

# QuantiFERON®-TB Gold Plus Blood Collection Tubes Instructions for Use

IVD

For In Vitro Diagnostic Use

This Instructions for Use is applicable for:

Product name	REF	$\Sigma$
QuantiFERON®-TB Gold Plus Blood Collection Tubes	622526	50
QuantiFERON®-TB Gold Plus High-Altitude Blood Collection Tubes	623526	50
QuantiFERON®-TB Gold Plus Blood Collection Tubes Dispenser Pack	622423	25
QuantiFERON®-TB Gold Plus High Altitude Blood Collection Tubes Dispenser Pack	623423	25
QuantiFERON®-TB Gold Plus Single-Patient Pack	622222	10
QuantiFERON®-TB Gold Plus High Altitude Single Patient Pack	623222	10



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[www.qiagen.com](http://www.qiagen.com)



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## Intended Use

The QuantiFERON®-TB Gold Plus (QFT®-Plus) Blood Collection Tubes are intended for the collection, storage, incubation, stimulation, and transportation of human blood.

For use with QuantiFERON-TB Gold Plus (QFT-Plus) ELISA, LIAISON® QuantiFERON-TB Gold Plus assay, or LIAISON QuantiFERON-TB Gold Plus II assay.

## Intended User

The QuantiFERON-TB Gold Plus (QFT-Plus) Blood Collection Tubes are used in settings where a blood sample is collected by a trained healthcare professional and processed in a laboratory environment.

# Description and Principle

## Summary and explanation

Refer to *QuantiFERON-TB Gold Plus ELISA Instructions for Use* for the summary and explanation regarding pathogens.

# Materials Provided

## Kit contents

Blood Collection Tubes		200 tubes	100 tubes	40 tubes
Catalog no.		622526	622423	622222
Number of tests/pack		50	25	10
QuantiFERON Nil Tube (gray cap, white ring)	Nil	50 tubes	25 tubes	10 tubes
QuantiFERON TB1 Tube (green cap, white ring)	TB1	50 tubes	25 tubes	10 tubes
QuantiFERON TB2 Tube (yellow cap, white ring)	TB2	50 tubes	25 tubes	10 tubes
QuantiFERON Mitogen Tube (purple cap, white ring)	Mitogen	50 tubes	25 tubes	10 tubes

**High Altitude (HA) Blood Collection Tubes (for use between 1020 and 1875 meters)**

		200 tubes	100 tubes	40 tubes
Catalog no.		623526	623423	623222
Number of tests/pack		50	25	10
QuantiFERON HA Nil Tube (gray cap, yellow ring)	Nil	50 tubes	25 tubes	10 tubes
QuantiFERON HA TB1 Tube (green cap, yellow ring)	TB1	50 tubes	25 tubes	10 tubes
QuantiFERON HA TB2 Tube (yellow cap, yellow ring)	TB2	50 tubes	25 tubes	10 tubes
QuantiFERON HA Mitogen (purple cap, yellow ring)	Mitogen	50 tubes	25 tubes	10 tubes
QFT-Plus Blood Collection Tubes Instructions for Use		1	1	1

**Important:** The QFT-Plus Blood Collection Tube(s) are single-use only.

**Important:** 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 QFT-Plus ELISA, LIAISON QuantiFERON-TB Gold Plus assay (REF 311010 or 311050), or LIAISON QuantiFERON-TB Gold Plus II assay (REF 311090 or 311095); please visit [www.qiagen.com](http://www.qiagen.com) to find the country-specific availability of this product, 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 that the contents of the tubes be thoroughly mixed with the blood. For blood directly drawn into the QFT-Plus Blood Collection Tubes, the QFT-Plus Blood Collection Tubes must be transferred to a 37°C incubator as soon as possible and within 16 hours of collection. Alternatively, blood may be collected into a single lithium- or sodium-heparin tube for storage prior to transfer to QFT-Plus Blood Collection Tubes and incubation. Blood specimens collected in lithium- or sodium-heparin tubes can be stored up to 16 hours at room temperature (17°C to

25°C) followed by transfer to QFT-Plus Blood Collection Tubes, or blood specimens in lithium- or sodium-heparin tubes can be transferred to QFT-Plus Blood Collection Tubes directly after collection. Blood specimens in lithium- or sodium-heparin tubes may also be stored at 2°C to 8°C for up to 48 hours prior to transfer to the QFT-Plus Blood Collection Tubes.

## Components of the kit

The principal components of the kit are explained below.

