COMMONWEALTH of VIRGINIA
Department of Health

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Dear Colleague,

Many of you may have recently received a Health Advisory from the Centers for Disease Control and Prevention (CDC) concerning the **nationwide shortages of tuberculin skin test (TST) antigen solutions.** Two brands of TST solution are distributed in the United States: Tubersol and Aplisol. Tubersol is in short supply for the second time this year, which is creating an increased demand for Aplisol and, in some areas, resulting in difficulty obtaining either product.

There are currently two methods available to determine the presence of tuberculosis (TB) infection: the traditional Mantoux TST using one of the TST antigens and an interferon gamma release assay (IGRA) blood test. The two FDA-approved IGRAs available for use in the United States are QuantiFERON Gold IN-Tube and T-SPOT-TB. Additional information on the use of IGRAs for determining the presence of TB infection can be found on the CDC web site at http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf.

CDC's key recommendations during this TST antigen shortage are as follows:

1.) Substitute an IGRA blood test for a TST.
2.) Substitute Aplisol for Tubersol, if available.
3.) Allocate use of TST antigens to priority uses such as TB contact investigations.
4.) Defer serial testing by TST for infection control in settings with a low likelihood of TB exposure. The CDC recommends consultation with public health and occupational health authorities prior to implementing this approach.

Currently, the Virginia Department of Health (VDH) recommendations for clinicians and local health departments include:

- **Carefully screen individuals for their risk factors to determine if testing for TB infection is indicated.** For individuals not entering a health care or correctional environment that requires testing as part of an infection control program, VDH's standard of practice is to assess each individual to determine if risk factors are present for acquiring TB infection or progressing to active TB disease, once infected.
    - Individuals with an identified risk factor are tested with a TST or IGRA.
    - **Individuals without an identified risk factor are provided a clearance letter stating that the individual has been evaluated and cleared of active TB in a communicable form.**

  This practice is consistent with published CDC guidance, which can be found online. Clinicians and facilities may adapt the following VDH documents for their own use. The VDH tool to assess individual risk, instructions for its use and a sample clearance statement can be found online.

- **For health care-related settings with an annual serial testing program, carefully evaluate current TB transmission risk and infection control policies and practices to determine if annual serial testing continues to be warranted.** CDC guidelines (2005) recommend that all health care settings conduct an initial and ongoing evaluation of the potential risk for transmission within their settings. This risk

assessment determines the types of administrative, environmental, and respiratory protection controls needed, including the frequency of testing for TB infection. For settings identified as low risk, only baseline testing is required; subsequent testing is only required in the event of a known exposure. The CDC guidelines can be found at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

- **Continue to perform baseline testing in health care settings and correctional facilities for new hires and for new admissions to long-term residence.** Use of an IGRA for this purpose is recommended. If TST antigen is used, 2-step baseline testing is required.

- **For facilities (such as health care settings and correctional facilities) with risk factors that necessitate continued serial testing, defer annual serial testing by TST until supplies of TST antigens return to normal.** For those programs utilizing IGRA tests as their test of choice, testing should continue as normal.

- **Reserve TST antigens for priority activities such as the investigation of individuals suspected to have active TB, the evaluation of those exposed to an active TB case, and children under 5 years of age who require testing.**

As always, local health district TB Control programs across Virginia are a resource for consultation on the evaluation and treatment of patients with TB diagnoses as well as infection control policies and practices. Contact information for local health districts throughout Virginia can be found at www.vdh.virginia.gov/LHD/index.htm. Assistance also is available through the state TB Control program at 804-864-7906.

Thank you for your ongoing efforts to diagnose and report suspected active TB and to evaluate and treat your patients with latent TB infection. In 2012, Virginia reported 235 TB cases, an increase from the 221 cases reported in 2011. While Virginia's rate of 2.9 cases of active TB per 100,000 population was below the national rate of 3.2 cases per 100,000, Virginia ranked 8th in the nation based on the number of cases. In 2012, 183 or 78% of Virginia's TB cases were reported among foreign-born persons. Thirteen pediatric cases, aged 0 to 14 were reported in 2012 as compared to 8 cases in 2011. Resistance to one or more first-line drugs, most frequently isoniazid, was present in 24 cases: five cases had evidence of multi-drug resistance.

TB remains a public health challenge in Virginia and your efforts to prioritize the use of TST antigens during this shortage will help us preserve the supply for evaluating those at highest risk for TB infection and progression to active disease.

Sincerely,

Cynthia C. Romero, MD, FAFP
Virginia State Health Commissioner