



POWERING AFFORDABLE CARE

by improving access to high quality TB blood testing for hospitals and health systems



The importance of TB testing for employee health

Hospitals and health systems play a crucial role in maintaining the health of their local communities. In order to care for others, employees must also be healthy. Comprehensive employee wellness programs—including pre-employment testing for various infectious diseases, like tuberculosis (TB)—are paramount to keeping front-line workers safe and helping to prevent community transmission.

TB remains a leading cause of infectious disease morbidity and mortality worldwide¹ and is an ongoing concern for employers managing the health of their employees. One study noted that the baseline prevalence of latent tuberculosis infection (LTBI) among healthcare workers screened for TB exposure was 14.6%—higher than the prevalence of LTBI in the local population, which was reported to be 12.7%.² The CDC recommends TB screening and testing of all US healthcare personnel upon hire as part of a TB Infection Control Plan.³

The advantages of blood vs skin prick TB testing

Traditional tuberculin skin tests (TSTs) are over a century old and feature some drawbacks from newer blood testing options, such as interferon-gamma release assays (IGRAs), that are more convenient, reliable, and effective for TB testing.

The TST has a sensitivity of 79% and specificity of 97%,⁴ with specificity being as low as 59% in bacillus Calmette-Guérin (BCG)-vaccinated patients. TSTs may be more likely to register a false-positive result in BCG-vaccinated individuals,⁵ and immunosuppressed people risk receiving false-negative results from TST.⁶

| | Blood test | TST |
|--|------------|-----|
| 1 test appointment vs 2 | ✓ | ✗ |
| Low false-positive rates compared to skin tests in BCG-vaccinated individuals ⁷ | ✓ | ✗ |
| Objective results Preferred by the CDC and other medical organizations for certain patient populations ⁶ | ✓ | ✗ |
| Not affected by BCG vaccine | ✓ | ✗ |
| Short- and long-term cost savings due to test efficiencies (one test appointment vs two, no follow-ups due to false positives, costs of missing LTBI) | ✓ | ✗ |
| Reduce screening appointments by 50% | ✓ | ✗ |

A more efficient way to test for TB: blood testing

Interferon-gamma release assays (IGRAs) are easy and convenient to perform and offer more accuracy in bacillus Calmette–Guérin (BCG)-vaccinated patients. IGRAs are preferred by the CDC for TB testing in most risk groups versus traditional tuberculin skin tests (TSTs).⁴ IGRAs are recommended in individuals 5 years or older who⁴:

- Are likely to be infected
- Have low or intermediate risk of disease progression
- It has been decided that testing for latent tuberculosis infection (LTBI) is warranted
- Have a history of BCG vaccination or are unlikely to return for their next visit

Accurate. Accessible. Efficient—TB blood testing from Quest Diagnostics

Quest Diagnostics is the only laboratory with 2 IGRA blood tests approved for use by the FDA: the QuantiFERON®-TB Gold Plus and T-SPOT®.TB.⁹ With either assay, only a single blood draw is required. Results are not subject to reader interpretation nor are they affected by BCG vaccination, providing a simpler, more effective process of TB testing as compared to TSTs.

QuantiFERON®-TB Gold Plus

- ✓ **Innovative CD4+ and CD8+ T-cell technology** delivers a more comprehensive evaluation of patients' immune response to TB
- ✓ **Flexible collection options:** 1 tube or 4 tubes
- ✓ **48-hour stability;** refrigeration required
- ✓ **Results available from a single patient visit** and report right into EHR
- ✓ **94% sensitivity⁸**
- ✓ **97.1% specificity⁸**

T-SPOT®.TB

- ✓ **Flexible collection options:** 1 tube or 4 tubes
- ✓ **Results available from a single patient visit** and report right into EHR
- ✓ **Approved** for immunocompromised patients
- ✓ **95.6% sensitivity** [95% CI 91.6%–98.1%] in culture confirmed populations⁹
- ✓ **97.1% specificity** [95% CI 94.5%–98.7%] in a US low-risk population⁹

⁸Quest Diagnostics has validated the use of this assay under CLIA for processing specimens more than 8 hours after collection, up to 54 hours.

A secondary health crisis: declining TB diagnoses during the COVID-19 pandemic

As healthcare services continue to stabilize following the COVID-19 pandemic, the collateral negative effects of the pandemic on other health issues are staggering. Decreases in diagnoses across a number of conditions have been noted since the onset of the pandemic, including heart disease,¹⁰ cancer,¹¹ type 2 diabetes,¹² and TB.¹³

While reported incidences of TB have increased 9.4% in 2021 following a large decrease in 2020, they remain below pre-pandemic levels.¹⁴ Hospitals and health care systems must recommit themselves to focus on TB prevention and control activities that can help protect their staff and local communities.



decline in reported TB diagnoses in 2020 vs prepandemic levels¹³

TB screening and testing for healthcare workers

Pre-employment and post-exposure TB testing of staff is crucial to help stop the spread of TB and keep employees and communities safe. **The CDC recommends TB screening and testing of all US healthcare personnel upon hire as part of a TB Infection Control Plan.**³

Pre-employment screening and testing³



Baseline individual TB risk assessment



TB symptom evaluation



A TB test (eg, TB blood test or a TB skin test)

Healthcare personnel should receive TB education every year³



Post-exposure screening and testing³



All healthcare personnel with a known TB exposure should receive a TB symptom evaluation and timely testing, if indicated



