

April 2019

QuantiFERON[®]-TB Gold Plus (QFT[®]-Plus) Blood Collection Tubes Package Insert

RX ONLY

IVD

For in vitro diagnostic use



www.QuantiFERON.com

REF

622536, 622433, 623536, 623433, 622529,
623529



QIAGEN, 19300 Germantown Road, Germantown,
MD 20874, USA. Phone: +1-800-426-8157

1095852 Rev. 04

Sample to Insight



Kit Contents

Blood Collection Tubes*		200 tubes	100 tubes	4800 tubes
Catalog no.		622536	622433	622529
QuantiFERON Nil Tube (gray cap, white ring)	Nil	50 tubes	25 tubes	1200 tubes
QuantiFERON TB1 Tube (green cap, white ring)	TB1	50 tubes	25 tubes	1200 tubes
QuantiFERON TB2 Tube (yellow cap, white ring)	TB2	50 tubes	25 tubes	1200 tubes
QuantiFERON Mitogen (purple cap, white ring)	Mitogen	50 tubes	25 tubes	1200 tubes
QFT Blood Collection Tubes Package Insert	–	1	1	4

* Not all product configurations are available in every country. Please refer to QIAGEN customer care (details on www.qiagen.com) for more information on what configurations are available for ordering.

High Altitude (HA) Blood Collection Tubes (for use between 1020 and 1875 meters)*		200 tubes	100 tubes	4800 tubes
Catalog no.		623536	623433	623529
QuantiFERON HA Nil Tube (gray cap, yellow ring)	Nil	50 tubes	25 tubes	1200 tubes
QuantiFERON HA TB1 Tube (green cap, yellow ring)	TB1	50 tubes	25 tubes	1200 tubes
QuantiFERON HA TB2 Tube (yellow cap, yellow ring)	TB2	50 tubes	25 tubes	1200 tubes
QuantiFERON HA Mitogen (purple cap, yellow ring)	Mitogen	50 tubes	25 tubes	1200 tubes
QFT Blood Collection Tubes Package Insert	–	1	1	4

* Not all product configurations are available in every country. Please refer to QIAGEN customer care (details on www.qiagen.com) for more information on what configurations are available for ordering.

Important: The blood draw volume of a tube is affected by altitude. High Altitude QFT-Plus Blood Collection Tubes have been validated to ensure that the correct volume of blood is collected if you are using the tubes above 1020 m (3350 ft), but below 1875 m (6150 ft).

Standard QFT-Plus Blood Collection Tubes should be used between sea level and 810 m (2650 ft).

If using QFT-Plus Blood Collection Tubes outside these altitude ranges, or if low blood draw volume does occur, blood can be collected using alternate collection methods, as described in the instructions below. The blood collection tubes supplied are for use only with the QFT-Plus assay, 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 QFT-Plus Blood Collection Tubes, so it is essential that the contents of the tubes be thoroughly mixed with the blood. The QFT-Plus tubes must be transferred to a 37°C incubator as soon as possible and within 16 hours of blood collection.

Alternatively, blood may be collected into a single lithium-heparin tube for storage prior to transfer to QFT-Plus Blood Collection Tubes and incubation. Blood specimens collected in lithium-heparin tubes can be stored at room temperature (17–25°C) but for no more than 12 hours from the time of collection prior to transfer to QFT-Plus Blood Collection Tubes and subsequent incubation. Blood specimens in lithium-heparin tubes may also be stored at 2–8°C up to 48 hours prior to transfer to the QFT-Plus Blood Collection Tubes. Refer to section “Blood collection into a single lithium-heparin tube and then transfer to QFT-Blood Collection Tubes” below.

Important: Blood collection tubes (QFT-Plus Blood Collection Tubes for direct draw, or lithium-heparin tubes when blood is collected into a single lithium-heparin tube initially) should be at room temperature (17°C to 25°C [62.6–77°F]) at the time of blood collection.

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.

Blood Collection and Hold Time Options

See Blood Collection Options below (Figures 1–3).

Direct draw into QFT-Plus Blood Collection Tubes

1. Label tubes appropriately.

Make sure each tube (Nil, TB1, TB2 and Mitogen) is identifiable by its label or other means once the cap is removed.

It is recommended to record the time and date of blood collection.

Important: QFT-Plus Blood Collection Tubes should be at room temperature 17–25°C (62.6–77°F) at the time of blood collection.

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2. For each patient, collect 1 ml of blood by venipuncture directly into each of the QFT-Plus Blood Collection Tubes. This procedure should be performed by a trained phlebotomist.
 - 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 that the correct volume is drawn.
 - b) The black mark on the side of the tubes indicates the validated range of 0.8 to 1.2 ml. If the level of blood in any tube is outside of the indicator mark, a new blood sample should be obtained. Under- or over-filling of the tubes outside of the 0.8 to 1.2 ml range may lead to erroneous results.
 - c) If a “butterfly needle” is being used to collect blood, a “purge” tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus Blood Collection tubes being used.
 - d) QFT-Plus Blood Collection Tubes can be used up to an altitude of 2650 feet (810 meters) above sea level. HA QFT-Plus Blood Collection Tubes should be used at altitudes between 3350 and 6150 feet (1020 and 1875 meters).
 - e) If using QFT-Plus Blood Collection Tubes outside these altitude ranges between 2650 and 3350 feet (810 and 1020 meters) or above 6150 feet (1875 meters), or if low blood draw volume occurs, users can collect blood with a syringe, and immediately transfer 1 ml to each of the 4 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 Blood Collection Tubes and adding 1 ml of blood to each (to the black mark on the side of the tube label which indicates the validated range of 0.8 to 1.2 ml). Replace the 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.

