

Reliable tuberculosis blood testing for your immunocompromised patients

The T-SPOT®.TB test is a unique, single-visit blood test for tuberculosis (TB) that offers the opportunity to detect latent TB before it activates. The test is effective with immunocompromised and BCG-vaccinated patient populations and is the only IGRA without a warning or limitation for screening immunocompromised individuals.¹

Immunocompromised patients have an increased risk for TB

Many conditions and treatments can weaken an individual's immune system, making them immunocompromised. Those with compromised immune systems face a higher risk of contracting TB and a higher risk of latent tuberculosis infection (LTBI) becoming active.²

T-SPOT®.TB: reliable TB testing in the immunocompromised

T-SPOT®.TB is the only TB test with sensitivity and specificity >95%¹—an accuracy that allows clinicians to confidently screen and detect TB infection in challenging patient populations including the immunocompromised. The test uses a proprietary enumeration process that includes washing, counting, and standardizing the number of T-cells in each specimen, an innovative approach that produces results physicians and patients can trust.

- Mitigates the risk that low T-cell count will impact patient results; this is especially critical in immunocompromised patients, including those receiving immunosuppressive therapy
- Utilizes a standard number of PBMCs (peripheral blood mononuclear cell) to correct for a patient's immune status
- Removes background interferon-gamma to maximize sensitivity (estimated sensitivity: 95.6%) and specificity (estimated specificity: 97.1%)¹
- Consistent results with repeat testing in healthcare workers³

Identifying those at risk

The Centers for Disease Control and Prevention (CDC) has identified the following persons with medical conditions that weaken the immune system and make them at higher risk for developing active TB disease^{4,5}:

- HIV infection (the virus that causes AIDS)
- Substance abuse
- Silicosis
- Diabetes mellitus
- Severe kidney disease
- Low body weight
- Organ transplants
- Head and neck cancer
- Medical treatments such as corticosteroids or organ transplant
- Specialized biologic/biosimilar treatment for rheumatoid arthritis, plaque psoriasis, and inflammatory bowel disease including Crohn's disease and ulcerative colitis among other autoimmune disease

Guidelines for biologic/biosimilar treatment

Administering biologic treatment causes suppression of the immune system, making those patients undergoing treatment more susceptible to infection.⁶ Screening for latent infections like tuberculosis (TB) and other infections like hepatitis is recommended by a number of leading health organizations.^{7,8}

The American College of Rheumatology (ACR) and American College of Gastroenterology (ACG) recommend screening for hepatitis B (HBV), hepatitis C (HCV), and latent TB infection in patients starting or currently receiving certain biologic agents.⁷⁻⁹

T-SPOT®.TB test order information

Test	Specimen Requirements
T-SPOT®.TB Test Code 906927 CPT Code* 86481	<ul style="list-style-type: none"> Adults ≥18 years: One room temperature 9 mL lithium heparin green-top tube (supply #38235). Pediatric sample volumes: <ul style="list-style-type: none"> <2 years: 2 mL 2-10 years: 4 mL ≥10 years: 6 mL Collect Monday – Friday ONLY. Do not collect on holidays or weekends. Do not spin or centrifuge samples. Do not refrigerate or freeze samples. Place sample in separate bag and apply the neon green T-SPOT®.TB label provided with your tubes to the outside of the specimen transport bag or tube. Lockbox use is not recommended, however, if necessary, configure the ice packs in an a-frame or lean-to formation.
Pre-biologic/biosimilar Screen Panel, HCV/HBV with Reflexes and T-SPOT®.TB Test Code 803980 CPT Codes*: 86803, 87340, 86317, 86704, 86481	<ul style="list-style-type: none"> 5 mL refrigerated serum from a serum separator tube AND 1 refrigerated EDTA lavender-top tube. Panel Components^: <ul style="list-style-type: none"> Hepatitis C Antibody with Reflex to HCV RNA, PCR w/Reflex to Genotype, LiPA® Hepatitis B Surface Antibody, Quantitative Hepatitis B Surface Antigen with Reflex Confirmation Hepatitis B Core Antibody, Total, with Reflex to IgM T-SPOT®.TB <p>^Panel components may be ordered separately.</p>

* The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

T-SPOT®.TB is approved by the US FDA.

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 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 product-specific warnings and other information can be found at www.tspot.com

References

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