

**Virginia Department of Health
Division of Disease Prevention, Tuberculosis Control & Prevention**

Guidance for Use of Purified Protein Derivative (PPD) Solution during the National Shortage

As you are aware, the TB Program and State Pharmacy have been monitoring a national shortage of Tubersol PPD solution used for tuberculin skin testing (TST). As the supply of Tubersol has decreased nationally, pressure has increased on the supply of the alternative product, Aplisol. At this time there is a shortage of all brands of PPD solution nationwide. Currently the Virginia State Pharmacy has a limited supply of PPD solution.

To ensure that PPD is reserved for the highest priority testing activities, the following guidance has been developed for use by local health districts:

General

1. If you have opened bottles of PPD solution that will expire 30 days after opening, please use the product so that it is not wasted even if this testing does not fall within the current use restrictions.

Cases/Suspects

1. Either an IGRA or TST may be used as part of the diagnostic work-up for persons being evaluated for active TB disease.

Contacts

1. **Contacts over the age of 5 years should be tested using a T-SPOT.TB blood test, except in those rare situations where it is impossible to draw blood on a client.**
 - a. In order to assist districts with the increased cost of using T-SPOT.TB for contact investigation (instead of performing a TST), the **TB Program will cover the cost of T-SPOT.TB testing for contacts until the supply of PPD normalizes or until the end of the fiscal year.** If the shortage persists, additional guidance will be provided.
 - b. Further information on the process for obtaining TB Program cost coverage for contact evaluation using the T-SPOT.TB test will be forwarded to districts in the next few days.
 - c. To assure that the “worried well” and lower priority contacts are not tested using the more expensive T-SPOT.TB, the TB Program must be advised of the investigation plan, including anticipated numbers before testing begins.
2. **For Contacts Age 12 and Under** – All children under age 5 need to be screened using a TST as IGRAs are not approved for this population. For contacts ages 5-12, districts may opt to use either a TST or an IGRA. This will assist in reducing the difficulties associated with drawing blood in younger children.
3. **For Contact Investigations in Progress** - For contact investigation in progress where a 1st round of testing has been completed, as supplies permit, use the same test material (Tubersol or Aplisol) for the 2nd contact evaluation as was used for the initial testing. There are minor difference between the products that could affect the outcome of the investigations and falsely skew the number of conversions. For this reason the same type of PPD should be used for both rounds of testing, if possible. Also tuberculin skin tests (TST) and Interferon Gamma Release Assays (IGRA: T-SPOT.TB, QuantiFERON) work on slightly different sections of the immune

system. This is why the CDC IGRA guidance recommends not switching between methods when doing serial TB infection testing as the different methods can produce discordant results.

- a. The pharmacy will immediately begin filling all orders for PPD solution with Aplisol. The remaining doses of Tubersol will be reserved for use in 2nd round contact evaluation. Districts will need to alert the Pharmacy that they need Tubersol for a contact investigation to access this supply.
- b. Although no one district has a huge supply of Tubersol, there are unopened vials scattered throughout the state. If needed for 2nd round testing we may need to share this supply of Tubersol with other districts. The transferred PPD supply will be replaced with Aplisol.

Refugees

1. All refugees 5 and over should be screened using an IGRA. Refugee children under age 5 receiving an initial refugee assessment should receive a TST. The Newcomer Health Program will reimburse the cost of the IGRA through their normal billing procedures.

Testing Children in Immunization Clinics

1. Children presenting to Immunization Clinics who are required to have TB screening can be screened using a risk assessment, tuberculin skin test or IGRA. Districts should use discretion and evaluate to determine if the testing can be deferred until the supply of PPD solution normalizes, i.e. those for September school admission.

Classified Immigrants

1. For TB Classified Immigrants who are required to follow-up with local health department due to overseas findings, perform an IGRA as part of their US assessment, if age appropriate (≥ 5 years of age). Follow the earlier instructions for contacts to bill the cost of the IGRA to TB Control.

Others

1. Testing for purposes other than contact evaluation should be by T-SPOT.*TB* only and at the client expense, with the exception of those that can be billed to the Refugee Program. If a district chooses to provide testing for purposes other than contact evaluation using a sliding scale fee, the TB Program will not provide reimbursement.