

August 8, 2013

The Michigan Department of Community Health Tuberculosis Control Program has learned of a renewed national shortage of Tubersol PPD reagent. The FDA has approved two reagents for tuberculin skin testing: Tubersol and Aplisol. Sanofi Pasteur, manufacturer of Tubersol, has confirmed they are experiencing a manufacturing delay and cannot supply Tubersol adequately to meet demand. JHP Pharmaceuticals, manufacturer of Aplisol, confirms they are manufacturing Aplisol at normal quantity but due to increased demand they are allocating the release of Aplisol.

In response to this renewed shortage of Tubersol and projected limited availability of Aplisol, we are recommending the following strategies:

1. Substitute interferon gamma release assay (blood tests) for tuberculin skin tests if possible. Two platforms for blood tests are available: QuantiFERON-TB Gold In-Tube and T-SPOT.TB. Information for QuantiFERON-TB Gold In-Tube is available at:

<http://www.questdiagnostics.com/home/physicians/testing-services/by-test-name/quantiferon.html>.

Information for T-SPOT.TB is available at:

http://www.oxfordimmunotec.com/North_America.

2. Allocate tuberculin skin tests to priority situations such as TB contact investigations, and to individuals at high risk of being exposed to TB or of progressing from TB infection to disease. Examples include children under 5, HIV-positive individuals, individuals with present or recent history of substance abuse, or persons recently arrived from high-burden countries.

We will provide updates as soon as additional information is available.

Michigan Health Alert Network