



QuantiFERON – TB Gold Tuberculosis Test (In-Tube Method) QFT-IT

Healthcare Provider Information

What is QuantiFERON-TB Gold?

QuantiFERON-TB Gold (In-Tube Method) or QFT-IT, is an Interferon Gamma Release Assay (IGRA) for detection of immune response to tuberculosis infection by means of a blood test. As a modern alternative for the 110 year old tuberculin skin test (TST), QFT-IT provides clinicians with an accurate, reliable and convenient TB diagnostic tool. Studies have shown an overall sensitivity of approximately 87.6% and a specificity of approximately 99.2%. The QFT-IT system utilizes specialized blood collection tubes containing antigens representing *M. tuberculosis* proteins or controls.

How does it Work?

QFT-IT is an indirect test for *M. tuberculosis* infection, based on the measurement of a cell mediated immune response to peptide antigens that simulate mycobacterial proteins. These proteins, ESAT-6, CFP-10 and TB7.7 are absent from all BCG strains and from most non-tuberculous mycobacteria. Individuals infected with *M. tuberculosis complex* organisms usually have lymphocytes in their blood that recognize these and other mycobacterial antigens. There is a Nil antigen that serves as the patient's internal negative control and a mitogen protein that serves as the patient's internal positive control. This recognition process involves the generation and secretion of the cytokine, interferon-gamma (IFN- γ). The QFT-IT test accurately measures the IFN- γ response in a sensitive ELISA.

Indications for Use

CDC specific recommendations state IGRAs can be used 1) in all situations in which the CDC recommends a TST (routine screening with both an IGRA and TST is not recommended), 2) for testing persons from groups that historically have poor rates of return for TST reading, 3) for testing persons who have received BCG (as a vaccine or for cancer therapy), 4) to test recent contacts of persons with infectious tuberculosis with special considerations for follow-up testing, 5) for periodic screening that addresses occupation exposure to TB. Clients may be screened prior to starting certain types of medications and it is useful for those with a reduced immune system. A positive result should prompt the same evaluation and management as a positive TST.

Scheduling Appointments for a Blood Draw

Please call the Spokane Regional Health District Clinic at 509-324-1600 to schedule a blood draw appointment. For information on SRHD's TB services, please call 509-324-1614.

Specimen Referral to the Laboratory

The QFT-IT system is a 3-tube blood draw into specific antigen-coated tubes. (See pg. 3 for detailed specimen collection and handling instructions.) Specimens may be referred by Health Care Providers directly to SRHD Lab. Prior to specimen submission, contact Paula Maxwell, Client Services Manager, at (509)324-1660 to set up a billing contract. No private insurance billing available.

Requesting Supplies

To receive a supply of QFT In-Tubes (3/set), requisitions and mailers, please call Shannon at (509) 324-1444. Packaging and shipping instructions will be provided with the mailers.

Where to Send the Sample

- Include the Spokane Regional Health District Laboratory QFT-IT requisition. Copies of the requisition can be faxed or emailed upon request.
- Specimens cannot be accepted on Fridays *and* the day before a holiday unless the QFT In-Tubes have been incubated prior to transport to the lab. (See pg. 2 "2012 Holiday Schedule for Accepting QFT Specimens")
- Incubated** specimens are accepted: Monday –Friday from 8:00 a.m. – 3:30 p.m.
- Specimens **not incubated** are accepted: Monday –Thursday from 8:00a.m. – 3:30 p.m.
- Deliver specimens to: Spokane Regional Health District Laboratory, Room 210
1101 West College Avenue, Spokane, WA 99201-2095.

Interpretation of Results

Negative:	Same interpretation as the TST, no further evaluation unless indicated by clinical judgment.
Positive:	Same interpretation as the TST. Radiographs and medical evaluation indicated.
Indeterminate:	QFT-IT may be indeterminate due to several reasons a (e.g., patient anergy, high background levels, gross hemolysis, gross lipemia, and inadequate mixing or handling of In-Tubes). A redraw is suggested in 8 - 12weeks.

Limitations

A patient's ability to respond to antigens is dependent on their immune system. Some individuals (1-2% of the population) may have high background levels of IFN- γ or heterophile antibodies that interfere with detection of responses to ESAT-6, CFP-10 and TB7.7. Medical treatments or conditions that impair immune function can potentially reduce IFN- γ response and prevent detection of a specific response to these antigens. Some specimens may not have sufficient lymphocytes to detect specific IFN- γ response.

The performance of the QFT-IT continues to be evaluated in the following groups of individuals:

- Individuals who have impaired immune response. Impaired immune response can be caused by HIV infection or AIDS, current treatment with immunosuppressive drugs including high doses of corticosteroids, tumor necrosis factor- alpha antagonists, and drugs used for managing organ transplantation, selected hematologic disorders (e.g. myeloproliferative disorders, leukemias, and lymphomas), specific malignancies (e.g., carcinoma of the head, neck, or lung), diabetes, silicosis, and chronic renal failure.
- Individuals with a high likelihood of *M. tuberculosis* infection progressing to tuberculosis disease.
- Patients who have been treated for either Latent Tuberculosis Infection (LTBI) or tuberculosis disease.
- Individuals with medical conditions other than, or in addition to, LTBI or tuberculosis disease.
- Individuals younger than 5 years.
- Pregnant women.