**Table 1. Reagents supplied**

Reagent	Active ingredients	Volume
Reagent	Active Ingredients	Volume
Nil	Heparin	n/a
TB1	ESAT-6 and CFP-10, Heparin	n/a
TB2	ESAT-6 and CFP-10, Heparin	n/a
Mitogen	phytohemagglutinin (PHA-P), Heparin	n/a

# Materials Required but Not Provided

## Additional reagents

- QuantiFERON-TB Gold Plus ELISA kit (cat. no): 622120
- QuantiFERON-TB Gold Plus Reference Lab Pack (cat. no): 622822



# Warnings and Precautions

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

## Safety information

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). These are available online in convenient and compact PDF at [www.qiagen.com/safety](http://www.qiagen.com/safety) where you can find, view, and print the SDS for each QIAGEN kit and kit component.

- Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures.

## Emergency information

CHEMTREC

Outside USA & Canada +1 703-527-3887

## Precautions

For in vitro diagnostic use only.

**Note:** The QFT-Plus Blood Collections Tube(s) are sterile prior to use.

If you suspect that the QFT-Plus Blood Collection Tube(s) have been damaged or sterilization has been compromised, please contact QIAGEN Technical Services.

# Reagent Storage and Handling

Attention should be paid to the expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

# Specimen Storage and Handling

The QuantiFERON-TB Gold Plus (QFT-Plus) Blood Collection Tubes are for use with QuantiFERON-TB Gold Plus ELISA, LIAISON QuantiFERON-TB Gold Plus assay (REF 311010 or 311050), or LIAISON QuantiFERON-TB Gold Plus II assay (REF 311090 or 311095). Please visit [www.qiagen.com](http://www.qiagen.com) to find the country-specific availability of this product). All samples should be treated as potentially hazardous.

# Protocol: Blood Collection

## Important points before starting

- Tubes should be between 17–25°C at the time of blood filling.
- 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 0.8–1.2 mL range may lead to erroneous results.
- 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 Blood Collection Tubes.
- Use QFT-Plus Blood Collection Tubes up to an altitude of 810 meters (2650 ft) above sea level. Use HA QFT-Plus Blood Collection Tubes at altitudes between 1020 and 1875 meters (3350 and 6150 ft).
- If using QFT-Plus Blood Collection Tubes at an altitude higher than 810 meters (2650 ft), but not between 1020 m (3350 ft) and 1875 m (6150 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 Blood Collection 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 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 Blood Collection 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 (17–25°C) before transferring to QFT-Plus Blood Collection 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 Blood Collection Tubes. Perform dispensing aseptically (ensuring appropriate safety procedures) by removing the caps from the 4 QFT-Plus Blood Collection 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.

### Setting up

- Label tubes appropriately.

### Handling reagents

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

### Things to do before starting

- Ensure each QFT-Plus Blood Collection Tube (Nil, TB1, TB2, and Mitogen) is identifiable by its label or other means once the cap is removed.

## Direct draw into QFT-Plus Blood Collection Tubes

### Procedure

1. For each patient, collect 1 mL of blood by venipuncture directly into each of the QFT-Plus Blood Collection Tubes.

**Note:** A trained healthcare provider should perform this procedure.

**Important:** Tubes should be between 17–25°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 0.8–1.2 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 Blood Collection Tubes.
  - d. Use QFT-Plus Blood Collection Tubes up to an altitude of 810 meters (2650 ft) above sea level. Use HA QFT-Plus Blood Collection Tubes at altitudes between 1020 and 1875 meters (3350 and 6150 ft).
  - e. If using QFT-Plus Blood Collection Tubes at an altitude higher than 810 meters (2650 ft), but not between 1020 m (3350 ft) and 1875 m (6150 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 Blood Collection 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 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.
2. Immediately after filling the 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:** Tubes should be between 17–25°C at the time of shaking. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

3. 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 (17–25°C).

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

4. Incubate the tubes UPRIGHT at 37°C ± 1°C for 16–24 hours.

**Note:** The incubator does not require CO<sub>2</sub> or humidification.

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

### Procedure

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.

**Note:** 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. Only use lithium- heparin or sodium- heparin as a blood anticoagulant because other anticoagulants interfere with the assay.

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.

**Note:** This procedure should be performed by a trained phlebotomist.

3. For hold times 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: Room Temperature Storage – Lithium or Sodium-Heparin Tube Handling**

Blood collected in lithium or sodium-heparin tube must be maintained at room temperature (17–25°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: Refrigerated – Lithium- or Sodium-Heparin Tube 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) 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.

**Note:** 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).



- 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.

### **Optional automated aliquoting**

The transfer step can be performed automatically using the Hamilton Aliquot STARlet workstation (P/N 173000-303) with hardware configuration P/N 49000-63 or Tecan Fluent Mix & Pierce workstation (P/N 30042011) using a 1 mL protocol or equivalent. For additional information, contact your local QIAGEN representative.

