



[Home](#) > [Medical Devices](#) > [Products and Medical Procedures](#) > [Device Approvals and Clearances](#)

Medical Devices

T-SPOT®.TB - P070006

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.



Product Name: T-SPOT.TB

PMA Applicant: Oxford Immunotec

Address: 2 Mount Royal Avenue, Marlborough, MA 01752

Approval Date: July 30, 2008

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070006a.pdf¹

What is it? T-Spot.TB is a laboratory test kit which contains reagents to detect the immune response of Thymus cells (T cells) found in an individual's white blood cells that are stimulated by proteins produced by the bacteria that causes [tuberculosis \(TB\)](#)². The test is to be used to help diagnose tuberculosis in individuals that may be infected. It should be used with an evaluation of the risk of the individual to contract TB, x-rays, previous infections, and other medical/diagnostic tests.

How does it work? A blood sample is collected from an individual. The white blood cells are separated and put into reaction wells coated with specific antibodies to Interferon-gamma, a substance released by the T cells when fighting TB infection.

- Proteins (antigens) produced by the bacteria that cause TB infection are added to the reaction wells to stimulate the release of Interferon-gamma from the T cells.
- This Interferon-gamma is then captured by the specific antibodies to Interferon-gamma coated to the bottom of the reaction wells. A second antibody is added which binds to the antibody/Interferon-gamma/antigen.
- A solution is added which produces dark blue spots in the reaction wells where the Interferon-gamma was secreted by the T cells.
- These dark blue spots are counted, and depending on how many of them are present, the sample is recorded as either positive; borderline/equivocal or negative for exposure to, or infection with the bacteria which cause tuberculosis.

When is it used? This test is used to evaluate individuals suspected of having been infected with TB disease.

What will it accomplish? Results of this test may help a doctor to evaluate individuals suspected of having active TB disease.

When should it not be used? The performance of this test has not been adequately evaluated with specimens from individuals younger than age 17 years, in pregnant women and with hemophilia.

Additional information: The Summary of Safety and Effectiveness and labeling will be available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p070006>³

Other Resources

- [NIH Medline Plus Tutorial - Tuberculosis](#)⁴

Links on this page:

1. http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070006a.pdf
2. <http://www.nlm.nih.gov/medlineplus/tuberculosis.html>
3. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p070006>
4. <http://www.nlm.nih.gov/medlineplus/tutorials/tuberculosis/htm/index.htm>