



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

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Dear TB Controller:

RE: Recommendations for responding to shortage of TB skin test antigens

There is currently a shortage of TUBERSOL and limited availability of APLISOL, the two products used for TB skin tests (TST) (see attached notifications from CDPH and CDC). Other tests for detecting TB infection such as Interferon Gamma Release Assays (IGRA) (e.g. QuantiFERON and T-SPOT) continue to be available, but cost may be a barrier.

CDPH recommends the following approaches in response to the shortage:

1. Substitute an IGRA blood test 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 preferable test for children under 5.
2. Allocate TSTs and IGRAs to priority situations
Box 1 contains information on persons who should be tested for latent TB infection. The highest priority is to test those at high risk for both infection and progression to TB disease. Note close contacts to active TB disease cases have an elevated risk of being both infected and progressing to disease. This approach will result in the deferment of screening of lower risk individuals. **CDC does not recommend testing persons who are not at risk for TB.**

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. Local health jurisdictions or individual schools requiring TB testing for school entry may wish to use symptom screening or a risk assessment (see Box 2) until TB skin test antigens (or IGRAs) are accessible. Documentation of the drug shortage context as a rationale to this approach may be helpful.

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 TB skin tests 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.

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 M. tuberculosis transmission as defined locally, 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 <ul style="list-style-type: none"> Transplant recipients Prolonged corticosteroid therapy (15 mg/day prednisone for 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?

References:

1. California Department of Public Health and California Tuberculosis Controller's Association. Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, 2006.
2. Centers for Disease Control and Prevention. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR, June 9, 2000/V49/No.RR-6, p.8.
3. Centers for Disease Control and Prevention. Updated Guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection — United States, 2010. MMWR 2010;59 (RR-5)
4. American Academy of Pediatrics. Red Book: 2012 Report of the Committee on Infectious Diseases. Pickering LK, ed. 29th ed. Elk Grove Village, IL.

Sincerely,

Jennifer Flood, M.D., M.P.H., Chief
Tuberculosis Control Branch
Division of Communicable Disease Control
Center for Infectious Diseases
California Department of Public Health