

Mycobacterium tuberculosis Infection

Determination by QuantiFERON-TB Gold Plus

Collection and Processing Instructions

Blood Collection

Note: All collection tubes need to be at room temperature (17–27 °C) at the time of draw.

A. Directly into 4 Tube QuantiFERON-TB Gold Plus Kit (Preferred)

1. Collect 1 mL of blood into each of 4 tubes.
 - **Tubes fill slowly.**
 - Use of a syringe may ensure correct blood volume.
 - When the tube is upright, blood must meet the small black mark on the label.
 - If butterfly needle is used, first collect other required tubes or use a “purge” tube to remove the air and then proceed with collecting the QTB tubes.
 - These tubes are manufactured to draw 1 mL of blood and perform optimally within the range of 0.8 to 1.2 mL. If the level of blood is outside of the black indicator line, another blood specimen should be collected (see figure 1).
2. Immediately invert the tubes firmly 10 times (see figure 2).
 - Entire inner surface of tubes must be coated with blood.
 - Overly energetic inverting may cause gel disruption and could lead to aberrant results.
 - Thorough mixing is required to ensure complete integration of the tube’s contents into the blood.
3. Label tubes appropriately. The label should be placed below colored Quantiferon band so back window and black marks are visible on all 4 collection tubes. Failure to label properly will lead to decreased efficiency and testing delays (see figure 3).
4. Maintain tubes at room temperature (17–27 °C) until incubation. Do not refrigerate or freeze.
5. Incubation of the 4 tubes must be started within 16 hours of collection.

B. Collection into a Single Heparin (Sodium or Lithium) Tube and Transfer to QFT-Blood Collection Tubes

1. Blood may be collected in a single blood collection tube containing heparin as the anticoagulant and then transferred to QFT-Plus blood collection tubes. Only use heparin as a blood anticoagulant because other anticoagulants interfere with the assay.
 - a. Label tubes appropriately. It is recommended to label the tube with the time and date of the blood collection.

Important: Blood collection tubes should be at room temperature (17–25 °C) at the time of blood collection.
2. Fill a heparin blood collection tube (minimum volume 5 mL) and gently mix by inverting the tube several times to dissolve the heparin.

(Section B. continued on page 2)

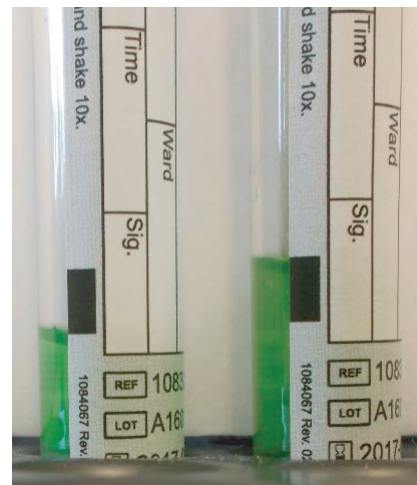


Figure 1. Under- or over-filling of the tubes outside of the 0.8 mL (bottom of black mark) to 1.2 mL (top of black mark) range may lead to erroneous results. Specimens with volumes outside of black mark will be rejected.



Figure 2. Entire inner surface of tube must be coated with blood.

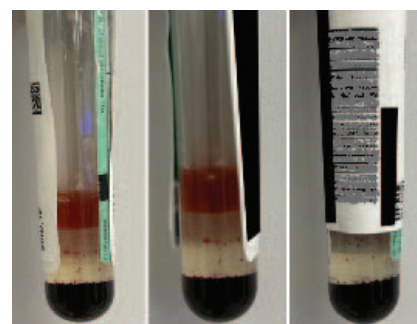


Figure 3. Tube labeling examples.

3. Following blood collection into a heparin tube, the following are options for hold time and temperatures prior to transfer of blood into the 4 QFT-Plus tubes.

Option 1 – Heparin Tube Room Temperature Storage and Handling

- a. Blood collected in heparin tube must be maintained at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for no more than 12 hours from the time of collection prior to transfer to QFT-Plus blood collection tubes and subsequent incubation.

Option 2 – Heparin Tube Refrigerated Storage and Handling

Important: Procedural steps a–d must be followed in sequence.

- a. Blood drawn into heparin tube can be held at room temperature ($17\text{--}25^{\circ}\text{C}$) 3 hours after blood collection.
- b. Blood drawn into heparin tube may be refrigerated ($2\text{--}8^{\circ}\text{C}$) immediately up to 48 hours.
- c. After refrigeration, heparin tube must equilibrate to room temperature ($17\text{--}25^{\circ}\text{C}$) prior to transfer to QFT-Plus blood collection tubes.
- d. Aliquotted QFT-Plus Blood Collection Tubes should be placed in the 37°C incubator within 2 hours of blood transfer.

Note: If QFT-Plus Blood Collection Tubes are not incubated at 37°C directly after transfer to QFT-Plus Blood Collection Tubes, invert the tubes to mix 10 times prior to incubation at 37°C . Total time from blood draw to incubation in QFT-Plus blood collection tubes should not exceed 53 hours.

4. Transfer of blood specimen to QFT-Plus blood collection tubes:
- a. Label each QFT-Plus blood collection tube appropriately. Ensure each tube (Nil, TB1, TB2 and Mitogen) is identifiable by its label or other means once the cap is removed. Failure to label properly will lead to decreased efficiency and testing delays (see Figure 3). It is recommended to transfer the recorded time and date of blood collection from the heparin tubes to the QFT-Plus blood collection tubes.
 - b. Samples must be evenly mixed by gentle inversion before dispensing into QFT-Plus blood collection tubes.
 - c. Dispensing should be performed aseptically, ensuring appropriate safety procedures, removing the caps from the 4 QFT-Plus blood collection tubes and adding 1 mL of blood to each tube. Replace the tube caps securely and mix tubes well before incubation.

Incubation and Centrifugation

Notes: The following types of specimens will be rejected:

- Grossly hemolyzed, lipemic, and icteric
- Not incubated
- Not centrifuged
- Received in heparin (sodium or lithium) tubes
- Incubation in waterbath or heat block

1. Incubate all 4 QFT-Plus tubes upright at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 16 to 24 hours.
2. Following incubation centrifuge for 15 minutes at 2,000–3,000 RCF (g).
3. Place all 4 QFT-Plus tubes together in the supplied QTB Transport bag (see figure 4).
4. Store refrigerate 2°C to 8°C . Stable 28 days refrigerated.



Figure 4. Shipping
(Ship QTB kit refrigerate: $2^{\circ}\text{--}8^{\circ}\text{C}$)