



TB Prevention and Control Program
Communicable Disease Prevention and Control
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[DPHHS Tuberculosis Program](#)

Recommendations for the Use of Tuberculin During the Nationwide Shortage – September 13, 2013

The Montana Department of Public Health & Human Services (DPHHS) issued a HAN on September 5, 2013 regarding the recurring nationwide shortage of tuberculin used for tuberculosis skin testing (TST). Refer to the HAN at the following link: <http://www.dphhs.mt.gov/publichealth/han/messages.shtml>.

The shortage involves both commercial products: TUBERSOL® (Sanofi Pasteur Limited) and APLISOL® (JHP Pharmaceuticals, LLC). The duration of the shortage is unknown but likely will be at least through October 2013. This notice advises Montana public health officials, clinicians, infection control practitioners, health-care facilities, administrators of high-risk settings, and administrators who must comply with existing Administrative Rules of Montana (ARM) on the screening of employees on adapting to the shortage. These recommendations are consistent with guidance from the Centers for Disease Control and Prevention (CDC) (1) and are in effect until the tuberculin shortage resolves and/or changes in ARM are in effect.

General Principles

During the tuberculin shortage, DPHHS recommends that local health departments, providers, correctional facilities, and health-care facilities adjust policies and compliance with ARMs as follows:

- 1) Substitute QuantiFERON®-TB Gold In-Tube (QFT-GIT) for TSTs when available. QFT-GIT can be used in most situations in which the TST is indicated. It is preferred for people who have received BCG vaccine (2, 3). The TST is still the preferred test for children under 5 years of age. QFT-GIT may not be available in all practice settings. The Montana Public Health Laboratory (MTPHL) does perform QFT-GIT testing. See the specimen collection and handling instructions from the MTPHL at the [DPHHS Tuberculosis Program](#) homepage. Additional resources on QFT-GIT are available from [QIAGEN](#), the manufacturer of QFT-GIT.
- 2) Public health departments and providers should allocate TSTs for priority situations and temporarily defer TSTs for certain persons and settings until the tuberculin supply is restored. **Table 1** (4) contains information on persons or groups who should be tested for latent TB infection. The highest priority is to test those at high risk for infection and/or progression to TB disease if infected. This approach will result in the deferment of testing of lower-risk individuals.
- 3) Follow the recommendations in **Table 2** for institutional TB testing either required by ARM or because of national, state, or institutional policy. The Montana TB Program previously developed TB

Risk Assessments for licensed health-care facilities (HCF), which can be found at the [DPHHS Tuberculosis Program](#) homepage. If HCFs have not completed a recent TB risk assessment, this should be completed now. Most HCFs in Montana are low risk for TB and will be able to eliminate annual TB testing for most employees upon completing the risk assessment and updating written TB screening policies that reflect the risk assessment outcome. The Montana TB Program has verified with the DPHHS Licensure Bureau that these recommendations will be taken into account when inspecting facilities during this nationwide shortage of tuberculin.

4) Tuberculin may become available from some suppliers or in some areas sooner than others. Public health and health-care facilities should continue to periodically check with suppliers or directly with the manufacturers to see if tuberculin is again available and complete deferred testing as soon as possible.

5) Continue to ensure that persons with symptoms of active TB disease receive immediate medical evaluation.

6) 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.

Table 1. Persons or Groups Who Should be Tested for Latent TB Infection

Persons at Increased Risk for Being Recently Infected	Conditions that Increase the Risk of Progression from LTBI to TB Disease
<ul style="list-style-type: none"> • Close contacts of a person with infectious, pulmonary TB • Persons who have immigrated from areas of the world with high rates of TB • Children and adolescents < 18 years of age who have one or more positive responses to the risk assessment (Box 1) (5) • Groups with high rates of <i>M. tuberculosis</i> transmission as locally defined, such as homeless persons, drug users, and persons with HIV infection • Persons who work or reside with people who are at high risk for TB in facilities or institutions such as correctional facilities, homeless shelters, and some health-care facilities • Mycobacteriology laboratorians (in facilities that perform TB smears and cultures) 	<ul style="list-style-type: none"> • HIV infection • Pulmonary fibrotic lesions on chest radiographs consistent with prior, healed TB • Diabetes mellitus (especially insulin-dependent) • Silicosis • Chronic renal failure/hemodialysis • Chronic immunosuppression, including transplant recipients and prolonged corticosteroid therapy (15 mg/day prednisone for 1 month) • Anti-Tumor Necrosis Factor-alpha agents • Other immunosuppressive therapy • Hematological malignancies (leukemia, lymphoma) • Cancer, particularly of the head, neck, or lung • Malnutrition and clinical situations associated with rapid weight loss • Chronic malabsorption • Low body weight (15% below ideal body weight) • Injection drug use

