Interferon Gamma Release Assay
Quantiferon-TB Gold In-Tube or T-Spot.TB Tests

WHAT ARE THEY?
Interferon Gamma Release Assay (IGRA) tests are whole-blood tests used as an aid in diagnosing Mycobacterium tuberculosis infection. Two tests are approved by the U.S. Food and Drug Administration (FDA). Quantiferon- B Gold In-Tube test (QFT) was approved in 2007 and T-Spot T.B Test (T-Spot) was approved in 2008. These tests cannot, in and of themselves, 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 bacille Calmette-Guérin (BCG) 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 QFT or borderline T-Spot.

WHAT ARE THE DISADVANTAGES AND LIMITATIONS?
- QFT samples must arrive at the Utah Public Health Laboratory (UPHL) within 15 hours of collection, or be incubated and spun within strict guidelines (contact the UPHL at (801) 965-2400 for more information on time constraints. Check with Oxford Laboratories regarding T-Spot procedures 1-877-598-2522.
- There are limited data on the use of IGRA 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 hematologic 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 IGRA.
- There are limited data on the use of IGRA to determine who is at risk for developing active TB disease.

QFT testing is available at UPHL. For more information please call (801) 965-2400 or visit http://health.utah.gov/lab/. T-Spot is available through Oxford Labs. For more information please call 1-877-598-2522 or visit http://www.tspot.com/

DIRECTORY OF UTAH LOCAL HEALTH DEPARTMENTS

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

Central Utah
70 Westview Drive
Richfield, Utah 84701
Phone: (435) 896-5451

Davis County
22 South State Street
Clearfield, Utah 84015
Phone: (801) 525-5200

Salt Lake County
660 South 200 East
Salt Lake City, Utah 84111
Phone: (385) 468-4100

San Juan
196 East Center Street
Blanding, Utah 84511
Phone: (435) 678-2723

Southeast Utah
28 South 100 East
Price, Utah 84501
Phone: (435) 673-3528

Tooele County
151 North Main Street
Tooele, Utah 84074
Phone: (435) 277-2300

TriCounty
133 South 500 East
Vernal, Utah 84076
Phone: (435) 247-1177

Southwest Utah
620 South 400 East
St George, Utah 84770
Phone: (435) 673-3528

Utah County
151 South University Avenue
Provo, Utah 84601
Phone: (801) 851-7000

Wasatch County
55 South 500 East
Heber City, Utah 84032
Phone: (435) 654-2700

Provider Guide
Testing for TB Infection &
Guidelines for Post-test Referral
July 2017

TUBERCULOSIS (TB) IS A REPORTABLE DISEASE
Required by Utah State Statute
Report all suspected and confirmed cases of TB to the Utah Department of Health and/or to your local health department. (See local health department contact information on back cover.)
Provider Guide to Testing for Tuberculosis (TB) Infection and Post-test Referral

Step 1: Classify the Results for TB Infection Test

<table>
<thead>
<tr>
<th>HIV-positive persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons with medical risk factors for TB (Table 2)</td>
</tr>
<tr>
<td>Injection drug Users</td>
</tr>
<tr>
<td>Recent arrivals from high-incidence areas (Table 1)</td>
</tr>
<tr>
<td>Persons at higher risk for exposure to or infection with TB (Table 1)</td>
</tr>
<tr>
<td>Mycobacteriology lab personnel</td>
</tr>
<tr>
<td>Children under age 5</td>
</tr>
<tr>
<td>Children/adolescents exposed to adults in high-risk categories (Tables 1 &amp; 2)</td>
</tr>
</tbody>
</table>

**IGRA Positive**

- **Mycobacterium tuberculosis** (MTB) infection likely in most circumstances. Refer questions to the Utah Public Health Laboratory at (801) 965-2400 or T-Spot at 1(877) 598-2522

**High-Risk Contacts**

- Certain high-risk contacts need medical follow-up, including a chest x-ray, even if their reaction is less than 5 mm because they are at high-risk of 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-risk 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 (4).

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

Any person with a newly positive TST or IGRA test result, including high-risk 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

**No**

Evaluate for active TB disease

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. To view up-to-date M. tuberculosis incidence information by country: www.who.int/tbc/countryprofiles/en/ |
| 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 |
| Injection drug users |

### Table 2. Medical risk factors for the development of active TB disease in TB-exposed individuals

- HIV infection (or risk for HIV in individuals who decline HIV testing) |
- New TB infection within the previous two years |
- Evidence of old, healed TB on 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) |
- Sarcoidosis |
- Chronic malabsorption syndromes |
- Intestinal bypass or gastrectomy |
- Being ≥10% or more below ideal body weight |
- Injection drug use

### Table 3. Guidelines for treatment of TB infection by patient risk factors, TST result, IGRA result, and age

<table>
<thead>
<tr>
<th>CATEGORY OF PERSON TESTED</th>
<th>TST ≤ 5 mm</th>
<th>TST &gt; 5 mm</th>
<th>TST &gt; 10 mm</th>
<th>TST &gt; 15 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case Contact: Children &lt; age 5</strong></td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
</tr>
<tr>
<td><strong>Case Contact: HIV-infected</strong></td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
</tr>
<tr>
<td><strong>Case Contact: Immunocompromised</strong></td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
<td>Treat**</td>
</tr>
<tr>
<td><strong>Case Contact: ≥ age 5 and immunocompetent</strong></td>
<td>Repeatx</td>
<td>Repeatx</td>
<td>Repeatx</td>
<td>Repeatx</td>
</tr>
<tr>
<td><strong>Immunocompromised persons</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>HIV-infected</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Fibrocystic changes on chest x-ray</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Injection drug user</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Resident/employee in an institutional setting</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Mycobacteriology lab personnel</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>High-risk clinical conditions</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Child &lt; age 5</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>Persons age &lt; 17 exposed to high-risk adults</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
<tr>
<td><strong>No risk factors</strong></td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
<td>Do Not Treat</td>
</tr>
</tbody>
</table>

**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. Immunocompromised individuals with a second negative TST or IGRA need to be evaluated by a physician.

**IGRA Positive**

- **Interferon Gamma Release Assay (IGRA):** A negative test result indicates that infection is unlikely but cannot be excluded if: symptoms are consistent with active TB disease, influenza is highly likely, or the test result is positive. Repeat TST or IGRA test after 8-10 weeks. Always obtain a chest x-ray and rule out active TB before starting treatment.

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