



CDC Recommendations – Nationwide Shortage of Tuberculin Skin Test Antigens

The manufacturer of APLISOL® notified the Centers for Disease Control and Prevention that they expect a nationwide shortage of the 5 ml tests beginning June 2019, and of the 1 ml tests by November 2019. APLISOL® is one of two PPD tuberculin antigens licensed by the Food and Drug Administration for performing tuberculin skin tests.

CDC Recommendations

The CDC has released [recommendations](#) for continued TB testing during the shortage of APLISOL® as well as approaches to prevent a decrease in TB testing capabilities:

- Substitute interferon-gamma release (IGRA) blood tests.
- Substitute TUBERSOL® for APLISOL® for skin testing.
- Prioritize allocation of TSTs.

The CDC recommends using TSTs only for those who are at risk of tuberculosis.

Those high-risk groups include:

- those with recent exposure to a person with tuberculosis;
- people born in or with recent travel to countries where tuberculosis is common;
- people living in (or who recently lived in) large group settings;
- those with health conditions or who are taking medications that alter immunity; and
- children, particularly those under the age of 5, if they are in one of the risk groups listed above.

In settings with a low chance of TB exposure, consider the deferment of routine serial TSTs (in consultation with public health and occupational health authorities).

The CDC does not recommend annual TB testing of health care professionals unless there is known exposure or ongoing transmission of the disease in the facility. See the [CDC TB Guidelines page](#) for more information about their recommendations.

State Rules

The Texas Administrative Code (TAC)¹ requires nursing facilities to:

- conduct and document an annual review that assesses the facility's current risk classification according to CDC guidelines;
- screen all employees for TB before they provide services in the facility, according to CDC guidelines;
- require those who provide services under an outside contract to provide evidence of current TB screening; and
- screen all residents at the time of admission in accordance with the attending physician's recommendations and current CDC guidelines.

If an employee or contractor has been exposed to a communicable disease, the facility must conduct and document a reassessment of the risk classification. The facility must also conduct and document subsequent screening based on the reassessed risk classification. The facility must maintain the documentation of the response.

If the facility determines or suspects a resident has been exposed to a communicable disease or has a positive screening, the must respond according to current CDC guidelines and the attending physician's recommendations. The facility must maintain documentation of the response.

Federal Regulations

Federal regulations² at §483.80 (F880) require facilities to "establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections."

CMS notes in the Interpretive Guidance for F880 "A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms- MDROs) and communicable diseases such as tuberculosis and influenza. Appropriate resident tuberculosis screening should be performed based on state requirements." The Interpretive Guidance also addresses "Assessing risks for tuberculosis (TB) based on regional/community data and screening staff to the extent permitted under applicable federal guidelines and state law..."

¹ [Texas Administrative Code, Title 40, Part 1, Chapter 19, Subchapter O, §19.1601 Infection Control](#)

² [Centers for Medicare and Medicaid Services \(CMS\) State Operations Manual, Appendix PP](#)

§483.70(e) (F838) Facility Assessment requires each facility to conduct and document a facility-wide assessment to determine what resources are necessary to provide care for residents, during both day-to-day operations and in emergency situations. This includes an all-hazards approach that addresses not only a facility-based risk assessment, but also a community-based risk assessment. For example, is the facility in an area/community that has a high incidence of tuberculosis? That would impact the Facility Assessment and help guide the facility's screening processes.

Email questions related to LTC Regulatory nursing facility, policy or rule to policyrulestraining@hhsc.state.tx.us. Email questions related to evidence-based best practices for infection prevention and control programs to QMP@hhsc.state.tx.us.