September 2023

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

Σ 50 (622526, 623526)

Σ 25 (622423, 623423)

Σ 10 (622222, 623222)

Version 1

IVD

For In Vitro Diagnostic Use

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

CE 0197

REF 622526, 622222, 622423,623526, 623222, 623423.

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R5 MAT 1132998EN

Sample to Insight

Contents

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 the QuantiFERON-TB Gold Plus (QFT-Plus) ELISA or LIAISON® QuantiFERON-TB Gold Plus 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 tube
QuantiFERON TB1 Tube (green cap, white ring)	TB1	50 tubes	25 tubes	10 tube
QuantiFERON TB2 Tube (yellow cap, white ring)	TB2	50 tubes	25 tubes	10 tube
QuantiFERON Mitogen Tube (purple cap, white ring)	Mitogen	50 tubes	25 tubes	10 tube
QFT-Plus Blood Collection Tubes Instructions for Use		1	1	1

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 Tube (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 the QFT-Plus ELISA or the LIAISON® QuantiFERON-TB Gold Plus assay (REF 311010

or 311050; please visit **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
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 format at **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 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 the QuantiFERON-TB Gold Plus ELISA or LIAISON QuantiFERON-TB Gold Plus assay (REF 311010 or 311050. Please visit **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 feet) above sea level. Use HA QFT-Plus Blood Collection Tubes at altitudes between 1020 and 1875 meters (3350 and 6150 feet).
- 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 (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 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 transfer 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.

   - 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.
   - 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 feet) above sea level. Use HA QFT-Plus Blood Collection Tubes at altitudes between 1020 and 1875 meters (3350 and 6150 feet).
   - 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 (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 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 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_2 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 3a–3d must be followed in sequence.

3a. Blood drawn into lithium- or sodium-heparin tube may be held at room temperature (17–25°C) up to 3 hours after blood collection.

3b. Blood drawn into lithium- or sodium-heparin tube may be refrigerated (2–8°C) for up to 48 hours.

3c. After refrigeration, lithium- or sodium-heparin tube must equilibrate to room temperature (17–25°C) prior to transfer to QFT-Plus Blood Collection Tubes.

3d. 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).

4a. 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.

4b. Samples must be evenly mixed by gentle inversion before dispensing into QFT-Plus Blood Collection Tubes.

4c. 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°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, for blood collection options).

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

   Note: The incubator does not require CO_2 or humidification.

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

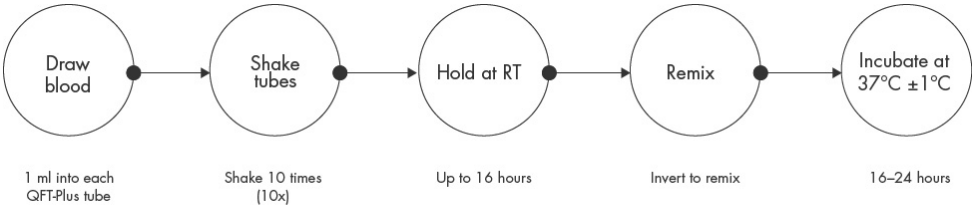


Figure 1. Blood collection option: Directly draw into QFT-Plus Blood Collection Tubes and hold at room temperature. The total time from blood draw in QFT-Plus Blood Collection Tubes to 37°C incubation must not exceed 16 hours.

Draw into Lithium-or Sodium-Heparin Tubes and hold at room temperature.

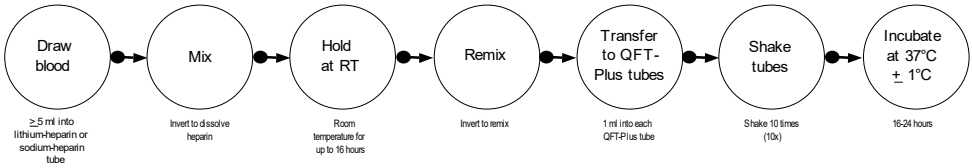


Figure 2. Blood collection option: Draw into lithium- or sodium-heparin tube and hold at room temperature. The total time from blood draw in lithium- or sodium-heparin tube to 37°C incubation must not exceed 16 hours.

Draw into Lithium- or Sodium-Heparin Tubes and hold at 2–8°C.

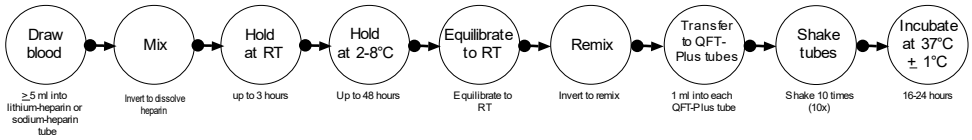


Figure 3. Blood collection option: Draw into lithium- or sodium-heparin tube and hold at 2–8°C. The total time from blood draw in lithium- or sodium-heparin tube to 37°C incubation must not exceed 53 hours.

8. After incubation, 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 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; please visit 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 technical assistance and more information, please see our Technical Support Center at **www.qiagen.com/Support** (for contact information, visit **www.qiagen.com**).

Comments and suggestions	
Underfilling of Blood Collection Tubes (BCT)	
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.
Overfilling of BCT	
a) Tube not at room temperature during blood collection	BCTs should be at room temperature 17–25°C (62.6–77°F) at the time of blood collection.
Blood clots	
a) 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.

Plasma not separated by gel

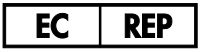
a)	Insufficient centrifugation speed or time	Harvesting of the plasma is facilitated by centrifuging the BCTs for 15 minutes at 2000–3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the BCTs should be re-centrifuged.

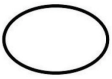
Gel disruption

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 definition
 <N>	Contains reagents sufficient for <N> reactions
	Use by
	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
	Authorized representative in the European Community / European Union
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Components
	Number
	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation

Symbol	Symbol definition
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Warning/caution or Caution, consult accompanying documents
	Sterilized using irradiation
	Single sterile barrier system
	Do not resterilize
	Do not reuse
	Contains biological material of animal origin
	Do not use if package is damaged and consult instructions for use

Symbol	Symbol definition
UDI	Unique Device Identifier
For use with the QuantiFERON-TB Gold Plus assay only An aid to detect *M. tuberculosis* infection.	For use with the QuantiFERON-TB Gold Plus assay only. An aid to detect *M. tuberculosis* infection
Each pack contains:	Each pack contains

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
Related products		
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** 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

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

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**. 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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