

ODP Responds to Nationwide Shortage of Tuberculin Skin Test Antigen **REISSUE**

ODP Announcement 19-111

AUDIENCE:

Licensed residential and day-services providers and other interested parties

PURPOSE:

The purpose of this announcement is to notify providers of a tuberculin skin test antigen shortage, offer suggested alternatives to the test, and present ODP's expectations for regulatory compliance during the shortage.

BACKGROUND:

The Centers for Disease Control and Prevention (CDC) has announced a nationwide shortage of tuberculin skin test antigens. The shortage is expected to last for 3 to 10 months. This shortage has the potential to lead to regulatory noncompliance for those providers required by regulation to obtain tuberculous skin tests for individuals and staff. More information about the shortage can be found at <https://www.health.pa.gov/topics/Documents/HAN/2019-PAHAN-448-06-07-ADV-TB.pdf>.

DISCUSSION:

Substituting Interferon Gamma Release Assay (IGRA) blood tests such as T-SPOT.TB or QuantiFERON Gold-Plus fulfills state screening requirements for tuberculin skin test screening.

In situations where an IGRA is not available or not recommended by a health care practitioner, the CDC acknowledges the need to prioritize allocation of tuberculin skin tests those at high risk for infection. The CDC recognizes that prioritization might require

the deferment of testing some persons. The CDC indicates that high-risk groups for infection include:

- People who are recent contacts exposed to persons with TB disease;
- People born in or who frequently travel to countries where TB disease is common;
- People who currently or used to live in large group settings, such as homeless shelters or correctional facilities;
- People with weaker immune systems, such as those with certain health conditions or taking certain medications that may alter immunity; and
- Children, especially those under age 5, if they are in one of the risk groups noted above.

MAINTAINING REGULATORY COMPLIANCE

During the shortage period, ODP will not consider failure to obtain a TB skin test for individuals or staff to be a violation provided that the provider:

- Attempts to obtain a TB skin test for all individuals and staff as required by the applicable regulation;
- Documents that attempts were made to obtain a TB skin test but were unsuccessful due to the antigen shortage; and
- Obtains an IGRA for anyone identified by the CDC as “high-risk” when a TB skin test is not available.

CONTACT:

Please contact the ODP Regulatory Administration Unit at RA-odplicensing@pa.gov with any questions about this announcement.