Table 2. DPHHS Testing Recommendations in Specific Settings

Setting	Recommendations
<p>Health Care Facility Employees ARM 37.106.313</p> <p>Long-Term Care Residents</p>	<p>At time of hire: Conduct TB symptom screen; if symptomatic for TB, get medical evaluation. Use QFT-GIT if available. If 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: Most HCFs in Montana are low-risk for TB and do not need to conduct annual testing of employees unless high-risk. See HCF risk assessments at the DPHHS Tuberculosis Program homepage. If annual testing is required due to risk, use QFT-GIT if available. If not available, administer TST. If unable to obtain any tuberculin, defer TST until tuberculin shortage resolves and screen for TB symptoms.</p> <p>At time of admission: Conduct TB symptom screen; if symptomatic for TB, get medical evaluation prior to admit. Use QFT-GIT if available. If 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. Note: For residents <18 years of age, one TST is adequate upon admission; 2-step testing is not needed or recommended.</p> <p>Annual re-testing: Most long-term HCFs in Montana are low-risk for TB and do not need to conduct annual testing of residents unless high-risk. See HCF risk assessments at the DPHHS Tuberculosis Program homepage. If annual testing is required due to risk, use QFT-GIT if available. If not available, administer TST. If unable to obtain any tuberculin, defer TST until tuberculin shortage resolves and screen for TB symptoms.</p>
<p>School Employees / Daycare Providers ARM 37.114.1010</p>	<p>At time of hire: Defer testing until shortage resolves. Employees with TB symptoms should receive a medical evaluation prior to beginning work.</p>
<p>Correctional Facility Inmates</p> <p>Employees</p>	<p>At time of admission: Conduct TB symptom screen. Use QFT-GIT if available. If not available, administer one TST (short-term jails should only test those who are expected to be held at least 1 week). 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 QFT-GIT if available. If not available, administer TST. If not able to obtain any tuberculin, defer annual TST until shortage resolves and conduct TB symptom screen. If symptomatic for TB, obtain medical evaluation.</p> <p>Testing inmates is a higher priority than testing employees. If necessary, use limited supplies for testing inmates and defer employee testing until shortage resolves.</p> <p>At time of hire: Conduct TB symptom screen. Use QFT-GIT if available. If QFT-GIT is not available, administer one TST and defer second step TST until tuberculin shortage resolves. If unable to obtain any tuberculin, defer both TSTs until shortage resolves.</p> <p>Annual re-testing: Conduct TB symptom screen. Use QFT-GIT if available. If not available, defer annual TST until shortage resolves.</p>

Box 1. TB Risk Assessment Questions for Children

- 1) Has a family member or contact had TB disease?
- 2) Has a family member had a positive TST or QFT-GIT result?
- 3) Was your child born in a high-risk country (countries other than the United States, Canada, Australia, New Zealand, or Western and North European countries)?
- 4) Has your child traveled (had contact with resident populations) to a high-risk country for more than 1 week?

References:

1. CDC. Nationwide Shortage of Tuberculin Skin Test Antigens: CDC Recommendations for Patient Care and Public Health Practice. Health Alert Network message issued September 4, 2013. <http://emergency.cdc.gov/HAN/han00355.asp>
2. 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>.
3. CDC. Interferon-Gamma Release Assays (IGRAs) - Blood Tests for TB Infection (fact sheet). <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm>.
4. CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR 2000; 49(No. RR-6). <http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf>
5. American Academy of Pediatrics, Red Book: 2012 Report of the Committee on Infectious Disease. Pickering LK, 29th ed. Elk Grove Village, IL.