OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

Recommendations for use of Purified Protein Derivative (PPD)
During Nationwide Shortage August 12, 2013

In April 2013, US Centers for Disease Control (CDC) issued an informational notification via the Health Alert Network (HAN) regarding nationwide shortages of **Tubersol®** (Sanofi Pasteur Limited) and **Aplisol®** (JHP Pharmaceuticals, LLC).

Tubersol and Aplisol, the only US Food and Drug Administration approved purified protein derivative (PPD) solutions for use in tuberculin skin testing (TST). At that time, it was anticipated that the shortages would be mitigated in June (and end shortly thereafter) when normal Tubersol production was expected to resume. However, over the last few weeks, the Ohio Department of Health (ODH) and other states have received reports of difficulties obtaining both Tubersol and Aplisol.

Information obtained by ODH and other states indicate the 50-test preparation may not be available and the 10-test preparation may only be available in limited supply leading to restricted allocations on customer orders by the supplier. The current projection for restoration of normal production of Tubersol is currently unknown. While we are not aware of any problems with Aplisol production, the shortage of Tubersol has resulted in increased demand for Aplisol, resulting in shortages of both PPD solutions.

As long as the shortages persist, ODH recommends following guidance published earlier this year by the Centers for Disease Control and Prevention (CDC), initially disseminated via HAN (and MMWR article, April 26, 2013/62(16);312-312)

1. Substitute interferon-gamma release assay (IGRA) blood tests for TSTs. The costs associated with using the blood tests can be greater than the cost of TSTs. The blood tests require phlebotomy, preparation of blood specimens, and specific laboratory services for analysis. Thus, these tests are not available in all practice settings. Clinicians who use the IGRA blood tests should be aware that the criteria for test interpretation are different than the criteria for interpreting TSTs.

2. Allocate TSTs to priority indications, such as TB contact investigations, as determined by public health authorities. This might require deferment of testing some persons. CDC does not recommend testing persons who are not at risk of TB.

3. Substitute APLISOL® for TUBERSOL® for skin testing. In crosssectional studies, the two products give similar results for most patients. Shortages of APLISOL® are expected to become more widespread, thus limiting the feasibility of this approach.

Note: Some surveillance programs for TB infection control rely on routine serial TSTs. 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. In settings with a low likelihood of TB exposure, the deferment of routine serial testing should be considered in consultation with public health and occupational health authorities.

References

1. CDC. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection—United States, 2010. MMWR 2010;59(No. RR-5).
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3. CDC. Treatment of tuberculosis. MMWR 2003;52(No. RR-11).
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5. CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR 2005;54(No. RR-17).