Health Advisory: Nationwide Shortage of Tuberculin Skin Test Antigens: CDC Recommendations for Patient Care and Public Health Practice

June 20, 2019

The Centers for Disease Control and Prevention (CDC) is anticipating a 3 to 10-month nationwide shortage of APLISOL®, one of two purified-protein derivative (PPD) tuberculin antigens licensed by the United States Food and Drug Administration (FDA) to perform tuberculin skin tests.

In order to prevent a decrease in TB testing capability due to the expected shortage of APLISOL®, the CDC recommends the following approaches:

- Substitute interferon-gamma release assay (IGRA) blood tests instead of a tuberculin skin test (TST).
- Substitute TUBERSOL® (another FDA-approved PPD tuberculin antigen) in place of APLISOL® when conducting a TST. In cross-sectional studies, the two skin test products give similar results for most patients.
- Prioritize TB testing to only groups that are at a high-risk for TB infection:
  - People who are recent contacts exposed to persons with TB disease;
  - People born in or who frequently travel to countries where TB disease is common;
  - People who currently or used to live in large group settings, such as homeless shelters or correctional facilities;
  - People with weaker immune systems, such as those with certain health conditions or taking certain medications that may alter immunity; and
  - Children, especially those under age 5, if they are in one of the risk groups noted above.

Note: Health care personnel in California are still required to undergo annual TB testing as mandated in California Code of Regulations Title 8, Section 5199 (Aerosol Transmissible Diseases Standard) and Title 22.
The full CDC Health Advisory can be found below and online (https://emergency.cdc.gov/han/han00420.asp).

If you are experiencing a shortage in PPD solution, please download the PPD Shortage form (found on our website at https://www.sfcdcp.org/tb-control/) and fax to the SFDPH TB Prevention and Control Program at (628) 206 – 4565. This will help us understand the degree to which you are affected by the shortage so that we may report our situation to our state and federal partners. For further consultation, please contact the SFDPH TB Prevention and Control Program at (628) 206 – 8524.

Program Contact Information:
SFDPH Tuberculosis Prevention and Control Program
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