



PUBLIC HEALTH ADVISORY TUBERCULIN SKIN TEST SOLUTION SHORTAGES

August 27, 2013

SITUATION: Ongoing shortages of Tubersol and limited availability of Aplisol, the purified protein derivative (PPD) solutions used for tuberculin skin testing (TST) may impact provider ability to assess patients for latent tuberculosis infection (LTBI).

BACKGROUND: In April 2013, the Centers for Disease Control and Prevention (CDC) issued information regarding nationwide shortages of Tubersol and Aplisol solutions. The 50-test preparation may not be available and the 10-test preparation may only be available in limited supply. The current projection for restoration of normal production of Tubersol is this fall. The shortage of Tubersol has created increased demand for Aplisol and shortages of both PPD solutions. Other tests for detecting TB infection such as Interferon Gamma Release Assay (IGRA) blood tests (e.g. QuantiFERON and T-SPOT) continue to be available, but cost may be a barrier.

ACTIONS RECOMMENDED TO CLINICIANS:

1. **Substitute an IGRA for a TST when available.** CDC recommends the use of IGRAs in all situations when a TST would be used; however a TST is still the preferred test for children under 5 years of age.
2. **Allocate TSTs and IGRAs to priority situations.** Box 1 describes persons who should be tested for LTBI: those at high risk for both infection and progression to TB disease, including close contacts to active TB disease cases. Screening of lower risk individuals would be deferred until testing supplies are available. **CDC does not recommend testing persons who are not at risk for TB.**

BOX 1

Persons at increased risk for being recently infected	Persons at increased risk of progression from LTBI to TB disease
<ul style="list-style-type: none"> - Close contacts of a person with infectious TB - Persons who have immigrated within the last 5 years from areas of the world with high rates of TB - Children and adolescents <18 years of age who have one or more positive responses to the risk assessment questionnaire (see Box 2) - Groups with high rates of <i>M. tuberculosis</i> transmission, such as homeless persons, drug users, and persons with HIV infection - Persons who work or reside with people who are at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for those with HIV/AIDS - Mycobacteriology laboratory workers 	<ul style="list-style-type: none"> - HIV infection - Pulmonary fibrotic lesions seen on chest radiograph consistent with prior healed TB (TB4) - Diabetes mellitus (especially insulin-dependent) - Silicosis - Chronic renal failure, hemodialysis - Chronic immunosuppression, e.g. <ul style="list-style-type: none"> - Transplant recipients - Prolonged corticosteroid therapy (15 mg/day prednisone for at least 1mo) - Anti-Tumor Necrosis Factor-alpha agents - Other immunosuppressive therapy - Hematological malignancies (leukemia, lymphoma) - Cancer of the head and neck or lung - Intestinal bypass or gastrectomy - Malnutrition and clinical situations associated with rapid weight loss - Chronic malabsorption - Low body weight (15% below ideal body weight) - Injection drug use



BOX 2

TB risk assessment questions for children:

- 1) Has a family member or contact had TB disease?
- 2) Has a family member had a positive TST result?
- 3) Was your child born in a high-risk country (countries other than the US, Canada, Australia, New Zealand, or Western and Northern European countries)?
- 4) Has your child traveled (had contact with resident populations) to a high-risk country for more than a week?

ADDITIONAL CONSIDERATIONS:

Diagnosis of TB disease: If there is high suspicion of TB disease, TST and IGRA should not be used to rule out active disease. Similarly, treatment should not be deferred when TB tests are unavailable.

School entry screening requirements: There is no state mandate requiring TB screening upon entry for elementary, high school or college students. Alameda County Public Health Department recommends using a risk assessment (see **Box 2**) to identify students at higher risk for TB infection who should be tested.

Health care workers in California: Effective 5/30/13, the use of the IGRA test for screening HCWs no longer requires a grant of program flexibility from CDPH Licensing & Certification (per All Facilities Letter 13-15). Revised California Code of Regulation, Title 22 allows the use of TB blood tests and TSTs if the test is licensed by the Federal Food and Drug Administration (FDA) and recommended by the CDC.

Switching test type or methods for serial testing programs such as health care worker or inmate screening: Switching products (e.g. from Tubersol to Aplisol) or methods (e.g. from TST to IGRA) might make serial results more difficult to interpret. However, in controlled studies, the concordance between TST results from Tubersol and Aplisol is high.

ADDITIONAL RESOURCES:

California Department of Public Health and California Tuberculosis Controller's Association. Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, 2006.

http://www.ctca.org/index.cfm?fuseaction=page&page_id=5040

California Tuberculosis Controller's Association. CTCA position on TB Testing of School-Age Children and Sample Risk Assessment, June 28, 2012.

http://www.ctca.org/index.cfm?fuseaction=menu&menu_id=5014

American Academy of Pediatrics. Red Book: 2012 Report of the Committee on Infectious Diseases. Pickering LK, ed. 29th ed. Elk Grove Village, IL.

Please contact the Alameda County Public Health Department TB Control Unit (510) 577-7000 if you have further questions.

Health ALERT: conveys the highest level of importance; warrants immediate action or attention.

Health ADVISORY: provides important information for a specific incident or situation; may not require immediate action.

Health UPDATE: provides updated information regarding an incident or situation; unlikely to require immediate action.