August 2019

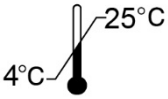
QuantiFERON®-TB Gold Plus (QFT®-Plus) Blood Collection Tubes Instructions for Use

Σ 50 (622526, 623526)

Σ 25 (622423, 623423)

Version 1

IVD



For in vitro diagnostic use

For use with QuantiFERON-TB Gold Plus ELISA or LIAISON® QuantiFERON-TB Gold Plus System

CE

REF 622526, 622423, 623526, 623423

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R7 MAT 1085208

QIAGEN

Contents

Blood Collection Tubes

Blood collection tubes		200 tubes	100 tubes
Catalog no.		622526	622423
QuantiFERON Nil Tube (gray cap, white ring)	Nil	50 tubes	25 tubes
QuantiFERON TB1 Tube (green cap, white ring)	TB1	50 tubes	25 tubes
QuantiFERON TB2 Tube (yellow cap, white ring)	TB2	50 tubes	25 tubes
QuantiFERON Mitogen Tube (purple cap, white ring)	Mitogen	50 tubes	25 tubes
QFT-Plus Blood Collection Tubes Package Insert		1	1

High Altitude (HA) Blood Collection Tubes (for use between 1020 and 1875 meters)		200 tubes	100 tubes
Catalog no.		623526	623423
QuantiFERON HA Nil Tube (gray cap, yellow ring)	Nil	50 tubes	25 tubes
QuantiFERON HA TB1 Tube (green cap, yellow ring)	TB1	50 tubes	25 tubes
QuantiFERON HA TB2 Tube (yellow cap, yellow ring)	TB2	50 tubes	25 tubes
QuantiFERON HA Mitogen Tube (purple cap, yellow ring)	Mitogen	50 tubes	25 tubes
QFT-Plus Blood Collection Tubes Package Insert		1	1

Important note: Altitude affects the blood collection volume of a tube. Use standard QFT-Plus Blood Collection Tubes between sea level and 810 m (2650 ft). Use High-Altitude (HA) tubes at altitudes between 1020 m (3350 ft) and 1875 m (6150 ft). If using QFT-Plus Blood Collection Tubes outside these altitude ranges, or if low blood-draw volume occurs, collect blood using alternate collection methods described below. The blood collection tubes supplied are for use only with the QFT-Plus ELISA or the LIAISON® QuantiFERON-TB Gold Plus System (REF: 311010), and the following instructions relate solely to the use of QFT-Plus Blood Collection Tubes.

Antigens have been dried onto the inner wall of the blood collection tubes, so it is essential to thoroughly mix the contents of the tubes with the blood. The tubes must be transferred to a

37°C incubator as soon as possible and within 16 hours of blood collection. Follow the procedures below for optimal results.

Precautions

For in vitro diagnostic use only.
When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs) available online in convenient and compact PDF format to view and print at www.qiagen.com/safety.

CAUTION: Handle human blood as if potentially infectious.

Observe relevant blood handling guidelines. Dispose of samples and materials in contact with blood or blood products in accordance with federal, state, and local regulations.

Direct draw into QFT-Plus Blood Collection Tubes

1. Label tubes appropriately. Ensure each tube (Nil, TB1, TB2, and Mitogen) is identifiable by its label or other means once the cap is removed.
2. For each patient, collect 1 ml of blood by venipuncture directly into each of the QFT-Plus Blood Collection Tubes. A trained phlebotomist should perform this procedure.

Important note: Tubes should be between 17° to 25°C at the time of blood filling.

A. As 1 ml tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling. This will ensure correct draw volume.

B. The black mark on the side of the tubes indicates the validated range of 0.8–1.2 ml. If the level of blood in any tube is outside the range of the indicator mark, obtain a

new blood sample. Under or over-filling of the tubes outside of the 0.8 to 1.2 ml range may lead to erroneous results.

C. If using a "butterfly needle" to collect blood, use a "purge" tube to ensure that the tubing is filled with blood prior to using the QFT-Plus tubes.

D. Use QFT-Plus Blood Collection tubes up to an altitude of 810 meters (2650 feet) above sea level. Use HA QFT-Plus Blood Collection Tubes at altitudes between 1020 and 1875 meters (3350 and 6150 feet).

