QuantiFERON®-TB Gold In-Tube Test

WHAT IS IT?

The QuantiFERON®-TB Gold In-Tube test (QFT-IT) is a serological whole-blood test for use as an aid in diagnosing *Mycobacterium tuberculosis* infection. This test was approved by the U.S. Food and Drug Administration (FDA) in 2007. This test cannot, in and of itself, rule in or out active tuberculosis disease.

WHAT ARE THE ADVANTAGES?

- Requires a single patient visit to draw blood sample.
- Results can be available within 24 hours.
- Does not boost responses measured by subsequent tests.
- Is not subject to reader bias.
- Is not affected by prior BCG (bacille Calmette-Guérin) vaccination.
- Can alert providers to patients with impaired T-cell immunity (e.g., persons with HIV, cancer, renal failure, or undergoing immunosuppressive therapy). Those unable to mount an immune response will most likely produce an indeterminate test result.

WHAT ARE THE DISADVANTAGES AND LIMITATIONS?

- Blood samples must arrive at the Unified State Laboratories: Public Health (USLPH) within 15 hours of collection, or be incubated and spun within strict guidelines (contact the USLPH at (801) 965-2400 for more information on time constraints).
- There are limited data on the use of QFT-IT 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 medication(s), selected hematological disorders, specific malignancies, diabetes, silicosis, chronic renal failure, and in pregnant women). Refer to the most recent publications available for current information on this matter.
- Errors in collecting or transporting blood specimens or in running and interpreting the assay can decrease the accuracy of the QFT-IT.
- There are limited data on the use of QFT-IT to determine who is at risk for developing active TB disease.

QuantiFERON®-TB Gold In-Tube testing is available at the Unified State Laboratories: Public Health (USLPH). For more information please call (801) 965-2400 or visit: *http://health.utah.gov/lab/*

Although not available at the USLPH, there is another interferon gamma release assay (IGRA) test available called the T-Spot® which was FDA approved on July 25, 2008.

DIRECTORY OF UTAH LOCAL HEALTH DEPARTMENTS

BEAR RIVER
655 East 1300 North
Logan, Utah 84341
Phone: (435) 792-6500
Fax: (435) 792-6600

CENTRAL UTAH
70 Westview Drive
Richfield, Utah 84701
Phone: (435) 896-5451
Fax: (435) 896-4353

DAVIS COUNTY
22 South State Street
Clearfield, Utah 84015
Phone: (801) 525-5200
Fax: (801) 525-5210

SALT LAKE VALLEY
610 South 200 East,
Room 209
Salt Lake City, Utah 84111
Phone: (801) 534-4600
Fax: (801) 534-4565

SOUTHEASTERN UTAH
28 South 100 East
Price, Utah 84501
Phone: (435) 637-3671
Fax: (435) 637-1933

SOUTHWEST UTAH
620 South 400 East,
Suite 400
St. George, Utah 84770
Phone: (435) 986-2551
Fax: (435) 652-4069

SUMMIT COUNTY
110 North Main Street
Kamas, Utah 84036
Phone: (435) 615-3072
Fax: (435) 783-6021

TOOELE COUNTY
151 North Main Street
Tooele, Utah 84074
Phone: (435) 277-2310
Fax: (435) 277-2314

TRI COUNTY
133 South 500 East
Vernal, Utah 84078
Phone: (435) 247-1177
Fax: (435) 781-0536

UTAH COUNTY
151 South University
Avenue, Suite 1800
Provider, Utah 84601
Phone: (801) 851-7029
Fax: (801) 343-8729

WASATCH COUNTY
55 South 500 East
Heber City, Utah 84032
Phone: (435) 654-2700
Fax: (435) 654-2705

WEBER-MORGAN
477 23rd Street
Ogden, Utah 84401
Phone: (801) 399-7252
Fax: (801) 399-7260

Fold Line

TUBERCULOSIS IS A REPORTABLE DISEASE

Required by Utah State Statute

Report all suspected and confirmed cases to the Utah Department of Health and/or to the local health department in your area (see listing on back cover).

