

***Maryland Recommendations Regarding the National Shortage of Purified Protein Derivative (PPD) Solution; Attachment to Health Officer Memorandum National Shortages of Tubersol® and Aplisol® for TB Skin Testing; April 2013***

These recommendations will remain in effect until the national shortage of PPD solution has abated.

**Highest Priority for Testing:**

- Persons suspected of having active TB disease.
- High-risk contacts to confirmed TB cases.
- Persons at high risk of developing active TB if infected (i.e., newly HIV infected individuals and children ≤ 4 years of age).

**Alternatives to Tubersol®:**

- Aplisol® may be used for TB skin testing (TST) in lieu of Tubersol® and is placed, read and interpreted the same way. CDC, in evaluating studies of both products, has determined that either is acceptable to use for screening purposes. It is recommended the same product be used consistently (i.e., do not switch products in the middle of a 2-step TST). The Heartland TB Regional Training and Medical Consultation Center has compiled a summary of the research and frequently asked questions (FAQs) regarding the two different PPD solutions ([http://www.heartlandntbc.org/goi/goi\\_aplisol\\_and\\_tubersol.pdf](http://www.heartlandntbc.org/goi/goi_aplisol_and_tubersol.pdf)).

**Available alternatives to either Tubersol® or Aplisol®:**

- Two Interferon gamma release assays (IGRA) are available for use in the United States; QuantiFERON –TB Gold InTube (QFT)® (Cellestis Quiagen) and T-Spot.TB® (Oxford Immunotec). Both IGRA tests are considered acceptable to use in place of either PPD product. The IGRA is a laboratory test and users need to interpret test results based on instructions from the manufacturer. Improper handling of the blood tubes for both IGRA products can affect the results reported, so staff should be fully trained before using.
  - IGRAs are more expensive than PPD solution but do not require repeat clinic visits by patients. Medicaid does cover the cost of IGRA testing for many eligible patients. Some private insurers will cover IGRA testing, but not all. Providers should check with the insurer.
  - A limited number of local health departments in Maryland are using IGRA tests, but the use is restricted. Private providers should not refer individuals to the local health departments for IGRA testing without checking with the local TB program first.

**Employee Screening (hospitals, nursing homes and other congregate settings):**

- **Current employees** may have serial annual testing deferred until the national shortage has resolved (currently expected to be mid-to late summer). If the institution's annual risk assessment indicates the entire facility or portions of the facility qualify as "low-risk", screening for signs/symptoms of TB may be done and documented in lieu of immediate testing on those employees considered at risk for TB exposure. IGRA tests may also be used, but institutions need to be aware that switching back and forth between TST and IGRA tests

is not recommended. For information on facility risk assessments, see the CDC's Centers for Disease Control and Prevention **Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005**, at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf> .

The DHMH Center for TB Control and Prevention (410-767-6698) and Dr. Brenda Roup, Nurse Consultant in Infection Prevention and Control for DHMH (410-767-6704) are available for consultation. Local health department TB Control programs are also available for consultation.

- **New employees** should continue to have either 2-step TST or an IGRA done as part of the hiring process if possible. A new employee who has documentation of a recent negative 2-step or negative IGRA test within the previous 12 months, has no signs or symptoms of TB, and is otherwise not at high risk for TB may have initial testing deferred. A review of TB risk factors and the signs/symptoms of TB should be documented in the employee's record with a copy of the approved documentation indicating prior testing.
- **Volunteers** in hospitals, nursing homes and other health care settings are also frequently included in TB screening programs that require serial testing. Volunteers who have documentation of previous TST or IGRA may have annual testing deferred until PPD solution supplies are more stable. New volunteers may have testing deferred, as with new employees, if working in a documented low risk setting.

**Correctional facilities:**

- Detention centers, local jails and prisons should discuss serial testing of employees and inmates with appropriate administrations and oversight agencies. The feasibility of deferring annual screening for a period of time on current employees should be discussed based on the risk assessment presented by the particular facility. Providing IGRA testing for employees in extremely high risk facilities is also an option. Maryland has reported 0-6 TB cases per year for all correctional facilities in the state over the past 5 years, accounting for  $\leq 3\%$  or less of the total number of annual cases reported.
- Recommendations developed and issued by the National Tuberculosis Coordinators Association/ National Tuberculosis Nurse Coalition Corrections Workgroup are summarized in the table below and may be shared with local correctional institutions.

