



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
William A. Hinton State Laboratory Institute
305 South Street, Jamaica Plain, MA 02130

DEVAL L. PATRICK
GOVERNOR

JOHN W. POLANOWICZ
SECRETARY

CHERYL BARTLETT, RN
COMMISSIONER

Bureau of Infectious Disease
Division of TB Prevention and Control
Tel: (617) 983-6970
Fax: (617) 983-6990
www.mass.gov/dph/cdc/tb

ADVISORY:

NATIONWIDE SHORTAGE OF TUBERCULIN SKIN TEST ANTIGENS: RECOMMENDATIONS FOR
PATIENT CARE AND OCCUPATIONAL HEALTH TESTING

Updated August 27, 2013

The Massachusetts Department of Public Health (DPH) has been made aware of a current national shortage of TUBERSOL[®], one of two purified-protein derivative (PPD) tuberculin products licensed by the U.S. Food and Drug Administration (FDA) for detecting TB infection. Limited availability of this reagent was announced recently by its manufacturer and this may last for an undetermined period of time.

The FDA has also been notified by the manufacturer of APLISOL[®], the other PPD tuberculin product licensed by the FDA, that this product is available in restricted quantity. Shortages of both TUBERSOL[®] and APLISOL[®] are being reported.

In an attempt to help providers and public health programs that currently use TUBERSOL[®] manage this situation, CDC has issued a statement that suggests several operational strategies [available at <http://emergency.cdc.gov/HAN/han00345.asp>]. CDC notes that switching products or methods might make serial changes in test results difficult to interpret: the apparent conversions of results from negative to positive or reversions from positive to negative could be caused by inherent inter-product or inter-method discordance.

Notwithstanding CDC's guidance, DPH recommends:

1. Substituting interferon gamma release assay (IGRA) blood tests for tuberculin skin tests (TST). (Note that TST is still the preferable test for children under 5 years of age.)
2. Avoid switching from one PPD tuberculin product to the other for serial testing if one product has been established in your practice, except in the case of new patients and for future/serial testing of those particular individuals.
3. Avoid switching from TST to IGRA for serial testing situations, such as occupational health testing programs.
4. Defer routine skin testing of persons in settings with low risk for exposure until TUBERSOL[®] availability is restored.

MDPH has a limited supply of TUBERSOL[®] that is designated for high-risk situations (*e.g.*, contact investigations; high risk immigrant and refugee screening; testing of high risk children). State-supplied TUBERSOL[®] can be made available for high-risk situations on a case-by-case basis. If your situation meets the above criteria, or if you need to consult the Division of TB Prevention and Control regarding access to TUBERSOL[®], please call 617 983 6970.