

PUBLIC HEALTH ADVISORY

NATIONWIDE SHORTAGE OF TUBERCULIN TEST ANTIGENS: CDC RECOMMENDATIONS FOR PATIENT CARE AND PUBLIC HEALTH PRACTICE AUGUST 5, 2019

Background

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 time frame 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>.

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. Please note that the TB skin test is the preferred test method for children under five years of age.

- 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 Riverside County TB Control. Prioritization might require the deferment of testing some persons. CDC recommends testing only for persons who are at risk of TB. 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 five, 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. Clinicians should assess test results based on the person's likelihood of infection and risk of progression to TB disease, if infected.

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. Although CDC does not recommend annual TB testing of health care, personnel unless there is a known exposure or ongoing transmission, health care facilities must adhere to CalOSHA Title 8 requirements.

Contact Barbara Cole at (951) 358-5107 or bcole@ruhealth.org for questions related to this advisory.

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