As with a negative TST result, a negative QFT-IT result alone might not be sufficient to exclude *M. tuberculosis* infection in these individuals. **Additional Information at:** www.cdc.gov/mmwr/pdf/rr/rr5905.pdf

SRHD 2012 HOLIDAY SCHEDULE - Closed the following holidays:

Monday, January 2, 2012	New Year's Day
Monday, January 16, 2012	Martin Luther King, Jr's Day
Monday, February 20, 2012	President's Day
Monday, May 28, 2012	Memorial Day
Wednesday, July 4, 2012	Independence Day
Monday, September 3, 2012	Labor Day
Monday, November 12, 2012	Veteran's Day
Thursday & Friday, November 22 & 23, 2012	Thanksgiving Day & day after
Monday, December 24, 2012	Christmas Eve
Tuesday, December 25, 2012	Christmas Day

The Laboratory can accept QFT In-Tubes during a holiday week on the following days:

QFT In-Tubes incubated:		QFT In-Tubes <i>NOT</i> incubated:	
If the holiday(s) falls on:	Specimens accepted:	If the holiday(s) falls on:	Specimens accepted:
Monday	T, W, TH, F 8:00 – 3 :30pm	Monday	T, W, TH 8:00 – 3 :30pm
Tuesday	M, W, TH, F	Tuesday	W, TH
Wednesday	M, T, TH, F	Wednesday	M, TH
Thursday	M, T, W, F	Thursday	M, T
Friday	M, T, W, TH	Friday	M, T, W
Thursday & Friday	M, T, W	Thursday & Friday	M, T

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QFT-IT - uses the following set of 3 heparin tubes provided by the Lab:

- **Gray cap** = Nil (Specimen Negative Control)
- **Red cap** = TB Antigens (ESAT-6, CFP-10 and TB7.7)
- **Purple cap** = Mitogen Control (Specimen Positive Control)

NOTE: Antigens have been dried onto the inner wall of the blood collection tubes so it is essential that the contents of the tubes be thoroughly mixed with the blood.

Specimen Collection for QFT-IT:

1. Collect **1mL** of blood into each of the 3 QFT-IT tubes:
 - For venipuncture collection, 1mL tubes draw blood slowly so keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling, to ensure that the correct volume is drawn. The black mark on the side of the tubes indicates the 1mL fill volume. Tubes must have between 0.8mL – 1.2mL of blood. If the level of blood in any tube is not close to the indicator line, draw another tube.
 - For syringe draws, remove the needle, ensuring appropriate safety procedures, transfer 1mL of blood from the syringe into each tube by removing the caps.
 - If a “butterfly needle” is being used to collect blood, a “purge” tube (not a QFT-IT tube) should be used to ensure that the tubing is filled with blood prior to the QFT-IT tubes being used.
2. Immediately after filling, shake tubes ten (10) times just firmly enough to ensure that the entire inner surface of the tube has been coated with blood. Thorough mixing is required to ensure solubilization of the antigens on the tube walls into the blood. If this step is omitted, the result may be compromised. Over-energetic shaking may cause gel disruption and could lead to aberrant results.
3. Label all tubes with the patient's **LAST NAME, FIRST; DATE AND TIME** drawn.
4. Samples must be submitted with an SRHD Laboratory, “Request for QuantiFERON-TB Gold (QFT-G)” requisition. Please fill out form completely and print clearly. The date, time drawn and incubation sections must be filled in.

Specimen Handling Options for QFT-IT:

OPTION 1 - No Incubation and Transport

- If no incubator is available, the 3 QFT-IT tubes must be received by the laboratory within **16 hours** of collection.
- Prior to incubation, **store and transport tubes at ambient temperature (22°± 5°C, 72°± 9°F)**.
- Do not transport on ice or refrigerate.

OPTION 2 - Incubate and Transport

- The 3 QFT-IT tubes should be transferred to a **37°± 1°C** incubator as soon as possible. Up to **16 hours** is allowed prior to incubation.
- If the blood is not incubated immediately after collection, re-mixing of the tubes by **inverting (10) ten times** must be repeated immediately prior to incubation.
- Incubate the tubes upright at **37°± 1°C** for **16-24 hours**. The incubator does not require CO₂ or humidification although a CO₂ incubator is acceptable.
- Following incubation, blood tubes may be held between **2°- 27°C** for up to **3 days** prior to centrifugation. The tubes must arrive at the lab within **3 days** of incubation. Tubes may be transported at ambient temperature.

OPTION 3 – Incubate, Centrifuge and Transport

- The 3 QFT-IT tubes should be transferred to a **37°± 1°C** incubator as soon as possible. Up to **16 hours** is allowed prior to incubation.
- If the blood is not incubated immediately after collection, re-mixing of the tubes by **inverting (10) ten times** must be repeated immediately prior to incubation.
- Incubate the tubes upright at **37°± 1°C** for **16-24 hours**. The incubator does not require CO₂ or humidification although a CO₂ incubator is acceptable.
- After incubation, centrifuge tubes for **15 minutes at 2000 – 3000 RCF (g)**. The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be re-centrifuged at a higher speed. **Plasma may be stored up to 28 days in the tube.**
- Following incubation, blood tubes may be held between **2°- 27°C** for up to **3 days** prior to centrifugation.