



Operational Guideline

TITLE: Storage and Management of Tuberculin Purified Protein Derivative

APPROVED BY:

	Date		Date	TARGET REVIEW DATE	PAGE 1
✓ Community Health Services Leadership Team	2011	✓ WRHA TB team	2015		
		✓ Population and Public Health	2011		

PURPOSE:

To promote consistency and competency in performing the tuberculin skin test (TST).

SCOPE & GOAL:

To support safety and accuracy of the tuberculin skin test (TST) through proper storage and handling of tuberculin purified protein derivative (PPD).

DEFINITIONS

Tuberculin purified protein derivative - An inactivated purified protein derived from a human strain of *Mycobacterium tuberculosis* bacteria that has been grown on a protein-free synthetic medium.

BACKGROUND

Tuberculin PPD is a clear and colorless solution of sterile isotonic phosphate buffered saline containing:

- Purified protein derivative of *M. tuberculosis*:** 5 tuberculin units (TU) per 0.1 mL
- Polysorbate 80:** 0.0006%
- Phenol:** 0.22% to 0.35% w/v

In Manitoba, tuberculin PPD is available as the brand name Tubersol®. Tubersol® is manufactured by Sanofi Pasteur Limited and available in vials of 1 ml solution. The stopper of the vial does not contain latex.

PROCEDURE

1. Tuberculin can be obtained by public health through the Manitoba Health vaccine procurement process ([link](http://www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf)).
2. Tuberculin must be
 - 2.1 Stored between 2°C and 8°C



Operational Guideline

TITLE: Storage and Management of Tuberculin Purified Protein Derivative

APPROVED BY:

	Date		Date	TARGET REVIEW DATE	PAGE 2
✓ Community Health Services Leadership Team	2011	✓ WRHA TB team	2015		
		✓ Population and Public Health	2011		

- 2.2 Stored in the dark, except when doses are being drawn. Sensitivity to light can adversely affect the tuberculin PPD solution.
- 2.3 Dated when opened
 - 2.3.1 In ink, document on the vial (e.g., “opened: March 21, 2011”).
- 2.4 Discarded when expired because oxidation and product degradation can impact potency. Discard the vial:
 - 2.4.1 Thirty days after the vial was first opened.
 - 2.4.2 If past the manufacturers expiration date printed on the vial.
- 2.5 Tuberculin should be transported following the policy for transportation and storage of vaccines for off-site clinics (link)
 - http://www.wrha.mb.ca/professionals/immunization/files/03_CPG_StorageOffSite.pdf
- 2.1 Cold chain failures can be managed in accordance with the WRHA Population and Public Health Cold Chain Failure Response Plan (link)
 - http://www.wrha.mb.ca/professionals/immunization/files//03_CPG_Storage_AppendixC.pdf

VALIDATION

In Manitoba, the primary method for testing for latent tuberculosis infection (LTBI) is the TST. Test results may be inaccurate if tuberculin PPD is not stored and managed properly.

RECOMMENDED READING

Cold Chain Resources (Manitoba Health)

<http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html>

Manitoba Communicable Disease Control Branch (2009). *Tuberculosis Communicable Disease Management Protocol*,

<http://www.gov.mb.ca/health/publichealth/cdc/protocol/tb.pdf>

Public Health Agency of Canada (2013) *Canadian tuberculosis standards* 7th Ed.

<http://www.phac-aspc.gc.ca/tbpc-latb/pubs/tb-canada-7/index-eng.php>

Tubersol® Product Monograph

https://www.vaccineshoppecanada.com/document.cfm?file=tubersol_e.pdf