Tuberculin PPD

Revision Date: October 26, 2018

Rationale for Update: Updated to align with current Canadian standards.

Please consult the Product Monograph[1] for further information about the vaccine.	
	TUBERSOL®
Manufacturer	Sanofi Pasteur Limited
Off-license use	None
Indications for use of provincially funded Tubersol®	Provincially funded Tubersol® is supplied to Alberta Health Services (AHS) for organized province-wide TST programs that are the responsibility of Public Health such as: • screening of health care workers (including students and volunteers) employment and if recommended because of high risk of exposure (but not for routine screening of staff unless the workplace has been assessed as a high-risk facility) • screening of contacts to cases of active Tuberculosis (TB) disease • screening of inmates and staff in correctional institutions AHS zone programs that reflect public health practice, approved by the AHS Medical Officer of Health to address specific demographics. For example, newcomer's clinics held to address medical needs of immigrants. Tubersol® is not currently supplied to private travel clinics, occupational health programs outside of those described above, or diagnostic purposes (either in facilities or physician offices).
	Tuberculin skin test (TST) may be recommended for the following populations:
	Contacts of a known active case of infectious TB.[2]
	Immigrants from countries with High TB incidence*.[2] • Children and adults ages 6 months to 20 years who have lived in a country with high TB incidence* **and** have immigrated within the last 2 years.[2] • All refugees younger than 50 years of age who have lived in a country with high TB incidence* **and** have immigrated within the past 2 years.[2] • Foreign-born individuals who are referred for medical surveillance.[2] NOTE: *High TB incidence is defined as a TB disease rate of 30 per 100,000 according to most recent World Health Organization (WHO) reports.[2] See WHO TB country profiles for incidence rates at http://www.who.int/tb/country/data/profiles/en/.[3] (Select country→'Estimates of TB Burden'→Incidence includes HIV and TB→Rate per 100,000).
	Individuals with medical conditions/therapies that increase risk of progression from latent TB infection (LTBI) to development of active TB disease.[2] • HIV/AIDS. • Chronic renal failure requiring dialysis. • Carcinoma of the head and neck.

	• Silicosis • Abnormal chest x-ray consistent with prior TB. • Transplant recipients or candidates who are currently on or in anticipation of immunosuppressive treatment.[2] • Treatment with TNF alpha inhibitors and/or other immunosuppressive medications such as chemotherapy or systemic corticosteroids (equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for 2 weeks or longer).[4]
	Indigenous • Current or historical residence in First Nations, Metis or Inuit communities.[2]
	Residents of congregate living • Residents of congregate living settings such as addiction or treatment rehabilitation centers and homeless shelters.[2] • Inmates of correctional institutions incarcerated for 1 year or more.[2] • Inmates incarcerated for less than a year with additional risk factors** for TB reactivation.[2] **Risk factors – medical conditions as listed above or immigrants from countries with high TB incidence.
	Homeless • Individuals using shelters and drop-in centres for the homeless and under-housed.[2]
	Health Care Workers, Post-secondary Health Care students, and Volunteers • Healthcare workers who work with populations at risk for TB.[2] • Post-secondary health care students (either in Alberta or in other provinces/countries). • Volunteers who work with populations at increased risk for TB who will be volunteering for 150 or more hours in a year (i.e. approximately one-half day per week).[2]
	Travellers • Long-term travellers to countries with high TB incidence will be screened according to Canadian Tuberculosis Standards (Table 4).[2] See WHO TB country profiles for incidence rates at http://www.who.int/tb/country/data/profiles/en/. [3] (Select country→'Estimates of TB Burden'→Incidence includes HIV and TB→Rate per 100,000).
Dose	0.1 mL
Route	Intradermal (ID) injection
Schedule	**Single-step TST** Single-step (one TST only) is recommended for most individuals, including post-secondary students at risk for potential occupational exposure to infectious TB.[2] **Two-step TST** The second TST should be administered 1 to 4 weeks after the initial test [1,2] Two-step testing criteria: • HCWs involved in high risk activities including: [2] o Cough-inducing procedures (such as sputum induction) o Autopsy

<table>
<tr><td></td><td colspan="2">

o Morbid anatomy and pathology examination
o Bronchoscopy
o Mycobacteriology laboratory procedures, especially handling cultures of M. tuberculosis

HCWs on high-risk units where patients with respiratory TB may be admitted.[2]
Correctional service workers who will undergo repeated screening with TSTs at regular intervals.[1,2]

