

DATE: April 15, 2013

TO: Acute and Long Term Care Facilities, Ambulatory Care Facilities, Hospice and Home Care Programs Administrators, Local Health Department Directors

FROM: NYSDOH Bureau of Tuberculosis Control

Update to 3/25/2013 Health Advisory:
Shortage of Purified Protein Derivative (PPD) for Tuberculin Skin Testing
Please distribute to appropriate staff.

Given that a shortage of both PPD tuberculin skin test (TST) solutions is continuing at least until the end of May and likely longer, practitioners and institutions should continue to prioritize their use of existing stock and explore further the use of the IGRA blood tests, QuantiFERON-TB Gold In Tube and TSpot TB, in settings where they have previously used TSTs.

The same guidance of 3/25/2013 on patient prioritization and delaying of serial testing, continues to apply. Highest priority persons for testing include as before:

- 1) persons who are contacts to infectious cases
- 2) persons being evaluated for suspected active TB
- 3) persons at increased risk for tuberculosis due to medical conditions
- 4) persons recently arrived from high TB incidence countries

Any of the available tuberculin skin tests or IGRA blood tests can be used in these situations, based on availability of product, population group and provider preference, in accordance with current guidance.

For persons starting work, in settings where pre-employment screening is required, a TB history (TB exposure, infection or disease and any prior diagnostic testing or treatment) along with a review of symptoms suggestive of active disease, should be recorded and for persons without prior history of TB, one of the 4 approved tests (TST or IGRA) should be done as available. A chest radiograph and other diagnostic assessment should be done as clinically indicated on any persons with history of active TB or symptoms suggestive of TB. CXRs should also be done on asymptomatic persons with past or current documented positive TST or IGRA tests, unless an earlier CXR report can be documented. If there is no indication of current infectious tuberculosis the employee can start work but unless previously diagnosed with infection or disease, must be tested by one of these tests as soon as possible to complete the initial assessment and to identify persons who need treatment for TB infection. Any procedure change in preemployment or serial testing must be documented and lists of persons needing screening tracked.

Similarly, clients prior to entry into long term care or other DOH regulated settings, should be evaluated for signs or symptoms of active tuberculosis before entry, and can be subsequently tested with TST or IGRA when feasible to do so, as soon as possible.

Questions about TB testing or this advisory can be directed to the NYS DOH Bureau of Tuberculosis Control at (518) 474-4845 or tbcontrol@health.state.ny.us. Questions about employee or client screening regulations can also be directed to the OHSM unit which oversees

the particular health care setting. Please see attached CDC HAN advisory which provides further general information on these tests.

This is an official
CDC HAN INFO SERVICE

Distributed via the CDC Health Alert Network
April 12, 2013, 11:00 EDT
CDC HAN-00345

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

Summary:

TUBERSOL®, a product of Sanofi Pasteur Limited, is in shortage nationwide until at least the end of May 2013. TUBERSOL® is one of two purified-protein derivative (PPD) tuberculin products that are licensed by the United States Food and Drug Administration (FDA). The manufacturer notified CDC that 50-dose vials of TUBERSOL® are unavailable and that the supplies of 10-dose vials will be limited. This notice advises public health officials, clinicians, and workers in occupational health and infection control about how to adapt to the shortage.

JHP Pharmaceuticals, LLC, the manufacturer of APLISOL®, the other PPD tuberculin product that is licensed by FDA, has notified FDA that the product is on allocation and is available in restricted quantity. Acute local shortages of APLISOL® are being reported to CDC by healthcare providers who switch from TUBERSOL® to APLISOL®.

Background:

Two kinds of immunological methods are used for detecting *Mycobacterium tuberculosis* infection: tuberculin skin tests (TSTs) and interferon- γ release assay (IGRA) blood tests. The indications for using these tests are the same for the two methods, although one or the other method is preferred for certain populations (1), and this could play a factor in setting priorities when one of the methods is unavailable. Together, these tests are the only means for detecting latent *M. tuberculosis* infection, and they contribute to diagnosing tuberculosis (TB) disease. When findings such as chest radiography and mycobacterial cultures are sufficient for confirming or excluding the TB diagnosis, the results from a TST or an IGRA blood test might not be needed (2). However, most TB cases in the United States are diagnosed with a set of findings including results from one of these tests. When TB disease is strongly suspected, specific treatment should be started regardless of results from tuberculin skin test or an IGRA blood test (1,3).

In controlled studies, the concordance between TST results from TUBERSOL® and APLISOL® is high. The concordance between results from a TST and an IGRA blood test or between results from the two commercial IGRA blood tests is lower (1).

Recommendations:

CDC recommends any of three general approaches for addressing the shortages of tuberculin skin test antigens:

1. Substitute IGRA blood tests for TSTs. The costs associated with using the blood tests can be greater than the cost of TSTs. The blood tests require phlebotomy, preparation of blood specimens, and specific laboratory services for analysis. Thus, these tests are not available in all practice settings. Clinicians who use the IGRA blood tests should be aware that the criteria for test interpretation are different than the criteria for interpreting TSTs (1).
2. Allocate TSTs to priority indications, such as TB contact investigations, as determined by public health authorities. This might require deferment of testing some persons. CDC does not recommend testing persons who are not at risk of TB (4).
3. Substitute APLISOL® for TUBERSOL® for skin testing. In cross-sectional studies, the two products give similar results for most patients. Shortages of APLISOL® are expected to become more widespread, thus limiting the feasibility of this approach.

Some surveillance programs for TB infection control rely on routine serial TSTs. Switching products or methods might make serial changes in test results difficult to interpret: the 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 (1,5). In settings with a low likelihood of TB exposure, the deferment of routine serial testing should be considered in consultation with public health and occupational health authorities.

References:

1. 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>.
2. American Thoracic Society. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95. <http://www.cdc.gov/tb/publications/PDF/1376.pdf>.
3. CDC. Treatment of tuberculosis. MMWR 2003;52(RR-11). <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>.
4. CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000;49(RR-6). <http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf>.
5. 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>.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, public information officers, epidemiologists, HAN coordinators, and clinician organizations##