

Recommendations for the Use of Tuberculin During the Nationwide Shortage -June 10, 2019

There currently is a nationwide shortage of tuberculin used for tuberculosis skin testing (TST). The shortage involves the commercial product: APLISOL® (JHP Pharmaceuticals, LLC) at this time, but based on previous experience of 2013, we expect the shortage to extend to TUBERSOL® (Sanofi Pasteur Limited) at some point in the near future due to demand. The duration of the shortage is unknown but is estimated to be three to ten months. This notice advises Kansas public health officials, clinicians, and workers in occupational health and infection control about how to adapt to the shortage. These recommendations are consistent with guidance from the Centers for Disease Control and Prevention (CDC) and are in effect until the tuberculin shortage resolves.

General Principles:

During the shortage, the Kansas Department of Health and Environment (KDHE) recommends that providers, local health departments, correctional facilities, and health care settings:

1. Do **NOT** administer TSTs to persons who have no risk factors for TB or to persons with a documented previous history of a positive TST or TB disease.
2. Substitute interferon gamma release assays (IGRAs) for TSTs when feasible. IGRAs can be used in most situations in which the TST is indicated and are preferred for people who have received BCG vaccine. QuantiFERON®-TB and T-SPOT®.TB have FDA approval for TB testing. IGRAs may not be available in all practice settings.
3. Temporarily defer TSTs for certain persons if tuberculin supply is low. The **highest priorities for tuberculin use are:**
 - a. Evaluating persons with suspected active TB disease,
 - b. TB contact investigations,
 - c. Evaluating newly-arrived refugees and “Class B” immigrants and refugees; however, IGRAs are being widely used for refugee screening in Kansas and are preferred for BCG-vaccinated persons, and
 - d. Persons at high risk of progressing to active TB, if infected (e.g., HIV+, age <5).
4. Continue to ensure that persons with symptoms of active TB disease receive immediate medical evaluation.
5. Follow the recommendations in the table below for institutional/provider TB testing.
6. Tuberculin may become available from some suppliers or in some areas sooner than others. Facilities should continue to periodically check with their suppliers so that they can obtain tuberculin and resume testing as soon as possible.
7. The option to purchase tuberculin from the KDHE TB Program will be suspended at least until the conclusion of the shortage to preserve available supply for the highest risk testing.

Recommendations for Prioritizing Tuberculin Use in Specific Settings		
Setting	Group	Recommendations
All Healthcare Facilities	Employees	<p>At time of hire: Conduct TB symptom screen. Use IGRA if available. If IGRA not available administer one TST and defer second step TST until tuberculin shortage resolves. If not able to obtain any tuberculin, defer both TSTs until shortage resolves.</p> <p>Annual re-testing: Conduct TB symptom screen. Use IGRA if available. If IGRA not available defer annual TST until shortage resolves.</p>
Correctional Facilities	Offenders	<p>At time of admission: Conduct TB symptom screen. Use IGRA if available. If IGRA not available administer one TST (county jails should postpone TST until day 11 or 12 of confinement). If tuberculin supply is low, defer second step TST until shortage resolves. If not able to obtain any tuberculin, defer both TSTs until shortage resolves.</p> <p>Annual re-testing: Conduct TB symptom screen. Use IGRA if available. If IGRA not available, defer annual TST until shortage resolves.</p> <p>Testing offenders is a higher priority than testing employees. If necessary, use limited supplies for testing offenders and defer employee testing until shortage resolves.</p>
Boarding Care/Nursing Homes / Addiction Treatment Facilities	Residents	<p>At time of admission: Conduct TB symptom screen. Use IGRA if available. If IGRA not available administer one TST and defer second step TST until shortage resolves. If not able to obtain any tuberculin, defer both TSTs until shortage resolves.</p>
Educational Settings	Post-Secondary Education Students	<p>At time of admission: Conduct TB symptom screen. Use IGRA if available. If IGRA not available administer one TST and defer second step TST until shortage resolves. If not able to obtain any tuberculin, defer both TSTs until shortage resolves.</p>
	Employees of Schools and Daycare	<p>Complete the <u>TB Symptom Screening Questionnaire</u> to determine if immediate further evaluation is needed. If there are no indications of tuberculosis signs and symptoms, this form may be used as documentation to meet the regulatory screening requirements and the tuberculin tests should be deferred at least three months or until the shortage is over.</p>
All Settings	Contact investigation	<p>Continue to use TST or IGRA to evaluate close contacts of persons with infectious (i.e., pulmonary or laryngeal) TB disease. Consult KDHE or local health department for guidance in identifying who should be included in contact testing.</p>
Public Health	Immigrant & refugee health assessments	<p>IGRA preferred. If not available, do one TST. Two-step TST testing is not indicated. Conduct TB symptom screen and other testing, as medically indicated.</p>

Questions should be directed to Kim Winans (Kimberly.d.winans@ks.gov), KDHE TB Nurse Consultant or Lisa Edgerton-Johnston (lisa.edgerton-johnston@ks.gov), KDHE Contact Investigation Coordinator and TB Education Specialist.

References:

Nationwide Shortage of Tuberculin Skin Test Antigens: CDC Recommendations for Patient Care and Public Health Practice
<https://emergency.cdc.gov/han/han00420.asp>

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 <https://academic.oup.com/cid/article/64/2/e1/2629583>