5. Mix tubes immediately after filling the QFT-Plus Blood Collection Tubes, by shaking 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.

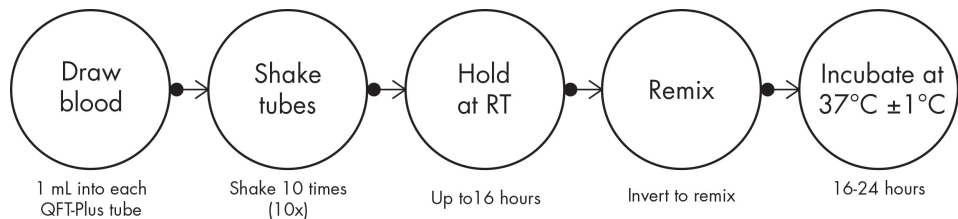
**Note:** Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

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  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  directly after blood collection and shaking, invert the tubes to mix 10 times (10x) prior to incubation at  $37^{\circ}\text{C}$ . (See Figures 1–3 for blood collection options).

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

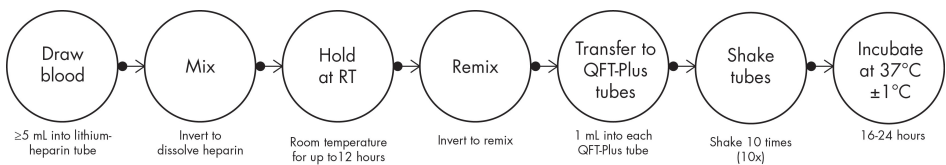
**Note:** The incubator does not require CO<sub>2</sub> or humidification.

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



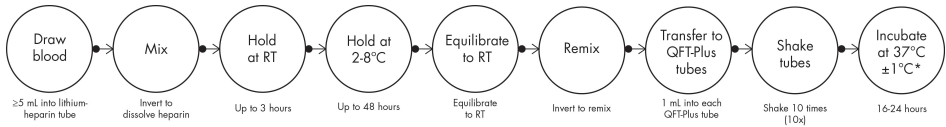
**Figure 1. Blood collection option: Direct draw into QFT-Plus Blood Collection Tubes and hold at room temperature.** The total time from blood draw in QFT-Plus Blood Collection Tubes to 37°C ± 1°C incubation must not exceed 16 hours.

**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 ± 1°C incubation must not exceed 16 hours.

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



**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 tubes to 37°C incubation must not exceed 53 hours.

8. After incubation, QFT-Plus Blood Collection Tubes may be held between 4–27°C for up to 3 days prior to centrifugation.
9. After incubation, centrifuge tubes for 5–15 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:** 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 QFT-Plus Blood Collection Tubes into either the QFT-Plus ELISA plate or onto the LIAISON QuantiFERON-TB Gold Plus assay (REF 311010 or 311050), or the LIAISON QuantiFERON-TB Gold Plus II assay (REF 311090 or 311095); please visit [www.qiagen.com](http://www.qiagen.com) to find the country-specific availability of this product).

Plasma samples can be stored for up to 28 days at 2–8°C or, if harvested, below -20°C for extended periods.

# Disposal

- Handle human blood and plasma as if potentially infectious. Observe relevant blood and blood handling guidelines.
- Dispose of samples and materials in contact with blood or blood products in accordance with federal, state, and local regulations.

# Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: [www.qiagen.com/FAQ/FAQList.aspx](http://www.qiagen.com/FAQ/FAQList.aspx) (for contact information, visit [www.qiagen.com](http://www.qiagen.com)). The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information and/or protocols in this handbook or sample and assay technologies (for contact information, visit [www.qiagen.com](http://www.qiagen.com)).

Comments and suggestions	
<b>Underfilling of Blood Collection Tubes (BCT)</b>	
a. BCT removed from the needle too soon.	As 1 mL BCTs draw blood relatively slowly, keep the BCT on the needle for 2–3 seconds once the BCT appears to have completed filling. This will ensure that the correct volume is drawn.
b. Tubing not primed while using butterfly needle	If a “butterfly needle” is used to collect blood, a “purge” tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus BCTs being used.
c. BCTs are past their expiration date	BCTs must be used within the expiration date printed on the tube label.
<b>Overfilling of BCT</b>	
Tube not at room temperature during blood collection	BCTs should be at room temperature 17–25°C at the time of blood collection.
<b>Blood clots</b>	
Insufficient mixing	Immediately after filling the BCTs, shake them ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCT’s walls.
<b>Plasma not separated by gel</b>	

### Comments and suggestions

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Insufficient centrifugation speed or time

Harvesting of the plasma is facilitated by centrifuging the BCTs for 5–15 minutes at 2000–3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the BCTs should be re-centrifuged.