Provider Guide

TUBERCULOSIS

Testing for TB Infection & Guidelines for Post-Test Referral

August 2011

UTAH DEPARTMENT OF HEALTH

Utah Department of Health
Tuberculosis Control Program
288 North 1460 West
Box 142104
Salt Lake City, Utah 84114-2104
Phone: (801) 538-6191
Fax: (801) 538-9913
Website: www.health.utah.gov/cdc/tb_home.htm

Provider Guide to Testing for TB Infection and Post-Test Referral

Step 1 — Classify the Results for TB Infection Test[Σ]

The following measurements of induration are classified as positive in a Tuberculin Skin Test (TST):

≥ 5 mm	≥ 10 mm	≥ 15 mm	QuantiFERON® (QFT®):[Ω] QuantiFERON® Positive
• HIV-positive persons • Persons with evidence of old, healed and untreated tuberculosis (TB) on a chest x-ray • Recent contacts of persons with active TB disease • Persons with organ transplants and other immunocompromised persons	• Persons with medical risk factors for TB ***(Table 2)*** • Substance abusers • Recent arrivals from high-incidence areas ***(Table 1)*** • Persons at higher risk for exposure to or infection with TB ***(Table 1)*** • Mycobacteriology lab personnel • Children under age 5 • Children/adolescents exposed to adults in high-risk categories ***(Tables 1 & 2)***	• Persons at low-risk for TB disease for whom testing is not generally indicated	• *Mycobacterium tuberculosis* (MTB) infection likely in most circumstances. Refer questions to the Unified State Laboratories: Public Health (USLPH) at (801) 965-2400

[Σ]**Tuberculin Skin Test (TST)**- Results are classified according to a patient's risk factors for tuberculosis. In general, a history of vaccination with BCG (bacille Calmette-Guerin) does not influence the need for tuberculin skin testing, the classification of TST results, or clinical decisions regarding the management of TST-positive individuals. ***See Tables 1, 2, and 3.***

[Ω]**QuantiFERON® (QFT)**- Negative indicates infection unlikely, but cannot be excluded if symptoms are consistent with active TB disease, if test is less than 8-10 weeks after exposure, or individual has increased likelihood of disease progression. ***See disadvantages and limitations on back cover.***

High-Priority Contacts - Certain high-priority contacts need medical follow-up even if their reaction is less than 5 mm because they are at high-risk of both developing active TB disease and having a false-negative TST result. These include: (1) immunocompromised contacts and (2) children younger than age 5 who were tested less than 8-10 weeks after the last exposure to TB. No further evaluation is necessary when high-priority contacts have a negative reaction to a TST given *more* than 8 weeks after the last exposure to TB. ***See Step 2 and Table 3 footnote (*).***

Step 2 — If indicated, obtain a chest x-ray and a medical evaluation

Any person with a newly positive TST or QuantiFERON® test result, including high-priority contacts of a patient with active TB disease (as defined in Step 1), should have a chest x-ray to evaluate for active TB disease. If the initial chest x-ray is normal, no follow-up chest x-rays are indicated.

Step 3 — Are TB symptoms present, or is the chest x-ray abnormal?

Yes

- Fever
- Chills
- Fatigue
- Loss of appetite
- Weight loss
- Night sweats
- Prolonged productive cough
- Chest pain
- Coughing up blood

Evaluate for active TB disease

No

Refer for treatment according to the guidelines in Table 3

Table 1. Persons at higher risk for exposure to or infection with TB

- Close contacts of persons known or suspected to have active TB disease.
- Foreign-born persons from areas where TB is common. **See: *www.health.utah.gov/cdc/tb_home.htm*** to view up-to-date *M. tuberculosis* incidence information by country.
- Residents and employees of high-risk congregate settings (e.g., correctional institutions, nursing homes, mental health facilities, other long-term residential settings, homeless shelters, etc.).
- Health care workers who serve high-risk patients.
- Medically underserved, low-income populations.
- High-risk racial or ethnic minority populations.
- Children exposed to adults in high-risk categories.
- Persons who inject illicit drugs.

Table 2. Medical risk factors for the development of active TB disease in TB-infected patients

- HIV infection (or risk for HIV in patients who decline HIV testing).
- New TB infection within the previous two years.
- Evidence of old, healed TB on a chest x-ray.
- Diabetes.
- End-stage renal disease.
- Prolonged corticosteroid therapy.
- Other immunosuppressive therapy.
- Cancer of the head and neck.
- Hematologic and reticuloendothelial diseases (e.g., leukemia and Hodgkin's disease).
- Silicosis.
- Chronic malabsorption syndromes.
- Intestinal bypass or gastrectomy.
- Being 10% or more below ideal body weight.
- Substance abuse.