Note:
A two-step protocol needs to be performed ONCE only if properly performed and documented. It never needs to be repeated. Any subsequent test can be one step, regardless of how long it has been since the last TST.[2]
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<tr><td>Timeframe for Tuberculin Skin Test (TST) reading</td><td colspan="2">48 to 72 hours after administration [2]
Note: Reading is to be done in person, by health care providers trained in this skill. Self-reading and reporting of TST results, is not acceptable. If the TST is not read within 72 hours, the result is not valid and must be repeated, unless there is 10 mm or more of induration present. The repeat test can be done immediately. Use opposite forearm, or the same forearm, at least 5 cm from the site of the previous TST.[2]</td></tr>
<tr><td rowspan="4">Interpretation of TST [2]</td><td>TST reaction size (mm of induration)</td><td>Situation in which reaction is considered positive</td></tr>
<tr><td>0-4 mm</td><td>• Child under 5 years of age and high risk of TB</td></tr>
<tr><td>5 mm and greater</td><td>• HIV infection.
• Close contact of an active infectious case with the past 2 years.
• History of abnormal chest x-ray with fibronodular disease (healed TB and not previously treated).
• Organ transplantation (related to immune suppressant therapy).
• TNF inhibitors.
• Other immune suppressive drugs such as corticosteroids (equivalent equivalent of ≥ 2 mg/kg/day or to 20 mg/day and greater of prednisone for 2 weeks or longer) or chemotherapy.[4]
• End-stage renal disease/dialysis.</td></tr>
<tr><td>10 mm and greater</td><td>Situation in which reaction is considered positive.</td></tr>
<tr><td colspan="2">• Identify the presence or absence of induration. Redness is to be ignored when assessing induration. Measure, using a caliper, the diameter of induration at the widest part transversely to the long axis of the forearm (i.e., from side-to-side, across the forearm). [2]
• TST readings must be recorded in millimeters, including 0 mm rather than negative. Reporting results as either negative or positive is not appropriate. [2]</td></tr>
<tr><td>Contraindications</td><td colspan="2">• Anaphylaxis or other hypersensitivity to any component of Tubersol® or its container.[1]
• Severe reaction (e.g., necrosis, blistering or ulcerations) to previous tuberculin skin testing (TST)[1]
• History of past active tuberculosis or treatment for tuberculosis infection or disease.[1]
• Extensive burns or eczema because of greater likelihood of adverse reactions or severe reactions.[1]</td></tr>
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Precautions	• TST should be administered on the same day as live vaccines are administered, or delay TB skin testing for ≥4 weeks after a live vaccine.[1,2] • TST should be deferred for four weeks following a major viral infection (e.g. measles, mumps, rubella).[1,2] • Impaired or attenuated cell-mediated immunity may cause a false negative tuberculin reaction.[1] • HIV-infected persons may have a compromised ability to react to tuberculin skin tests.[1] • Due to immature immune systems, many infants less than 6 months of age who are infected with *M. Tuberculosis* do not react to tuberculin tests.[1]
Possible reactions	**Common:** • Pain, pruritus, discomfort and bruising at the injection site.[1] • Injection site redness or rash (without induration) may occur within 12 hours of testing.[1] **Rare:** • Injection site vesicles, ulcer or necrosis in highly sensitive persons. [1] • Injection site scar as a result of strongly positive reactions. [1] • Pyrexia and generalized rash.[1] • Angioededema, urticaria and anaphaylaxis [1] Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.*[5]
Pregnancy	While pregnancy is not a contraindication to the administration of TST, routine screening tests in the absence of symptoms, HIV infection or recent contact with an infectious TB case are usually deferred until after delivery.[1,2]
Lactation	Breastfeeding women may receive TST.[1,2]
Program Notes	• 1960 January – Introduced into program.

References

[1] Sanofi Pasteur Limited. (2016, February 11). Tubersol®: Tuberculin purified protein derivative (Mantoux). *Product Information*.

[2] Public Health Agency of Canada. (2014) *Canadian Tuberculosis Standards, 7th edition*. Retrieved October 3, 2018 from https://www.canada.ca/en/public-health/services/infectious-diseases/canadian-tuberculosis-standards-7th-edition.html

[3] World Health Organization (WHO). Geneva: WHO, 2018. Tuberculosis country profiles available at http://www.who.int/tb/country/data/profiles/en/

[4] National Advisory Committee on Immunization. (2018). *Canadian Immunization Guide*. (Evergreen ed.). Ottawa, ON. Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[5] Alberta Health. (2018, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.* https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/f2da2a7a-e350-4bab-b2c2-77677beeb22b/download/aip-adverse-events-following-immunization-policy.pdf