & Midwives Standard of Practice, Consent.

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 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 one month (30 days) from date of first puncture, or the vial expiry date if earlier than the post-puncture expiry** (1).
    - In use for an undetermined length of time (i.e. open vials without the date of first puncture)(12).

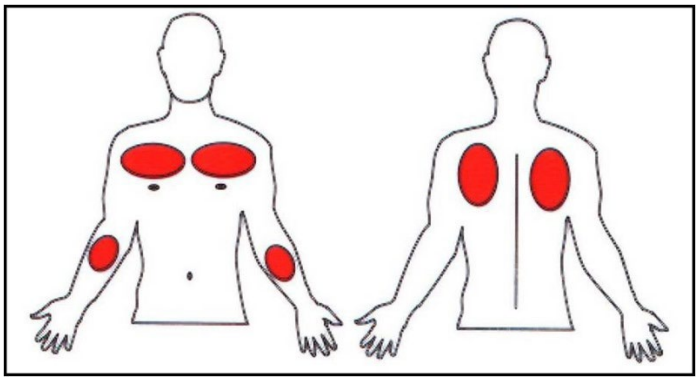
[2] Refer to the BCCDC CDC Manual, Chapter 2-Immunization Program, Appendix E-Management of Biologicals for information on biological products, cold chain management and forms.

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 the left 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



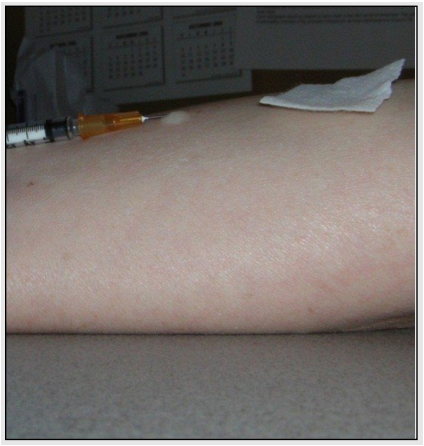
Prepare to Administer the Test

- 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.
    - 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 (1)



- Potential issues with intradermal administration where a repeat TST is indicated (1):
    - 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.
    - Tip: No more than two attempts at TST administration are recommended by any one health care provider. Where possible, ask another health care provider for assistance to plant the 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 used, and wash hands.

Documenting the TST Plant

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

Reading the Tuberculin Skin Test

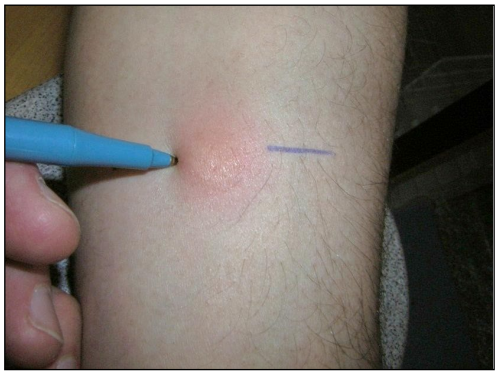
Examine the TST site 48 to 72 hours after the TST plant. After 72 hours, the TST result is invalid and must be repeated, unless 10 mm or more induration is present.

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.
    - Tip: Closing your eyes can help you to focus on what you feel, not what you see.
    - Tip: If a client's arm is tense and you are having difficulty palpating induration, ask them to relax their arm or raise their forearm (bend elbow) to a 45° angle.
- Mark the left border of the indurated area by moving the tip of a pen at a 45° or 90° 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.
    - Tip: If the pen does not stop at the edge of the induration at a 45° angle, try the pen method at a 90° angle. The client may experience more pressure with the pen at a 90° angle.

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



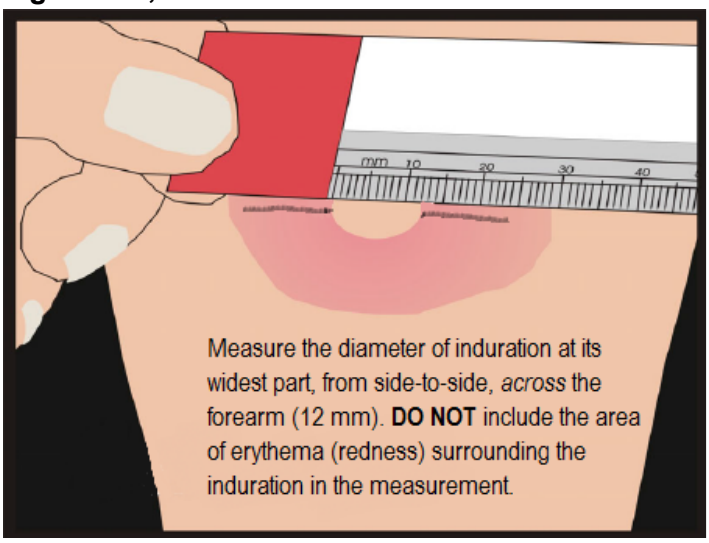
Measuring Induration

- 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 below**). 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.

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.

Figure A-4, Measurement of tuberculin skin test induration



Documenting the TST Reading

On the TB screening form, (or your agency's health care information system) ensure the following fields are completed:	
Date/Time	YYYY/MM/DD and time of the read
Size of induration	**In millimetres (mm)**
	In whole numbers (no decimals). If the measurement falls between (mm) demarcations on the ruler, record the smaller of the two numbers, i.e., round down.
Read by (print)	Health care provider name and designation
Interpretation	Interpretation of induration per Table 4, TB DST. Tick either the positive or negative box
Any adverse reactions. (e.g., blistering or rash) must be clearly documented.	

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 two-step TST results as single TSTs.
- Document the results of the two-step TST as per agency guidelines.

NOTE:

- 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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