CAHAN San Diego
California HEALTH ALERT NETWORK

To: CAHAN San Diego Participants
Date: August 28, 2013

**Continuing Nationwide Shortage of Tuberculin Skin Testing (TST) Antigen**

This CAHAN is intended to assist local providers in screening for tuberculosis (TB) during the ongoing shortage of TST antigen products licensed by the Food and Drug Administration (FDA).

The Centers for Disease Control and Prevention (CDC) has informed health departments that TUBERSOL® (Sanofi Pasteur Limited) will not be produced at normal levels until "sometime in the fall, perhaps October."[1] The alternative TST antigen product, APLISOL® (JHP Pharmaceuticals), is only available in extremely restricted quantity and remains on allocation for all providers. Based on these shortages, the California Department of Public Health (CDPH) recently provided updated recommendations for managing TB screening that are incorporated into the following **recommendations for San Diego providers:**

1. Do not test those who are not at risk for TB. Allocate TSTs to priority indications, such as testing persons recently exposed to an active TB case, newly arrived immigrants and refugees, HIV-infected individuals and others with risk factors for exposure and progression to active TB disease.[2]

2. Do not routinely skin test elementary, high school or college students for school entry. There is no state mandate requiring TST entry screening. Use symptom screening or risk assessment as a basis for testing as needed.

3. Defer routine serial testing in settings with a low likelihood of TB exposure until the TST supply improves, consulting with occupational health professionals when applicable. Switching products or methods for populations that require serial TB screening might make serial changes in test results difficult to interpret. Apparent conversions of results from negative to positive or reversions from positive to negative could be caused by inherent inter-product or inter-method discordance.[3, 4]

4. Use interferon gamma release assays (IGRAs) as diagnostic aids in *Mycobacterium tuberculosis* infection. Two FDA-licensed IGRA blood tests are available to detect *M. tuberculosis* infection. The blood tests have the same indications as the skin tests and may be used in all situations in which TST is recommended despite preferences indicated in latest CDC guidelines.[3] The use of either IGRA or TST is acceptable medical and public health practice. Clinicians who use the IGRA blood tests should be aware of criteria for test interpretation.[3]

5. Consider using IGRA blood tests for health care workers and others who require screening under California Code of Regulation, Title 22. Effective May 30, 2013, any TB test that is FDA licensed and CDC recommended meets the screening requirement. IGRA blood tests no longer require a grant of program flexibility from CDPH Licensing & Certification.[5] Use caution when individuals require serial tests as noted above.

6. Recognize that when active TB disease is suspected, the results from a TST or an IGRA blood test might not be needed when findings such as chest radiography and mycobacterial smears and cultures are sufficient for confirming or excluding the TB diagnosis.[6]

7. Contact Sanofi at 1-800-VACCINE (822-2463) or JHP at 1-877-547-4547 to obtain updates on TST supply. To inquire about using IGRAs, contact local representatives of Oxford Immunotec (manufacturer of TSpot TB ®) at 1-877-208-7768 or Qiagen (manufacturer of QuantiFERON ®) at 1-800-426-8157.

**The County of San Diego Health and Human Services Agency (HHSA) does not supply testing material to local providers. Patients should not be directed to HHSA clinics based on shortages in your practice, agency or organization. For more information or questions on specific patient management, please call the TB Control Branch at 619-692-8621.**

Thank you for your continued participation.

**References**

[1] http://www.tbcontrollers.org/resources/tb-drug-and-biologic-shortage/#.UhmdDIITGL1

[2] CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000;49(RR-6). http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf

[3] CDC. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection — United States, 2010. MMWR 2010;59 (RR-5). http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf.

[4] CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR 2005;54(RR-17) http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

[5] http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-13-15.pdf

[6]CDC. Treatment of tuberculosis. MMWR 2003;52(RR-11). http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf

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