



# Health Alert Network

**Tri-County Health Department**

Serving Adams, Arapahoe and Douglas Counties

Phone 303/220-9200 • Fax 303/741-4173 • [www.tchd.org](http://www.tchd.org)

Follow us on Twitter @TCHDHealth

John M. Douglas, Jr., M.D. Executive Director

The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.

## HAN ADVISORY

Number of pages including cover: 4

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

Message ID: 6/14/2019 12:15:00 PM

Recipients: HAN Community Members.

From: TRI-COUNTY HEALTH DEPARTMENT

Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **Tri-County Health Department is forwarding you the attached HAN. You may have already received this broadcast if you are on the CDPHE distribution list, however, we wanted to ensure you did not miss this important information. No response is required.**

***\*\*CDPHE has adequate supplies of Aplisol® for local public health agency use during TB investigations. CDPHE recommends private providers order Tubersol® if Aplisol® is not available.\*\****

=====

You have received this message based upon the information contained within our Health Alert Network Notification System. If you have a different or additional e-mail or fax address that you would like us to use, or if you have additional questions, call 720-200-1477.

### Categories of Health Alert Network Messages:

**Health Alert:** Conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** Provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** Provides updated information regarding an incident or situation; unlikely to require immediate action.

**Info Service/Public Health Brief:** Provides general information that is not necessarily considered to be of an emergent nature.

**You may download a copy of this HAN from the TCHD website at  
<http://www.tchd.org/259/Health-Alert-Network>**

# This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network  
June 6, 2019, 1130 ET (11:30 AM ET)  
CDCHAN-00420

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

### **Summary**

The Centers for Disease Control and Prevention (CDC) is expecting a 3 to 10 month nationwide shortage of APLISOL®, a product of Par Pharmaceuticals. APLISOL® is one of two purified-protein derivative (PPD) tuberculin antigens that are licensed by the United States Food and Drug Administration (FDA) for use in performing tuberculin skin tests. The manufacturer notified CDC that they anticipate a supply interruption of APLISOL® 5 mL (50 tests) beginning in June 2019, followed by a supply interruption of APLISOL® 1 mL (10 tests) in November 2019. The expected shortage of APLISOL® 1 mL (10 tests) could occur before November 2019, if demand increases before then. The 3-10 month timeframe for the nationwide shortage is the manufacturer's current estimate and is subject to change.

To monitor the status of this supply interruption, visit FDA's "Center for Biologics Evaluation and Research (CBER)-Regulated Products: Current Shortages" webpage: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages>.

### **Background**

Two types of immunological methods are used for detecting *Mycobacterium tuberculosis* infection: tuberculin skin tests (TSTs) and interferon-gamma release assay (IGRA) blood tests. TSTs and IGRAs are used for diagnosing latent TB infection and may aid in diagnosing TB disease. Additional evaluation and testing is necessary to distinguish between latent TB infection and TB disease, and to determine the correct treatment (1). 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 (1). Most TB cases in the United States are diagnosed with a set of findings including results from one of these tests.

Two FDA-approved PPD tuberculin antigens are available in the United States for use in performing TSTs: TUBERSOL® and APLISOL®. In controlled studies, the concordance between the two products is high (2).

When TB disease is strongly suspected, specific treatment should be started regardless of results from TST or an IGRA blood test (3,4).

### **Recommendations**

CDC recommends three general approaches to prevent a decrease in TB testing capability because of the expected shortage of APLISOL®.

- Substitute IGRA blood tests for TSTs. Clinicians who use the IGRA blood tests should be aware that the criteria for test interpretation are different from the criteria for interpreting TSTs (3).
- Substitute TUBERSOL® for APLISOL® for skin testing. In cross-sectional studies, the two skin test products give similar results for most patients.

- Prioritize allocation of TSTs, in consultation with state and local public health authorities. Prioritization might require the deferment of testing some persons. CDC recommends testing only for persons who are at risk of TB (5-7). High-risk groups for TB infection include:
  - 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.

While overall test concordance is high, switching between PPD skin test products or between TSTs and blood tests in serial testing may cause apparent conversions of results from negative to positive or reversions from positive to negative. This may be due to inherent inter-product or inter-method discordance, rather than change in *M. tuberculosis* infection status (3,8). Clinicians should assess test results based on the person's likelihood of infection and risk of progression to TB disease, if infected (1).

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. Annual TB testing of health care personnel is not recommended unless there is a known exposure or ongoing transmission (8).

## References

1. Lewinsohn, David M., et al. "Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children." *Clinical Infectious Diseases* 64.2 (2017): e1-e33. <https://academic.oup.com/cid/article/64/2/e1/2629583>
2. Villarino ME, Burman W, Wang Y, et al. Comparable specificity of 2 commercial tuberculin reagents in persons at low risk for tuberculous infection. *JAMA*. 1999;281(2):169–171. <http://dx.doi.org/10.1001/jama.281.2.169>
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): 1-25. <https://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf>
4. Nahid, Payam, et al. "Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America clinical practice guidelines: treatment of drug-susceptible tuberculosis." *Clinical Infectious Diseases* 63.7 (2016): e147-e195. <https://academic.oup.com/cid/article/63/7/e147/2196792>
5. Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(RR-6): 1-51. <https://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf>
6. Centers for Disease Control and Prevention. Guidelines for the investigation of contacts of persons with infectious tuberculosis; recommendations from the National Tuberculosis Controllers Association and CDC, and Guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR* 2005;54(No. RR-15): 1-47. <https://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>
7. US Preventive Services Task Force. Screening for latent tuberculosis infection in adults: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;316(9):962–969. DOI: <http://dx.doi.org/10.1001/jama.2016.11046>

8. Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis screening, testing, and treatment of U.S. health care personnel: recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal Wkly Rep 2019;68:439–443. DOI: <http://dx.doi.org/10.15585/mmwr.mm6819a3>

*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, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##