QuantiFERON®-TB Gold Test

What is it?

The QuantiFERON®-TB Gold test (QFT-G) is a whole-blood test for use as an aid in diagnosing *Mycobacterium tuberculosis* infection, including latent tuberculosis infection (LTBI) and tuberculosis (TB) disease. This test was approved by the U.S. Food and Drug Administration (FDA) in 2005.

How does it work?

Blood samples are mixed with antigens (substances that can produce an immune response) and controls. For QFT-G, the antigens include mixtures of synthetic peptides representing two *M. tuberculosis* proteins, ESAT-6 and CFP-10. After incubation of the blood with antigens for 16 to 24 hours, the amount of interferon-gamma (IFN-gamma) is measured.

If the patient is infected with *M. tuberculosis*, their white blood cells will release IFN-gamma in response to contact with the TB antigens. The QFT-G results are based on the amount of IFN-gamma that is released in response to the antigens.

Clinical evaluation and additional tests (such as a chest radiograph, sputum smear, and culture) are needed to confirm the diagnosis of LTBI or TB disease.

What are the advantages?

- Requires a single patient visit to draw a blood sample.
- Results can be available within 24 hours.
- Does not boost responses measured by subsequent tests, which can happen with tuberculin skin tests (TST).
- Is not subject to reader bias that can occur with TST.
- Is not affected by prior BCG (bacille Calmette-Guérin) vaccination.

What are the disadvantages and limitations?

- Blood samples must be processed within 12 hours after collection while white blood cells are still viable.
- There are limited data on the use of QFT-G in children younger than 17 years of age, among persons recently exposed to *M. tuberculosis*, and in immunocompromised persons (e.g., impaired immune function caused by HIV infection or acquired immunodeficiency syndrome [AIDS], current treatment with immunosuppressive drugs, selected hematological disorders, specific malignancies, diabetes, silicosis, and chronic renal failure).
- Errors in collecting or transporting blood specimens or in running and interpreting the assay can decrease the accuracy of QFT-G.
- Limited data on the use of QFT-G to determine who is at risk for developing TB disease.

When should you use the test?

QFT-G can be used in all circumstances in which the tuberculin skin test (TST) is currently used, including contact investigations, evaluation of recent immigrants who have had BCG vaccination, and TB screening of health care workers and others undergoing serial evaluation for *M. tuberculosis*. However, caution should be used when testing certain populations because of limited data in the use of QFT-G.

Before the QFT-G is conducted, arrangements should be made with a qualified laboratory and courier service, if needed, to ensure prompt and proper processing of blood.

What are the steps in administering the test?

- Confirm arrangements for testing in a qualified laboratory and arrange for delivery of the blood sample in time for the laboratory to initiate testing within 12 hours of blood collection.
- Draw a sample of whole blood from patient into a tube with heparin anti-clotting agent, according to manufacturer's instructions.
- Schedule an appointment for the patient to receive test results and, if then needed, medical evaluation and possible treatment for TB disease or LTBI.

How do you interpret test results?

Interpretation of QFT-G results is based on IFN-gamma concentrations in test samples. Each QFT-G result and its interpretation should be considered in conjunction with other epidemiological, historical, physical, and diagnostic findings.

A positive result suggests that *M. tuberculosis* infection is likely; a negative result suggests that infection is unlikely; and indeterminate result suggests QFT-G results cannot be interpreted as a result of low mitogen response or high background response.

A diagnosis of LTBI requires that TB disease be excluded by medical evaluation, which should include checking for signs and symptoms suggestive of TB disease, a chest radiograph, and, when indicated, examination of sputum or other clinical samples for the presence of *M. tuberculosis*.

Additional Information

Centers for Disease Control and Prevention. Guidelines for the investigation of contacts of persons with infectious tuberculosis and Guidelines for using the QuantiFERON®-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. MMWR 2005; 54 (No. RR-15).
http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. *MMWR* 2005; 54 (No.RR-17).
http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

Get-QFT (Locator site for QuantiFERON®-TB Gold)
http://www.quantiferon.com*

* This link is provided solely as a service to our users. It does not constitute an endorsement of the QFT-Gold testing institutions included on the website by CDC or the Federal Government, and none should be inferred. CDC is not responsible for the content found at this link.