3. Immediately after filling the 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 the tube walls.

Important: Over 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 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain tubes at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$ [$71.6^{\circ}\text{F} \pm 9^{\circ}\text{F}$]). 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 .
5. Incubate the QFT-Plus Blood Collection Tubes UPRIGHT at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 16 to 24 hours. The incubator does not require CO_2 or humidification.

Blood collection into a single lithium-heparin tube and then transfer to QFT-Blood Collection Tubes

1. Blood may be collected in a single blood collection tube containing lithium-heparin as the anticoagulant and then transferred to QFT-Plus Blood Collection Tubes. Only use lithium-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 $17\text{--}25^{\circ}\text{C}$ ($62.6\text{--}77^{\circ}\text{F}$) at the time of blood collection.

2. Fill a lithium-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-heparin tubes prior to transfer and incubation in QFT-Plus Blood Collection Tubes (See Figures 1–3 Blood Collection Options).

Option 1 – Lithium-Heparin Tube Room Temperature Storage and Handling: Blood collected in lithium-heparin tube must be maintained at room temperature ($22^{\circ}\text{C} \pm 5^{\circ}\text{C}$ [$71.6^{\circ}\text{F} \pm 9^{\circ}\text{F}$]) for no more than 12 hours from the time of collection prior to transfer to QFT-Plus tubes and subsequent incubation.

Option 2 – Lithium-Heparin Tube Refrigerated Storage and Handling

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

- a) Blood drawn into lithium-heparin tube may be held at room temperature ($17\text{--}25^{\circ}\text{C}$) up to 3 hours after blood collection.
- b) Blood drawn into lithium-heparin tube may be refrigerated ($2\text{--}8^{\circ}\text{C}$) up to 48 hours.
- c) After refrigeration, lithium-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.

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-heparin tube to QFT-Plus Blood Collection Tubes.

Important: QFT-Plus Blood Collection Tubes should be at room temperature ($17\text{--}25^{\circ}\text{C}$ [$62.6\text{--}77^{\circ}\text{F}$]) 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-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 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ 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 for blood collection options.)
7. Incubate the QFT-Plus Blood Collection Tubes UPRIGHT at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ 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

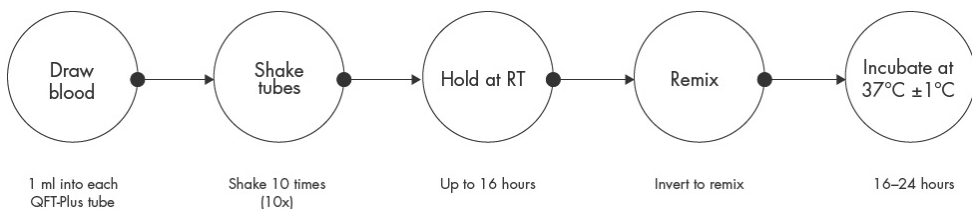


Figure 1. Blood collection option: Direct draw into QFT-Plus Blood Collection Tubes and hold at room temperature. The total time from blood draw in QFT-Plus Blood Collection Tubes to 37°C incubation must not exceed 16 hours.

Draw into lithium-heparin tube and hold at room temperature

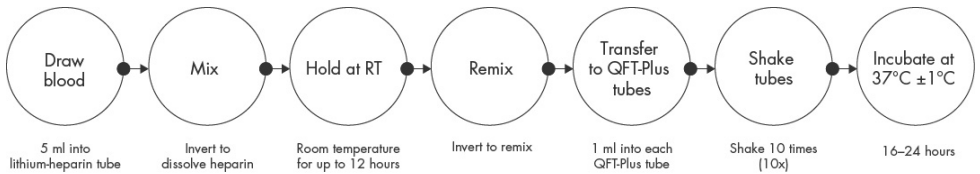
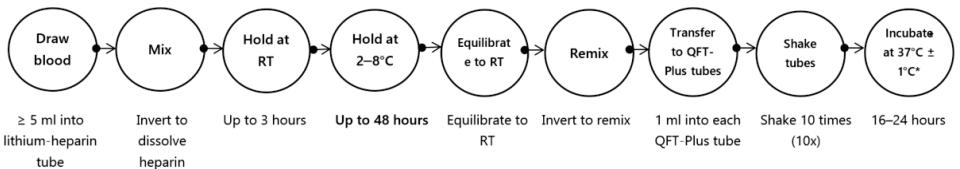


Figure 2. Blood collection option: Draw into lithium-heparin tube and hold at room temperature. The total time from blood draw in lithium-heparin tube to 37°C incubation must not exceed 12 hours.

Draw into lithium-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-heparin tube and hold at 2–8°C. The total time from blood draw in lithium-heparin tube to 37°C incubation must not exceed 53 hours.

Symbols

The following symbols may appear on the packaging and labeling:

Symbol	Symbol definition
	Legal manufacturer
	For in vitro diagnostic use
	Batch code
	Catalog number
	Global Trade Item Number
	Use by
	Temperature limitation
	Consult instructions for use
	Do not reuse
	Keep away from sunlight
	Sterilized using irradiation

Contact Information

For technical assistance and more information, please call toll-free 800-362-7737, see our Technical Support Center at www.qiagen.com/contact or contact one of the QIAGEN Technical Service Departments (see back cover or visit www.qiagen.com).

Significant Changes

Significant changes in this edition of the QF-TB Gold Plus BCT Package Insert are summarized in the table below:

Section	Page	Change(s)
Various	Various	Update lithium-heparin tube storage conditions post blood draw.

Trademarks: QIAGEN®, Sample to Insight®, QFT®, QuantiFERON® (QIAGEN Group).

For up-to-date licensing and product-specific disclaimers, see the *QuantiFERON-TB Gold Plus (QFT-Plus) BCT Package Insert*

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