



New Device Approvals

QuantiFERON® -TB - P010033

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: QuantiFERON® -TB
Manufacturer: Cellestis Limited
Address: 1046A Dandenong Road, Carnegie, Melbourne, Victoria 3163, Australia
Approval Date: November 28, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010033a.pdf>

What is it? QuantiFERON®-TB is a laboratory test to help detect infection with the organism *Mycobacterium tuberculosis* which may later become active tuberculosis (TB).

How does it work? The patient's blood samples are placed in several chambers along with mycobacterial antigens. If the patient is infected with *Mycobacterium tuberculosis* organisms, the lymphocytes in the blood will recognize these antigens and secrete a substance, gamma interferon. Detection and quantification of gamma interferon form the basis of the test. The test result shows whether infection with *Mycobacterium tuberculosis* is likely. Many people are infected with this organism but do not have active TB disease. However some people who are infected will develop TB disease sometime during their lifetime. Based on the test results, the physician may decide to treat the infection either to reduce the risk of developing TB disease later or to prevent spread of the organism to others.

When is it used ? The test is used when it is necessary to determine whether a patient has been exposed to or is infected with *M. tuberculosis*.

What will it accomplish? Test results should aid the physician in determining treatment options.

When should it not be used? ? The test should not be used in patients who:

- have a weakened immune system, including those with AIDS or leukemia, certain diabetics and transplant recipients,
- are on drugs that suppress the immune system,

- are under 17 years old or
- are pregnant

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p010033.html>

Other:

Centers for Disease Control and Infection: " Frequently Asked Questions on Tuberculosis:
<http://www.cdc.gov/nchstp/tb/faqs/qa.htm>

National Institutes for Health (NIH): " Summaries of tuberculosis research:
<http://www.niaid.nih.gov/aids/therapeutics/research/tb-00.htm>

(Updated 5/14/2002)