### Gel disruption








Tubes a) Tubes shaken too vigorously










Immediately after filling the BCTs, shake them ten (10) times just firmly enough to make sure the entire inner surface of the BCT is coated with blood. This will dissolve antigens on the BCTs walls.

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



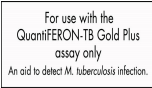

# Symbols

The following symbols appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol title/ Number	Symbol description
 0197	CE Mark / N/A	Marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation (EU) 2017/746 and other applicable European Union harmonization legislation providing for its affixing*
	Manufacturer / 5.1.1	Indicates medical device manufacturer**
	Date of manufacture / 5.1.3	Indicates the date when the medical device was manufactured**
	Use-by date / 5.1.4	Indicates the date after which the medical device is not to be used**
	Batch code / 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified**
	Catalog number / 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified**
	Sterilized using irradiation / 5.2.4	Indicates a medical device that has been sterilized using irradiation**

Symbol	Symbol title/ Number	Symbol description
	Do not re-sterilize / 5.2.6	Indicates a medical device that is not to be re-sterilized**
	Do not use if package is damaged and consult instructions for use / 5.2.8	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information**
	Single sterile barrier system / 5.2.11	Indicates a single sterile barrier system**
	Temperature limit / 5.3.7	Indicates the temperature limits to which the medical device can be safely exposed**
	Do not re-use / 5.4.2	Indicates a medical device that is intended for single use only**
	Consult instructions for use or consult electronic instructions for use / 5.4.3	Indicates the need for the user to consult the Instructions for Use**
	Caution / 5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator, awareness, or operator action to avoid undesirable consequences**
	In vitro diagnostic medical device / 5.5.1	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device**
	Contains sufficient for <n> tests / 5.5.5	Indicates the total number of tests that can be performed with the medical device**



Symbol	Symbol title/ Number	Symbol description
	Unique device identifier / 5.7.10	Indicates a carrier that contains unique device identifier information**
	N/A / N/A	Global Trade Item Number
	N/A / N/A	For use with the QuantiFERON-TB Gold Plus assay only. An aid to detect <i>M. tuberculosis</i> infection
	N/A / N/A	Each pack contains

\* Regulation (EU) 2017/746

\*\* Regulation: ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer

# Contact Information

For technical assistance and more information, please see our Technical Support Center Centre at [www.qiagen.com/Support](http://www.qiagen.com/Support), call 00800-22-44-6000, or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit [www.qiagen.com](http://www.qiagen.com)).

# Ordering Information

Product	Contents	Cat. no.
QuantiFERON-TB Gold Plus Blood Collection Tubes	200 tubes (50 Nil, TB1, TB2, and Mitogen)	622526
QuantiFERON-TB Gold Plus Blood Collection Tubes Dispenser Pack	100 tubes (25 Nil, TB1, TB2, and Mitogen)	622423
QuantiFERON-TB Gold Plus Single-Patient Pack	40 tubes (1 Nil, TB1, TB2, and Mitogen/pack), pack of 10	622222
QuantiFERON-TB Gold Plus High-Altitude Blood Collection Tubes	200 tubes (50 Nil, TB1, TB2, and Mitogen)	623526
QuantiFERON-TB Gold Plus High Altitude Blood Collection Tubes Dispenser Pack	100 tubes (25 Nil, TB1, TB2, and Mitogen)	623423
QuantiFERON-TB Gold Plus High Altitude Single Patient Pack	40 tubes (1 Nil, TB1, TB2, and Mitogen/pack), pack of 10	623222
<b>Related Products</b>		
QuantiFERON-TB Gold Plus ELISA	2-plate kit	622120
QuantiFERON-TB Gold Plus Reference Lab Pack	20-plate kit	622822

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit Instructions for Use. QIAGEN kit Instructions for Use are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

# Document Revision History

Revision	Description
R3, August 2021	Reverted catalog numbers to original
R4, March 2023	Deleted References section
R5, September 2023	Added new DiaSorin LIAISON QuantiFERON-TB Gold Plus assay reference
Rev. 06, September 2025	Added new DiaSorin LIAISON QuantiFERON-TB Gold Plus II assay reference; updated Symbols section

### Limited License Agreement for QuantiFERON®-TB Gold Plus Blood Collection Tubes Kit

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

1. The product may be used solely in accordance with the protocols provided with the product and this Instructions for Use and for use with components contained in the panel only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this panel with any components not included within this panel except as described in the protocols provided with the product, this Instructions for Use, and additional protocols available at [www.qiagen.com](http://www.qiagen.com). Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.
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3. This panel and its components are licensed for one-time use and may not be reused, refurbished, or resold.
4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.
5. The purchaser and user of the panel agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the panel and/or its components.

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