

DPHHS HAN

Information Service

Cover Sheet

DATE: April 12, 2013

SUBJECT: Nationwide shortage of tuberculin skin test antigens; recommendations for patient care and public health practice

For LOCAL HEALTH DEPARTMENT reference only

DPHHS Subject Matter Resource for more information regarding this HAN, contact:

**Communicable Disease & Prevention Bureau
Epidemiology/TB Section
1-406-444-0273**

INSTRUCTIONS:

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1-800-701-5769**

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Categories of Health Alert Messages:

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Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please call DPHHS to update contact information at 444-0919

DPHHS policy is to forward all HAN messages from the Centers for Disease Control and Prevention (CDC)

Information Sheet

Date: April 12, 2013

Subject: Nationwide Shortage of Tuberculin Skin Test Antigens

On March 1, 2013 DPHHS notified constituents of a nationwide shortage of TUBERSOL®. This week Sanofi Pasteur, the manufacturer of TUBERSOL®, notified CDC that the nationwide shortage will last at least until the end of May 2013. APLISOL®, the other PPD tuberculin product manufactured by JHP Pharmaceuticals, LLC, is on allocation and is only available in restricted quantity.

Information: Please see the attached CDC Health Alert Network (HAN) Info Service regarding the nationwide shortage of tuberculin skin test antigens and CDC recommendations for patient care and public health practice.

DPHHS Recommendations:

- **The Montana TB Program recommends checking your local supply and determining if your supplier has TUBERSOL® or APLISOL® available to purchase now.**
- If available and appropriate, screen for latent TB infection (LTBI) with the QuantiFERON® Gold In-Tube (QFT-GIT) test instead of a tuberculin skin test (TST). A CDC fact sheet on the use of this test methodology can be found at the following link: <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf>. In addition, the Montana Public Health Laboratory offers the QFT-GIT test. If you would like more information please contact the lab directly at 800-821-7284.
- Prioritize TSTs if necessary. High priority groups include the following:
 - Contacts to an infectious case of TB
 - Persons who are immunosuppressed and need TB screening for medical purposes
 - Persons entering into or being screened as part of an infection control plan at *high-risk settings*, such as correctional facilities, drug treatment facilities, etc.
 - Evaluation of persons with symptoms suggestive of TB disease, if necessary, as part of a comprehensive evaluation for diagnosing TB disease (*When findings such as chest x-ray and mycobacterial cultures are sufficient for confirming or excluding an active TB diagnosis, the results from a TST or QFT-GIT might not be needed.*)
- If necessary, defer annual screening of low-risk employees being tested as part of a routine infection control plan
- Do not *routinely* use both a tuberculin skin test (TST) and the QFT-GIT to diagnose latent TB infection in patients. The CDC recommendations for situations in which testing with both the QFT-GIT and a TST may be considered can be found at the following link: <http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf>

Please direct questions or concerns to Denise Ingman, TB Program Manager, at 406-444-0273 or dingman@mt.gov.

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

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