Table 3. Guidelines for treatment of latent tuberculosis infection by patient risk factors, TST result, QuantiFERON® result, and age*¥

CANDIDATES FOR TREATMENT OF LATENT TUBERCULOSIS INFECTION (LTBI)

CATEGORY OF PERSON TESTED	TST < 5 mm	TST ≥ 5 mm	TST ≥ 10 mm	TST ≥ 15 mm	or	QFT®-Pos[π]	QFT®-Neg
Case Contact: Children < age 5[✳]	Treat[✳✳]	Treat	Treat	Treat		Treat	Treat[✳✳]
Case Contact: HIV-infected[¢]	Treat[✳✳]	Treat	Treat	Treat		Treat	Treat[✳✳]
Case Contact: Immunocompromised[✳]	Treat[✳✳]	Treat	Treat	Treat		Treat	Treat[✳✳]
Case Contact: ≥ age 5 and immunocompetent[£]	Repeat[✳✳✳]	Treat	Treat	Treat		Treat	Repeat[✳✳✳]
Immunocompromised persons	Do Not Treat	Treat	Treat	Treat		Treat	Do Not Treat
HIV-infected	Do Not Treat	Treat	Treat	Treat		Treat	Do Not Treat
Fibrotic changes on chest x-ray	Do Not Treat	Treat	Treat	Treat		Treat	Do Not Treat
Recent arrival from endemic country[Φ]	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
Injection drug user	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
Resident/employee in an institutional setting[§]	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
Mycobacteriology lab personnel	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
High-risk clinical conditions[‡]	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
Child < age 5	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
Persons < age 17 exposed to high-risk adults	Do Not Treat	Do Not Treat	Treat	Treat		Treat	Do Not Treat
No risk factors (TST discouraged)	Do Not Treat	Do Not Treat	Do Not Treat	Treat		Treat	Do Not Treat

For more information on treatment or to refer a patient for treatment, please see the Directory of Local Health Departments (back cover).

£ The window period is the time span between the date of an initial tuberculin skin test (TST) or QuantiFERON® (QFT®) with a negative reaction and the date of the follow-up TST or QFT® that should take place 8-10 weeks after exposure. After the window period has ended, a repeat test should be administered to each contact who had an initial negative reaction.

✳ QFT® is not FDA approved to test those under 5 years of age. Case contacts who are under 5 years of age or immunocompromised, initially testing negative should be started on therapy. Testing should be repeated 8-10 weeks after last exposure to TB. Treatment can be discontinued after second negative TST or QFT® in children. Immunocompromised patients with a second negative TST or QFT® need to be evaluated by a physician.

✳✳ Treat and repeat TST or QFT® test after 8-10 weeks.

✳✳✳ Repeat TST or QFT® test after 8-10 weeks.

¢ HIV-infected contacts should receive a full course of treatment even if they have a second reaction of < 5 mm or a negative QFT®.

¥ TST and QFT® are not contraindicated for persons who have been vaccinated with BCG (bacille Calmette-Guérin). Test results for *M. tuberculosis* infection for individuals with a history of BCG should be interpreted by using the same diagnostic cut points used for individuals without a history of BCG vaccination.

π Rarely QFT® may cross-react with *M. kansasii, M. szulgai, or M. marinum* resulting in a false-positive result.

Φ See ***www.health.utah.gov/cdc/tb_home.htm*** to view up-to-date *M.tuberculosis* incidence information by country.

§ TST Conversion: An increase in reaction size of ≥ 10 mm within 2 years should be considered a TST conversion indicative of recent infection with *M. tuberculosis*.

‡ Silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g. leukemias and lymphomas), other specific malignancies (e.g. carcinoma of the head and neck or lung), being ≥ 10% below ideal body weight, gastrectomy, intestinal bypass.

In all situations of high suspicion of tuberculosis, a person with a negative TST or QFT® should be further evaluated with radiological, bacteriological, HIV, or other testing as appropriate.