



Philadelphia Department of Public Health  
**Division of Disease Control**

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**Health Advisory**  
**Nationwide Shortage of Tuberculin Skin Test Antigens:**  
**PDPH Recommendations for Patient Care and Public Health Practice**  
**April 23, 2013**

**Summary**

Manufacturers of purified protein derivative (PPD) used in the tuberculin skin test (TST) are experiencing significant delays in production, resulting in a nationwide shortage. Tubersol® is in shortage nationwide until at least the end of May 2013. There may still be limited supplies of 10-dose vials available. The manufacturer of Aplisol® (another form of tuberculin), has notified the FDA that the product is available in restricted quantities only. The Philadelphia Department of Public Health (PDPH) Tuberculosis (TB) Control Program has received numerous reports of local shortages of both Aplisol® and Tubersol®.

**Background**

Two kinds of immunological methods are used for detecting *Mycobacterium tuberculosis* infection: tuberculin skin tests (TSTs) and interferon- $\gamma$  release assay (IGRA) blood tests. The indications for use of these tests are the same, although one method may be preferred over the other for certain populations (e.g. the utility of IGRAs in children under the age of five years is not completely defined). TSTs and IGRAs are the only means for detecting latent *M. tuberculosis* infection. However, their utility in diagnosing active TB infection is variable. When TB disease is strongly suspected, specific treatment should be started regardless of results from a tuberculin skin test or IGRA blood test.

In controlled studies, the concordance between TST results from TUBERSOL® and APLISOL® is high. The concordance between results from a TST and an IGRA, or between results from the two commercial IGRA blood tests is lower.

**RECOMMENDATIONS FOR PATIENT CARE DURING SHORTAGES OF TUBERCULIN SKIN TEST ANTIGENS:**

For patients suspected of active tuberculous infection:

- Generally, work-up should proceed directly to chest radiograph and collection of specimens for acid-fast bacilli (AFB) smear and culture. IGRA testing may augment the work-up in some cases, particularly in pediatrics.

For patients suspected of latent tuberculous infection (LTBI):

- Consider screening for latent tuberculous infection with an interferon- $\gamma$  release assay (IGRA) instead of a TST in the following high-risk situations:
  - Contacts to a person with pulmonary, pleural or laryngeal TB (esp. if the source's acid-fast smear is positive)
  - Persons at high risk of progression to active TB, e.g., HIV infected, immunocompromised, or initiating treatment with an immune modulator
  - Pre-employment screening for workers in high-risk situations, e.g., healthcare, daycare
- Consider deferring screening for LTBI until TST reagent available in the following situations:
  - Routine testing as part of pre-employment physicals for persons to be employed in low-risk settings
  - Routine annual screening programs
  - Admissions to congregant settings, such as shelters and long-term care facilities
  - Asymptomatic persons who have immigrated from TB-endemic regions of the world

Please call PDPH, TB Control Program at 215-685-6873 if you have questions or need additional information.

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