### Recommendations for Responding to Tuberculin Shortages

- Prioritize TSTs for screening inmates at intake:
  - As part of an evaluation of persons with symptoms suggestive of TB disease,
  - Persons infected with HIV,
  - Contacts to a person with pulmonary or laryngeal TB,
  - Persons arrived from high TB incidence countries within the past year,
  - And, prior to transfer to another facility (those who are due for an annual TST)
- Consider deferring annual screening of employees and inmates—other than priority candidates listed above—unless sufficient tuberculin is available.
- Consider alternative screening tests such as an Interferon Gamma Release Assay (IGRA)—blood tests for TB infection (T-SPOT.*TB* and QuantiFERON®—GIT) or chest X-ray.

National Tuberculosis Coordinators Association/ National Tuberculosis Nurse Coalition Corrections Workgroup\_01/24/2013

#### Testing for School or Work:

- Individuals should have testing deferred if possible, or be referred for IGRA testing.

#### Refugee and Immigrant Health Screening:

- IGRA testing is preferred for foreign-born individuals who have been vaccinated previously with BCG. Refugee Medical Assistance will support the cost of this testing through a private laboratory.
- Migrant workers without access to insurance should be screened for signs and symptoms of TB on hire. Employers of large numbers of migrant workers (i.e., poultry processing plants, large scale nursery operations) should consult with their local health department regarding annual and/or new hire TB testing requirements. IGRA tests are an option.

#### Employees of Local Health Departments and other Community Based Health Centers:

- Serial testing of employees should be limited to those in HIV, STI and TB clinics only. IGRA testing is an option. Other employees should have testing deferred. Documentation of an annual review of TB risks and signs/symptoms of TB may be an option for low risk employees.
- New employees should continue to have either 2-step TST or an IGRA done as part of the hiring process if possible. A new employee who has documentation of a negative 2-step or negative IGRA test within the previous 12 months, has no signs or symptoms of TB, and is otherwise not at high risk for TB may have initial testing deferred.

**Summary Tables for Assessment of TB Infection Risk, Risk of Developing TB if Infected and Signs/Symptoms of Active TB Disease:**

**TB Infection Risk**

- Current high risk contact of a person known or suspected to have TB
- Has been in another country where TB is common for  $\geq 3$  months
- Infant, child or adolescent exposed to an adult(s) from high-risk category
- Requires baseline/annual screening due to HIV status or other disease risk
- Moved to US from country where TB is common has been in the US for  $< 5$  years
- Resident or employee of a high TB risk congregate setting
- Healthcare worker who serves high-risk clients
- Homeless within the past two years
- Injects illicit drugs or uses crack cocaine
- Medically underserved

**High Risk for Developing TB Disease if Infected**

- Recent arrived in US ( $\leq 2$  years)
- HIV positive
- Contact to known TB case or recently infected
- infant or child  $<$  one year of age
- Risk for HIV infection, but HIV status is unknown
- Illicit drug use
- History of inadequately treated TB

Active TB Signs/Symptoms	
<ul style="list-style-type: none"> <li>● Cough for &gt; 2 weeks</li> <li>● Hemoptysis</li> <li>● Fever, unexplained</li> <li>● Unexplained weight loss</li> <li>● Fatigue *</li> <li>● Poor appetite *</li> <li>● Night sweats *</li> </ul> <p>* evaluate in context of other individual characteristics, health concerns, prior history of TB evaluation and/or treatment</p>	<p><b>Pediatric patients (&lt; 6 years of age) also evaluate for:</b></p> <ul style="list-style-type: none"> <li>● Wheezing</li> <li>● Failure to Thrive</li> <li>● Decreased activity, playfulness, and/or energy</li> <li>● Changes in personality, e.g., ↑ irritability</li> <li>● Lymph node swelling</li> </ul>

#### References:

- **CDC Health Alert Network (HAN):** *Nationwide Shortage of Tuberculin Skin Test Antigens: CDC Recommendations for Patient Care and Public Health Practice;* <http://emergency.cdc.gov/HAN/han00345.asp>
- For information on **facility risk assessments** see the CDC's Centers for Disease Control and Prevention, **Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.** *MMWR 2005; 54(No. RR-17)*, <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf> .
- For general questions please contact the following:
  - Local health department TB Control Coordinator
  - Maryland Department of Health and Mental Hygiene Center for TB Control and Prevention (410-767-6698)
  - Maryland Department of Health and Mental Hygiene Nurse Consultant in Infection Prevention and Control, Dr. Brenda Roup, (410-767-6704)