Healthcare personnel with a previous negative TB test result should be tested immediately and retested 8-10 weeks after exposure

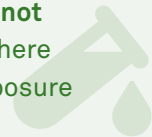


For consistency, the same type of TB test should be used for pre-employment testing and for any follow-up testing



Healthcare personnel with a previous positive TB test result do not need to be retested after TB exposure

Annual testing is not required unless there is a known TB exposure or outbreak³



Some states may have different regulations—always follow your state's guidance³



Choose Quest to help you stop the spread of TB in your workplace

Healthcare workplace TB screening programs are essential to public health. When evaluating which testing methodology is the right fit for your hospital, consider that the traditional TST requires more staff time, may be more costly in the short- and long-term, and provides a less accurate detection of TB than newer IGRA blood tests. The 2 FDA-approved, IGRA blood tests offered by Quest Diagnostics require only a single blood draw, are cost-efficient, and deliver objective results for your employees, making these tests an optimal choice.

Let us help you find a testing model that's right for your health system

Explore our solutions →

The T-SPOT[®].TB test is an in vitro diagnostic test for the detection of effector T cells that respond to stimulation by *Mycobacterium tuberculosis* antigens ESAT-6 and CFP-10 by capturing interferon gamma (IFN- γ) in the vicinity of T cells in human whole blood collected in sodium citrate or sodium or lithium heparin. It is intended for use as an aid in the diagnosis of *M tuberculosis* infection. The T-SPOT.TB test is an indirect test for *M tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

Up-to-date relevant warnings, precautions, side effects, and contraindications can be found at: <http://www.oxfordimmunotec.com/north-america/>

QuantIFERON-TB Gold Plus. This test is a blood-based interferon-gamma release assay (IGRA) used as an aid in the diagnosis of *Mycobacterium tuberculosis* infection. It is an immune response-based, indirect test for *M tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations. Additional testing is needed to determine if a person who has tested positive has latent tuberculosis (TB) infection or TB disease.

This in vitro diagnostic test uses a peptide cocktail simulating ESAT-6, CFP-10, and TB7.7 proteins to stimulate cells in heparinized whole blood. Detection of interferon- γ (IFN- γ) by ELISA is used to identify in vitro responses to those peptide antigens that are associated with *Mycobacterium tuberculosis* infection.

References

1. CDC. Tuberculosis. Updated April 6, 2020. Accessed August 25, 2022. <https://www.cdc.gov/globalhealth/newsroom/topics/tb/index.html>
2. Chia SZG, How KBM, Chlebicki MP, et al. A retrospective review of tuberculosis exposure among health care workers in a tertiary hospital. *Am J Infect Control*. 2020;48(6):650-655. doi:10.1016/j.ajic.2019.10.014
3. CDC. TB screening and testing of health care personnel. Updated August 30, 2022. Accessed August 29, 2022. <https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm>
4. USPSTF. Final recommendation statement: latent tuberculosis infection screening. Published September 6, 2016. Accessed August 30, 2022. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/latent-tuberculosis-infection-screening>
5. Al-Orainey IO. Diagnosis of latent tuberculosis: can we do better? *Ann Thorac Med*. 2009;4(1):5-9. doi:10.4103/1817-1737.44778
6. Lewinson DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children. *Clin Infect Dis*. 2017;64(2):111-115. doi:10.1093/cid/ciw778
7. CDC. Tuberculin skin testing fact sheet. Updated November 2, 2020. Accessed August 29, 2022. <https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>
8. Qiagen. TB testing with QFT-Plus. Accessed August 29, 2022. <https://www.qiagen.com/us/applications/tb-management/products>
9. T-SPOT[®]. TB. Package Insert. Oxford Immunotec; 2021. Accessed August 29, 2022. <https://www.tspot.com/wp-content/uploads/2021/04/TB-PI-US-0001-V9.pdf>
10. Einstein AJ, Shaw LJ, Hirschfeld C, et al. International impact of COVID-19 on the diagnosis of heart disease. *J Am Coll Cardiol*. 2021;77(2):173-185. doi:10.1016/j.jacc.2020.10.054
11. Kaufman HW, Chen Z, Niles J, et al. Changes in the number of US patients with newly identified cancer before and during the coronavirus disease 2019 (COVID-19) pandemic. *JAMA Netw Open*. 2020;3(8):e2017267. doi:10.1001/jamanetwopen.2020.17267
12. Carr MJ, Wright AK, Leelarathna L, et al. Impact of COVID-19 on diagnoses, monitoring and mortality in people with type 2 diabetes: a UK-wide cohort study involving 14 million people in primary care. medRxiv. Epub February 14, 2021. doi:10.1101/2020.10.25.20200675
13. CDC. Media statement: effect of COVID-19 on TB in the United States. CDC. Published March 24, 2022. Accessed August 29, 2022. <https://www.cdc.gov/media/releases/2022/s0324-tuberculosis-covid-19.html>
14. Filardo TD, Feng P, Pratt RH, et al. Tuberculosis — United States, 2021. *MMWR Morb Mortal Wkly Rep*. 2022;71(12):441-446. doi:10.15585/mmwr.mm7112a1

Image content features models and is intended for illustrative purposes only.

QuestDiagnostics.com

Quest, Quest Diagnostics, any associated logos, and all associated Quest Diagnostics registered or unregistered trademarks are the property of Quest Diagnostics. All third-party marks—[®] and [™]—are the property of their respective owners. © 2022 Quest Diagnostics Incorporated. All rights reserved. 11/2022

