COMPONENT B: Testing



This resource provides an overview of diagnostic tests for TB infection for clinical and non-clinical staff from agencies in Massachusetts that provide latent TB infection services. It includes links to tools and resources, and provides answers to questions, including:

- What is the purpose of a TB test?
- What TB tests are available and how do they work?
- Where can I find more information on testing for TB infection?
- What are the next steps after TB testing is completed?
- What messages should I give to individuals about testing for TB infection?
- What data considerations should I be aware for testing individuals for TB?

What is the purpose of a TB test?

A tuberculosis (TB) diagnostic test is done to determine whether or not a person has TB infection. The Massachusetts Department of Public Health (MDPH) recommends only doing TB tests for people determined to be at increased risk of having TB infection. Your agency should first assess the individual's risk (see <u>Fact Sheet</u>, <u>Component A: Risk Assessment</u>). For individuals found to be at increased risk, your agency can administer one of two types of diagnostic tests: (1) a TB blood test or (2) a tuberculin skin test.

These TB tests help inform the clinician whether an individual likely has TB infection or not. However, additional evaluation is needed to determine whether the infection is latent or active. Therefore, for individuals with a positive test result, your agency's next step will be to ensure they are evaluated by a clinician to distinguish between latent TB infection and active TB disease (see <u>Fact Sheet, Component C: Evaluation</u>). This Fact Sheet describes the tests used to diagnose TB infection and information on next steps, communicating with individuals, and data considerations related to the TB test. The Fact Sheet also describes where to find more detailed information.





What tests for TB infection are available?

As described above, there are two types of diagnostic tests: (1) a TB blood test or (2) a tuberculin skin test (TST). The following is a summary of key information on the TB blood test and the TST from MDPH and the Centers for Disease Control and Prevention (CDC):

- TB blood test (Interferon-Gamma Release Assay IGRA)
 - The TB blood test uses a blood sample to diagnose TB infection.
 - Only one visit is required to draw blood for the IGRA test.
 - The test looks for the release of interferon-gamma, so it is known as an Interferon-Gamma Release Assay (IGRA). IGRA tests measure the response to TB proteins when they are mixed with a small amount of blood.
 - Production of interferon-gamma may be influenced by many factors. If test results are negative or borderline, but you still suspect TB infection based on other factors in the individual's history, the IGRA may be repeated.
 - IGRA tests are the preferred method of TB testing for people 2 years of age and older who have received the bacillus Calmette–Guérin (BCG) vaccine. The IGRA test does not react to BCG so therefore, BCG does not cause a false-positive result.
 - Two IGRA tests are approved by the Food and Drug Administration (FDA) for use in the United States: QuantiFERON®-TB Gold In-Tube PLUS (QFT-G) and T-SPOT®TB.
 - IGRA results are quantitative.
 - More information on IGRAs and when to use them can be found in the CDC's Fact Sheet on Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection
- Tuberculin skin test (TST)
 - To administer a TST, a health care provider injects a small amount (0.10ml) of testing fluid (called tuberculin or PPD, which stands for purified protein derivative) into the dermis of the skin on the lower part of the arm.
 - At 48-72 hours, the skin test reaction must be examined by a trained health care worker. The health care worker measures any swelling (induration) where the tuberculin was injected; the measurement is used to interpret if the reaction to the test is positive or negative.
 - Two formulations of PPD are available for skin testing: Tubersol® and Aplisol®.
 - TST is an acceptable alternative for any individual, regardless of BCG history, in situations where a TB blood test (IGRA) is not available, too costly, or otherwise not feasible.
 - More details on how to administer, read, and interpret a TST can be found in the CDC Fact Sheets on <u>Tuberculin Skin Testing</u>, and on <u>Targeted Tuberculosis Testing and Interpreting</u> <u>Tuberculin Skin Test Results</u>.

It is not usually recommended to test a person with both a TST and an IGRA. However, there are situations where conducting both tests may be useful. The table "Summary of TB diagnostic tests (IGRA and TST usage)" from MPDH's webpage on <u>Testing for Tuberculosis Infection: Guidelines on the Use of</u> <u>Interferon-Gamma Release Assays and the Tuberculin Skin Test in Massachusetts</u> has more information on those situations.

If a person previously had TB disease, they will continue to test positive for TB infection, even if they have completed treatment. For this reason, it is not recommended to test them again using either IGRA or TST. Similarly, if there is documentation that the individual had a positive TB test in the past, you should not re-test them for TB infection.



Where can I find more information on testing for TB infection?

