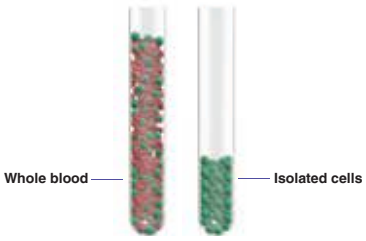
Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

# T-SPOT®.*TB*: The Science Behind The Test

The vast majority of T-SPOT®.*TB* test results are either Positive or Negative; however, a small percentage of test results can be Borderline (equivocal), where the higher of (Panel A minus nil control) and (Panel B minus nil control) is 5, 6, or 7 spots.[1]

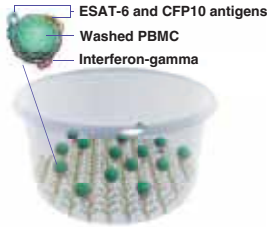
| | |
|---|---|
| **Accurate across patient populations** | • Effective in challenging patient populations[1]<br>- Immunocompromised<br>- BCG-vaccinated<br>- Pediatrics<br>• FDA-approved borderline zone provides test resolution for results around the cut-off point[2,3] |
| **Consistent results** | • Invalid rate of 0.6% in a study of >645,000 tests[2]<br>• 98.9% concordance and 0.8% mean conversion rate in a study of >42,000 healthcare worker serial tests[4] |
| **One tube with no refrigeration[1]** | • Standard phlebotomy<br>• One visit<br>• No on-site pre-analytical steps<br>• No on-site incubation or refrigeration |

**1.**



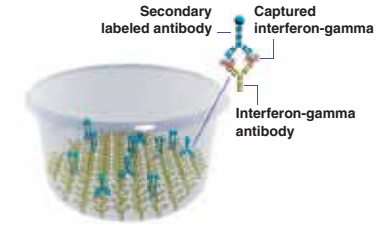

A blood specimen is collected using routine phlebotomy and a standard blood collection tube from which a subset of white blood cells, known as peripheral blood mononuclear cells, are isolated. The cells are washed, counted, and normalized to create a standard cell suspension.

**2.**




A standard number of cells are added into specially designed plates and stimulated with TB-specific antigens, ESAT-6 and CFP10. Cells responding to these antigens release interferon-gamma.

**3.**




Interferon-gamma antibodies are used to directly capture interferon-gamma as it is released by the cells. A secondary labeled antibody is added and binds to the captured interferon-gamma.

**4.**


A detection reagent is added and reacts with the secondary labeled antibody. This reaction produces spots, which are a footprint of where the interferon-gamma was released. Spots are then enumerated.

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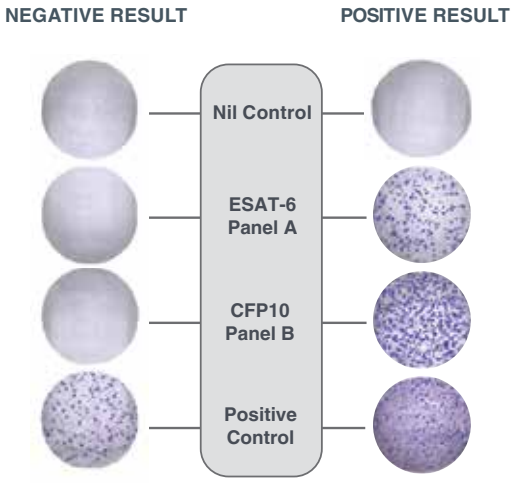
# **Interpretation** of results

- Interferon-gamma is captured and presented as spots from T cells sensitized to TB infection
- Results are interpreted by subtracting the spot count in the negative (NIL) control from the spot count in Panels A and B
  - Positive ≥ 8 spots
  - Negative ≤ 4 spots
  - Borderline 5, 6, or 7 spots
  - Invalid
- The inclusion of a borderline category is intended to reduce the likelihood of false-positive or false-negative results around the test cut-off

**Note:** It is recommended that borderline and invalid results be retested with a new specimen.




## T-SPOT®.*TB* test order information

| Test Code | CPT Code* | Specimen Requirements |
|---|---|---|
| 906927 | 86481 | • Adults ≥18 years: One room temperature 9 mL lithium heparin green-top tube (supply #38235).<br>• Pediatric sample volumes:<br>• <2 years: 2 mL<br>• 2-10 years: 4 mL<br>• ≥10 years: 6 mL<br>• Collect Monday – Friday ONLY. Do not collect on holidays or weekends.<br>• Do not spin or centrifuge samples.<br>• Do not refrigerate or freeze samples.<br>• 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.<br>• Lockbox use is not recommended, however, if necessary, configure the ice packs in an a-frame or lean-to formation. |


References

1. Oxford Immunotec. T-SPOT®.*TB* Package Insert PI-TB-US-V6. May 2017.
2. Rego K, Pereira K, MacDougall J, Cruikshank W. Utility of the T-SPOT®.*TB* test's borderline category to increase test resolution for results around the cut-off point. *Tuberculosis.* 2018;108:178-185. doi:10.1016/j.tube.2017.12.005
3. Mazurek GH, Jereb J, Vernon A, et al. Updated guidelines for using interferon gamma release tests to detect Mycobacterium tuberculosis infection—United States, 2010. *MMWR Recomm Rep.* 2010;59:1-25.
4. King TC, Upfal M, Gottlieb A, et al. T-SPOT®.*TB* interferon-gamma release test (IGRA) performance in healthcare worker screening at 19 US hospitals. *Am J Respir Crit Care Med.* 2015;192(3):367-373. doi:10.1164/rccm.201501-0199OC


*The CPT® codes provided are based on American Medical Association 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.

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