

QuantiFERON-TB Gold (QFT) Supplemental Information

Tuberculosis is a communicable disease caused by infection with M. Tuberculosis complex organisms, which typically spreads to new hosts via airborne droplet nuclei from patients with respiratory tuberculosis disease. A newly infected individual can become ill from tuberculosis within weeks to months, but most infected individuals remain well. Latent tuberculosis infection (LTBI), a non-communicable asymptomatic condition, persists in some, who might develop tuberculosis disease months or years later. The main purpose of diagnosing LTBI is to consider medical treatment for preventing tuberculosis disease. Until recently the tuberculin skin test (TST) was the only available method for diagnosing LTBI. The QFT test is both a test for LTBI and a helpful aid for diagnosing M. tuberculosis complex infection in sick patients. A positive result supports the diagnosis of tuberculosis disease, but infection by other mycobacteria could also lead to positive results. Other medical and diagnostic evaluations are necessary to confirm or exclude tuberculosis disease.

Specimen Collection

1. Collect Blood

- Use only the provided QuantiFERON-TB Gold Plus tubes
- Tubes should be stored at 17°-25°C
- Fill each tube to the black mark
- 1 ml of blood is needed in each tube
- Do not overfill or underfill tubes

2. Shake Tubes

- Shake tubes ten times after filling
- Ensure the entire inner surface of the tube is coated with blood

3. Label Tubes

- Label all tubes with patient name or unique identifier
- Do not cover or in any way obscure the fill line on the tube

4. Determine if specimens will be incubated at your facility or at the SDPHL

Option 1: Incubate at Your Facility

- Reshake if tubes were not immediately incubated following blood draw
- Incubate tubes upright at 37°C for 16-24 hours
- Label tubes as “Incubated”
- Place the series of four tubes and requisition form in biohazard specimen bag
- Ship to the SDPHL within 3 days of incubation.
- Draw Mon-Wed only to allow transport to the lab within 3 days of incubation.

Option 2: Incubate at the SDPHL

- Label tubes as “Not Incubated”
- Place the series of four tubes and requisition form in biohazard specimen bag
- Ship to the SDPHL
- Tubes **MUST be received within 16 hours** of collection

Criteria for Unacceptable Specimens

1. The specimen was not properly labeled with the patient's name or a unique identifier.
2. The patient identifier on the specimen does not match the identifier on the form.
3. Blood not incubated within 16 hours of collection.
4. Blood not centrifuged within 3 days of collection.
5. The specimen did not contain the correct volume of blood.
6. The specimen did not arrive in appropriate temperature transport range.

Warnings and Precautions

- A negative QFT results does not preclude the possibility of M. Tuberculosis infection or tuberculosis disease: false negative results can be due to stage of infection (e.g., specimen obtained prior to the development of cellular immune response), co-morbid conditions which affect immune functions, incorrect handling of the blood collection tubes following venipuncture, incorrect performance of the assay, or other immunological variables.
- A positive QFT result should be followed by further medical evaluation and diagnostic evaluation for active tuberculosis disease (e.g., AFB smear and culture, chest X-ray).
- A positive QFT result should not be the sole or definitive basis for determining infection with M. Tuberculosis. Incorrect performance of the assay may cause false-positive responses.