E. If using QFT-Plus Tubes at an altitude higher than 810 meters (2650 ft), but not between 1020 m (3350 ft) and 1875 m (1610 ft), or if low blood-draw volume occurs, users can collect blood with a syringe and immediately transfer 1 ml of blood to each of the 4 QFT-Plus tubes. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the caps from the 4 QFT-Plus tubes, and adding 1 ml of blood to each tube (to the center of the black mark on the side of the tube label). Ensure each tube (Nil, TB1, TB2, and Mitogen) is identifiable by its label or other means once the cap is removed. Replace the caps securely and mix as described below. Alternatively, blood may be collected in a single generic blood collection tube containing lithium heparin or sodium heparin as the anticoagulant and then transferred to the QFT-Plus tubes. Only use lithium heparin or sodium heparin as a blood anticoagulant because other anticoagulants interfere with the assay. Fill a blood collection tube (5-ml minimum volume) and gently mix by inverting the tube several times to dissolve the lithium heparin or sodium heparin. Blood tubes must be maintained and transported at room temperature (22°C ± 5°C) before transfer to QFT-Plus tubes for incubation, which must be initiated within 16 hours of blood collection. If blood has been collected in a lithium-heparin or sodium-heparin tube, samples must be evenly mixed by gentle inversion before dispensing into QFT-Plus tubes. Perform dispensing aseptically (ensuring appropriate safety procedures) by removing the caps from the 4 QFT-Plus tubes and adding 1 ml of blood to each (to the center of the black mark on the side of the tube label). Replace the tube caps securely and mix as described below.

3. Immediately after filling tubes, shake them ten (10) times just firmly enough to ensure the entire inner surface of the tube is coated with blood. This will dissolve antigens on tube walls.

   Important note: Tubes should be between 17° to 25°C at the time of shaking. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

4. Following labeling, filling, and shaking, the tubes must be transferred to a 37°C ± 1°C incubator as soon as possible and within 16 hours of collection. Prior to incubation, maintain and transport the tubes at room temperature (22°C ± 5°C).

   If the blood is not incubated immediately after collection, users must immediately re-mix the tubes by inverting 10 times prior to incubation.

5. Incubate the tubes UPRIGHT at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO_2 or humidification.

Blood Collection into a single lithium- or sodium-heparin tube and then transfer to QFT-Plus Blood Collection Tubes

1. Blood may be collected in a single blood collection tube containing lithium or sodium heparin as the anticoagulant and then transferred to QFT-Plus Blood Collection Tubes. Only use lithium or sodium heparin as a blood anticoagulant because other anticoagulants interfere with the assay. 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 lithium- or sodium-heparin blood collection tube (minimum volume 5 ml) and gently mix by inverting the tube several times to dissolve the heparin. This procedure should be performed by a trained phlebotomist.

3. Hold time and temperature options for lithium- or sodium-heparin tubes prior to transfer and incubation in QFT-Plus Blood Collection Tubes (See Figures 1–3 Blood Collection Options).

   Option 1 – Lithium- or Sodium-Heparin Tube Room Temperature Storage and Handling

   Blood collected in lithium- or sodium-heparin tube must be maintained at room temperature (22°C ± 5°C) for no more than 16 hours from the time of collection prior to transfer to QFT Plus Blood Collection Tubes and subsequent incubation.

   Option 2 – Lithium- or Sodium-Heparin Tube Refrigerated Storage and Handling

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

   a. Blood drawn into lithium- or sodium-heparin tube may be held at room temperature (17–25°C) up to 3 hours after blood collection.
   b. Blood drawn into lithium- or sodium-heparin tube may be refrigerated (2–8°C) for up to 48 hours.
   c. After refrigeration, lithium- or sodium-heparin tube must equilibrate to room temperature (17–25°C) prior to transfer to QFT-Plus Blood Collection Tubes.
   d. Aliquoted QFT-Plus Blood Collection Tubes should be placed in the 37°C incubator within 2 hours of blood transfer.

   If QFT-Plus Blood Collection Tubes are not incubated at 37°C directly after transfer to QFT-Plus Blood Collection Tubes and shaking, 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 from a lithium- or sodium-heparin tube to QFT-Plus Blood Collection Tubes (Important: QFT-Plus Blood Collection Tubes should be at room temperature [17–25°C (62.6 –77°F)] at the time of blood collection.):

   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. It is recommended to transfer the recorded time

and date of blood collection from the lithium- or sodium-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 as described below. Ensure each tube (Nil, TB1, TB2 and Mitogen) is identifiable by its label or other means once the cap is removed.

5. Mix tubes. 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.

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

6. Following labeling, filling and shaking, the tubes must be transferred to a 37°C ± 1°C incubator within 2 hours. 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 (10x) prior to incubation at 37°C. (See Figures 1–3, next page, for blood collection options).