The <u>MDPH web page on testing</u> for TB infection contains information from their 2018 guidance on testing, including the table mentioned above. The <u>MDPH web page on tuberculosis</u> has additional information and tools that your agency can refer to in planning and conducting TB activities. You can select the section on "<u>Tuberculosis information for health care providers and</u> <u>public health professionals</u>" which has several sub-sections, including one on "<u>Screening and</u> <u>Testing for TB infection</u>." Examples of helpful documents that can be found there include:

- Model Standing Orders for Tuberculin Skin Testing (updated annually)
- Policy for distribution of DPH-purchased PPD
- Booster or Recall Effect and Two-Stage Tuberculin Skin Testing.

The CDC updated their <u>Summary of U.S. Recommendations for Latent TB Infection Testing and</u> <u>Treatment</u> in 2020.

What are the next steps after TB testing is completed?

A positive reaction to IGRA or TST usually means the person has TB infection. To establish a diagnosis of latent TB infection or active TB disease, a person who has a positive IGRA or TST result requires further evaluation. The evaluation consists of a history and physical exam, chest X-ray, and possibly additional tests to rule out active TB disease (information on evaluation for TB disease is addressed in <u>Fact Sheet, Component C: Evaluation</u>).

If the medical exam and chest X-ray rule out active TB disease, the clinical team can make a diagnosis of latent TB infection.

If your agency does not conduct these evaluations on-site, your agency must link individuals with positive test results to clinics or providers that have the capacity to provide the evaluation. Facilities that provide these services with MDPH contractual support are <u>listed</u> on MDPH's <u>TB website</u>. However, there may be other facilities and providers (typically infectious disease specialists or pulmonologists) within your community who provide TB evaluation services. You should investigate resources within your community, identify these providers, and establish relationships with one or more clinics or providers to ensure that you are able to link individuals in need of evaluation services to a provider that is appropriate to address each individual's needs and circumstance.

If your agency has administered a TST or IGRA and the result was positive, you must provide documentation on the Integrated Testing Services Linkage form as soon as you receive a positive result. For questions on the ITLS Form, please reach out to the Office of Health Care Planning (OHCP) Monitoring and Evaluation (M&E) team at <u>BIDLS.OHCP@mass.gov</u>.



How should I communicate with individuals about testing for TB infection?

Key messages to be conveyed to individuals being tested for TB include:

All individuals getting a TB test:

- Please let the provider know if any of the following apply, since they may affect the provider's decision on whether to give you a TB test, what type of test to give, or how to interpret the test:
 - You have received the BCG vaccination
 - You previously had a "positive" reaction to a TB skin test or a TB blood test
 - You have previously been diagnosed with TB
 - You have previously been treated for TB
- This test is being done to see if you have TB infection.
- If the test is positive, we will help to connect you with a provider for further evaluation to know what next steps are.

Individuals tested using TST:

- After the test is administered, do not scratch the site or cover it with a bandage.
- You will need to return to the clinic in 48-72 hours to have the test read and recorded by a trained health care worker.
- The test can only be read by someone who is trained to do so.
- If the test is not read within 72 hours, you may need to be rescheduled for another TB skin test.



As with any health education session, it is best to approach this communication as a conversation with the individual and make sure there is time for them to ask questions. You should also check that they understand what you're telling them. Some approaches to do this include the <u>Teach-Back method</u>, and the <u>Ask Me 3 method</u>.

MDPH has more <u>resources for providing TB information to individuals</u> on their website, including resources in languages other than English. The CDC also has a number of <u>materials</u> <u>for communicating about TB to individuals and the general public</u>, some of which are available in languages other than English.



What data considerations should I be aware of for testing individuals for TB infection?

The table below includes the indicators that are considered key measures of performance of TB testing services. For each indicator, the table has information on whether the relevant data used to calculate the indicator are required to be reported to MDPH or recommended to be collected (but not reported to MDPH), as well as information on where to record these data. To learn more about collecting and reporting data, please review the <u>Component F Fact Sheet</u>: <u>Reporting and Analysis</u>.

Type of Indicator	Description of Indicator	Data for this indicator are <u>required</u> to be reported or are <u>recommended</u> to be collected?	How the data will be tracked
Process Indicator	# TB tests conducted	Required to be reported	Integrated Testing and Linkage to Services (ITLS)
Outcome Indicator	#/% Individuals tested for TB infection (among those at risk)	Required to be reported	ITLS
Outcome Indicator	#/% Individuals with positive TB test (among those tested)	Required to be reported	ITLS

For information about how to use process mapping to plan for and administer TB testing, please see the Fact Sheet on "Process Mapping for Latent TB Infection Services."

These Fact Sheets are intended to serve as a resource for agencies receiving funding from the Massachusetts Department of Public Health (MDPH), Bureau of Infectious Disease and Laboratory Sciences (BIDLS) to provide infectious disease services, including TB testing and latent TB infection services through the HIV/HCV/STI/TB Prevention, Linkage, and Retention in Care and Treatment Request for Response (DPH RFR Document Number: 181926).

