WHAT ARE THE DISADVANTAGES AND LIMITATIONS?

• Blood samples must be processed by your assigned laboratory within 16 hours of collection, or be incubated on-site within strict guidelines (contact TB Clinic for more information about on-site handling and incubation).
• There is limited data on the use of QFT-IT in children younger than 5 years of age.
• Errors in collecting or transporting blood specimens or in running and interpreting the assay can decrease the accuracy of QFT-IT.
• The ability of QFT to predict the risk of LTBI progression to TB disease has not been clearly determined. Current evidence indicates an equal to or higher risk of progression when compared to the TST.

WHAT IS IT?

The QuantiFERON® TB 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 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

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WHAT ARE THE ADVANTAGES?

• Requires a single patient visit to draw blood sample.
• Does not boost responses measured by subsequent tests.
• Is not subject to reader bias.
• Is not affected by prior BCG (bacille Calmette-Guérin) vaccination and most other mycobacteria.
• 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.

TUBERCULOSIS PROVIDER GUIDE

TUBERCULOSIS IS A REPORTABLE DISEASE

San Francisco Department of Health
Tuberculosis Clinic
San Francisco General Hospital
2460 22nd Street
Building 90, 4th Floor (Ward 94)
San Francisco General Hospital
Tuberculosis Clinic
San Francisco Department of Health

Guidelines for Post-Test Referral

Testing for TB Infections &

QuantiFERON® - TB Gold In-Tube Test

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Clinical questions related to QuantiFERON®-TB In-Tube testing may be directed to TB Clinic at 415.206.8524

Although not utilized in San Francisco, there is another interferon gamma release assay (IGRA) test called the T-Spot® which was FDA approved on July 25, 2008.
### Targeted Testing of high risk populations for TB Infection and Post-Test Referral

**Step 1** Symptom Review and Risk Factor Assessment (Table 1)

<table>
<thead>
<tr>
<th>Yes, risk factor(s) and ≥1 symptom(s)</th>
<th>No, but risk factors present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged cough ≥ 3 weeks Unexplained weight loss</td>
<td></td>
</tr>
<tr>
<td>Night sweats Chronic fever Chest pain Coughing up blood</td>
<td></td>
</tr>
</tbody>
</table>

Urgent CXR and medical evaluation needed. Consult TB Clinic if CXR abnormal.

**Step 2** Classify the Results for TB Infection Test

The following Tuberculin Skin Test (TST) measurements of induration are classified as positive.*

<table>
<thead>
<tr>
<th>≥ 5 mm</th>
<th>≥ 10 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive Abnormal CXR Recent contact to persons with active TB disease Immunosuppressed (on corticosteroids or organ transplant drugs)</td>
<td>All others with TB risk factors (Table 1 &amp; 2)</td>
</tr>
</tbody>
</table>

Note: CDC classification of ≥15mm not recognized in California

QuantIFERON® (QFT®) result classifications:

<table>
<thead>
<tr>
<th>QuantIFERON Positive®</th>
<th>QuantIFERON Negative</th>
<th>QuantIFERON indeterminate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicates TB Infection</td>
<td>Indicates no TB Infection</td>
<td>Indicates test failure. Options are to repeat test or do TST.</td>
</tr>
</tbody>
</table>

Caution! As with the TST - false negative can occur with active TB and immunocompromised persons.

**Step 3** TB test positive: CXR and medical evaluation indicated.

**REFERRAL CRITERIA FOR TB CLINIC MEDICAL EVALUATION:**

- Must be resident of the City and County of San Francisco and
- Have a positive TB test and
- Meet criteria for LTBI treatment listed in Table 3 below and
- completed TB 47 interagency referral form or patient summary on physician letterhead.

**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 (excluding Canada, Western Europe, Australia and Japan)
- Residents and employees of high-risk congregate settings (e.g., institutional settings, nursing homes, daycares centers, homeless shelters, jails)
- Healthcare workers who serve high-risk patients
- Medically under-served, low income populations
- High-risk racial or ethnic minority populations
- Children exposed to adults in high-risk categories
- Chronic substance abuse

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

- Diabetes Mellitus
- HIV infection (or risk for HIV in patients who decline HIV testing)
- New TB infection within the previous two years (TB test converter)
- Evidence of old, healed TB on CXR
- End-stage renal disease
- Corticosteroid therapy (for ≥ 3 wks)
- Other immunosuppressive therapy (solid organ transplant)
- Cancer of the head and neck
- Hematologic and reticuloendothelial diseases (e.g., leukemia and Hodgkin’s disease)
- Chronic malabsorption syndromes, intestinal bypass or gastrectomy.
- Being 10% or more below ideal body weight
- Injection drug users
- Current or past tobacco use

**Table 3. SF TB Clinic guidelines for treatment of latent tuberculosis infections by patient risk factors, TST result, QuantiFERON® result and age**

<table>
<thead>
<tr>
<th>CATEGORY OF PERSON TESTED</th>
<th>TST&lt;5 mm</th>
<th>TST≥5 mm</th>
<th>TST≥10 mm</th>
<th>QFT-Pos 6</th>
<th>QFT-Neg</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB Case Contact: Children &lt; age 5 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Case Contact: HIV-infected 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Case Contact: Immunocompromised 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Case Contact: ≥ age 5 &amp; immunocompetent</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompromised persons or HIV-infected</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibroc changes on chest x-ray</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign born &lt;35 yrs or with medical risk factor (Table 2)</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent arrival from endemic country (in US &lt; 5 years) 6</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection drug user known to be HIV-</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resident/worker in institutional settings &lt; 35 years old 2</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare worker &lt; 35 years old</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High risk medical conditions (Table 2)</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Converters within 2 years 7</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No risk factors ≥21 (found through inadvertent testing)

**Footnotes**

1. Case contacts who are under 5 years of age or immunocompromised, initially testing negative should be started on therapy.
2. 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.
3. TB and treat TST or QFT® after 8-10 weeks.
4. HIV-infected contact should receive a full course of treatment even if they have a second negative TST or QFT®.
5. QFT® preferred in BCG-vaccinated persons due to higher specificity than TST.
6. Rarely QFT® may cross-react with M. kansasi, M. szulgai, or M. marinum, resulting in a false positive result.
7. Those born outside the US (except Canada, Western Europe, Australia and Japan).
8. When active TB is suspected because of symptoms or an abnormal CXR, a negative TST or QFT® result does not rule out disease, and further evaluation is indicated.