7. Incubate the QFT-Plus Blood Collection Tubes UPRIGHT at 37°C ± 1°C for 16 to 24 hours.

   The incubator does not require CO_2 or humidification.

Draw into QFT Plus Blood Collection Tubes and hold at room temperature.

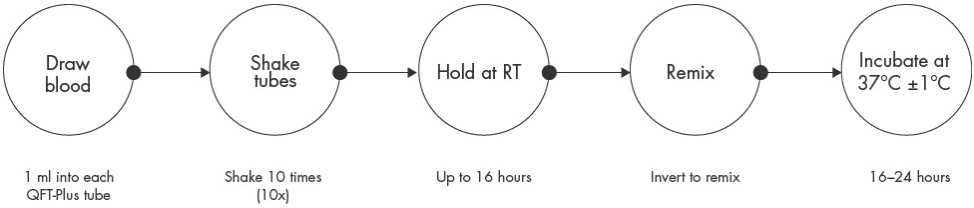


Figure 1. Blood collection option: Directly draw into QFT-Plus Blood Collection Tubes and hold at room temperature. The total time from blood draw in QFT-Plus Blood Collection Tubes to 37°C incubation must not exceed 16 hours.

Draw into lithium- or sodium-heparin tube and hold at room temperature.

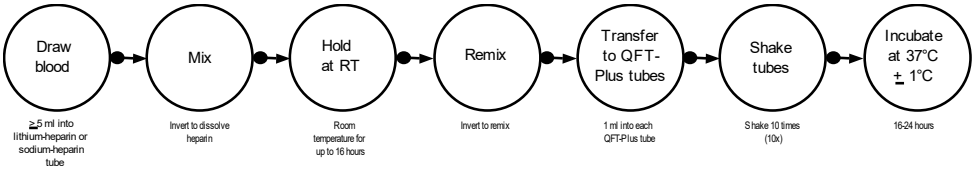
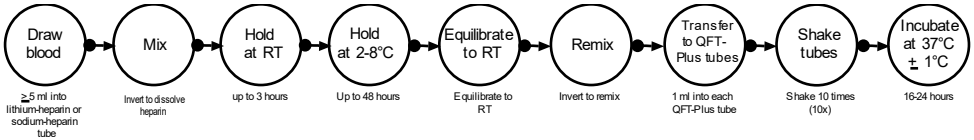


Figure 2. Blood collection option: Draw into lithium- or sodium-heparin tube and hold at room temperature.
The total time from blood draw in lithium- or sodium-heparin tube to 37°C incubation must not exceed 16 hours.

Draw into lithium- or sodium-heparin tubes and hold at 2–8°C.



Aliquotted QFT-Plus Blood Collection Tubes should be placed in a 37°C incubator within 2 hours of blood transfer to QFT-Plus Blood Collection Tubes.

Figure 3. Blood collection option: Draw into lithium- or sodium-heparin tube and hold at 2–8°C.
The total time from blood draw in lithium- or sodium-heparin tube to 37°C incubation must not exceed 53 hours.

8. After incubation, blood collection tubes may be held between 4°C to 27°C for up to 3 days prior to centrifugation.
9. After incubation, centrifuge tubes for 15 minutes at 2000 to 3000 RCF (*g*). The gel plug will separate the cells from the plasma. If this does not occur, centrifuge the tubes again.

   It is possible to harvest the plasma without centrifugation; however, this requires additional care to remove the plasma without disturbing the cells.
10. Harvest plasma samples using only a pipette.

    Important note: After centrifugation, avoid pipetting 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 either the QFT-Plus ELISA plate, including when automated ELISA workstations are used, or onto the LIAISON QuantiFERON-TB Gold Plus System (REF: 311010). Plasma samples can be stored for up to 28 days at 2–8°C or, if harvested, below –20°C for extended periods.

Symbols

The following symbols may appear on the packaging and labeling:

Symbol	Symbol definition
	Contains reagents sufficient for <N> reactions
	Legal manufacturer
	CE-IVD marked symbol
	For in vitro diagnostic use
	Global Trade Item Number
	Temperature limitation
	Consult instructions for use
	Do not reuse
	Material number
Rn	R is for revision of the Instructions for Use and n is the revision number

Handbook Revision History

Document	Changes
R5 04/2019	Lithium heparin/Sodium heparin changes New work instructions for 2–8°C blood collection workflow
R6 08/2019	Added reference to QFT-Plus ELISA to front cover
R7 08/2019	Removed extra page

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