

QuantiFERON[®]-TB Gold Plus — assay

Option 1: Receive lithium-heparin tubes

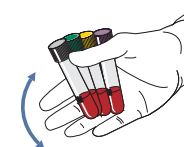
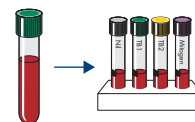
Lithium-heparin tube processing guidelines

- Blood drawn into a lithium-heparin tube and maintained at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$) must be transferred to QFT-Plus Blood Collection tubes and incubated within 12 hours from the time of collection.
- Blood drawn into lithium-heparin tube and refrigerated may remain at $2\text{--}8^{\circ}\text{C}$ for 16 to 48 hours.
 - After refrigeration, the lithium-heparin tube must equilibrate to room temperature ($17\text{--}25^{\circ}\text{C}$) prior to transfer to QFT-Plus Blood Collection Tubes.



Transfer of blood specimen to QFT-Plus Blood Collection Tubes

1. Label each QFT-Plus Blood Collection Tube appropriately.
2. Samples must be evenly mixed by gentle inversion before dispensing into QFT-Plus Blood Collection Tubes.
3. Dispensing should be performed aseptically, ensuring appropriate safety procedures. Remove the caps from the 4 QFT-Plus Blood Collection Tubes and add 1 ml of blood to each tube.
4. Immediately after filling the QFT-Plus Blood Collection Tubes, shake them ten (10) times just firmly enough to make sure the entire inner surface of the tube is coated with blood. This will dissolve antigens on tube walls.



Important: Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

5. Transfer the QFT-Plus Blood Collection Tubes to a $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator within 2 hours.

Proceed to step 6.

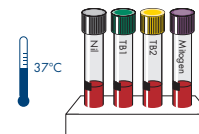
Option 2: Receive unincubated QFT-Plus Blood Collection Tubes

QFT-Plus tubes processing guidelines

- Blood drawn directly into QFT-Plus Blood Collection Tubes must be transferred to a $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator as soon as possible, and within 16 hours of collection.

Incubate the QFT-Plus Blood Collection Tubes

6. If QFT-Plus Blood Collection Tubes are not incubated at 37°C directly after blood collection and shaking, invert the tubes to mix 10 times prior to incubation at 37°C .
7. Incubate QFT-Plus Blood Collection Tubes UPRIGHT at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 16 to 24 hours.

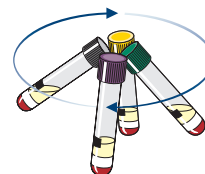


Proceed to step 8.

Option 3: Receive incubated QFT-Plus Blood Collection Tubes

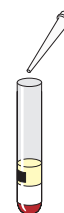
Centrifuge QFT-Plus tubes and harvest plasma

- After incubation of the QFT-Plus Blood Collection Tubes at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$, tubes may be held between 4°C and 27°C for up to 3 days prior to centrifugation.
- Centrifuge tubes at 2000–3000 x g (RCF) for 15 minutes
 - Centrifuged tubes should be handled with care to avoid mixing of plasma.
 - Plasma in centrifuged tubes is stable for up to 28 days when stored at $2\text{--}8^{\circ}\text{C}$.
- Harvest plasma samples using a pipet.



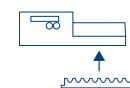
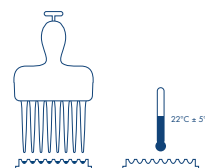
Important: After centrifugation, avoid pipetting plasma up and down or mixing plasma by any means prior to harvesting. At all times, take care not to disturb material on the surface of the gel.

- Plasma samples can be loaded directly from centrifuged blood collection tubes into the QFT-Plus ELISA plate.
- Plasma samples can be stored in centrifuged blood collection tubes for up to 28 days at 2°C to 8°C . Harvested plasma samples can also be stored below -20°C (preferably less than -70°C) for extended periods.



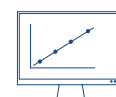
Perform QFT-Plus ELISA

- Add 50 μl of working-strength conjugate to each well of the QFT-Plus ELISA plate.
- Add 50 μl of test plasma or standards to the appropriate wells of the QFT-Plus ELISA plate.
- Incubate for 120 ± 5 minutes at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$).
- Wash the ELISA plate wells with 400 μl wash buffer at least 6 times.
- Add 100 μl of substrate solution. Incubate for 30 minutes at room temperature.
- Add 50 μl of stop solution. Read absorbance at 450 nm (620–650 nm ref).



Calculate results

- Calculate results using the most current version of the QuantiFERON-TB Gold Plus Analysis Software for your region, available for download at www.QuantiFERON.com.



For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.



For comprehensive instructions for use, refer to the QFT-Plus ELISA package insert, available in multiple languages, at www.QuantiFERON.com.

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