Rev. 12, March 2026

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

IVD

For In Vitro Diagnostic Use

Rx ONLY For prescription use only

This Instructions for Use is applicable for:

Product name	REF	Σ
QuantiFERON-TB Gold Plus Blood Collection Tubes	622536	50
QuantiFERON-TB Gold Plus High-Altitude Blood Collection Tubes	623536	50
QuantiFERON-TB Gold Plus Blood Collection Tubes Dispenser Pack	622433	25
QuantiFERON-TB Gold Plus High Altitude Blood Collection Tubes Dispenser Pack	623433	25
QuantiFERON-TB Gold Plus Blood Collection Tubes (Bulk)	622529	1200
QuantiFERON-TB Gold Plus High-Altitude Blood Collection Tubes (Bulk)	623529	1200

www.qiagen.com

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Sample to Insight

Table of Contents

1. Intended Use

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

2. 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 Tube (purple cap, white ring)	Mitogen	50 tubes	25 tubes	1200 tubes

* 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

* 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 ELISA or the LIAISON QuantiFERON-TB Gold Plus assay (REF: 311020 or 311040, or the LIAISON QuantiFERON-TB Gold Plus II assay (REF: 311080 or 311085); 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 QFT-Plus Blood Collection Tubes, so it is essential that the contents of the tubes be thoroughly mixed with the blood. The QFT-Plus Blood Collection 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 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 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 or sodium-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 "Blood collection into a single lithium or sodium-heparin tube and then transfer to QFT-Plus Blood Collection Tubes" on page 8.

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

3. Precautions

For in vitro diagnostic use only.

For prescription use only. Federal law restricts this device to sale by or on the order of a physician.

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** where you can find, view, and print the SDS for each QIAGEN kit and kit component.

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.

4. Blood Collection and Hold Time Options

See Figures 1–3 for blood collection options.

4.1. 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 after 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 at the time of blood collection.

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.
   - As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds after the tube appears to have completed filling. This will ensure that the correct volume is drawn.
   - 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 of the indicator mark, a new blood sample should be obtained. Under- or over-filling of the tubes outside of the 0.8–1.2 mL range may lead to erroneous results.
   - 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.
   - QFT-Plus Blood Collection Tubes can be used up to an altitude of 2650 ft (810 m) above sea level. HA QFT-Plus Blood Collection Tubes should be used at altitudes between 3350 and 6150 ft (1020 and 1875 meters).
   - If using QFT-Plus Blood Collection Tubes outside these altitude ranges between 2650 and 3350 ft (810 and 1020 m) or above 6150 ft (1875 m), 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 0.8–1.2 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 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 ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain tubes at room temperature (17–25°C). 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 ± 1°C for 16–24 hours.

   The incubator does not require CO_2 or humidification.

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

- 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.

1. 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.
2. Refer to the following 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– Lithium or Sodium-Heparin Tube Room Temperature Storage and Handling**

Blood collected in lithium or sodium-heparin tube must be maintained at room temperature (17–25°C for no more than 12 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) 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.

  e. 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.

     Important: Total time from blood draw to incubation in QFT-Plus Blood Collection Tubes should not exceed 53 hours.

3. 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 at the time of blood collection.

   a. Label each QFT-Plus Blood Collection Tubes 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 after 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.

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

5. Following labeling, filling, and shaking, the tubes must be transferred to a 37 ± 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).
6. Incubate the QFT-Plus Blood Collection Tubes UPRIGHT at 37 ± 1°C for 16–24 hours.

   The incubator does not require CO_2 or humidification.

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

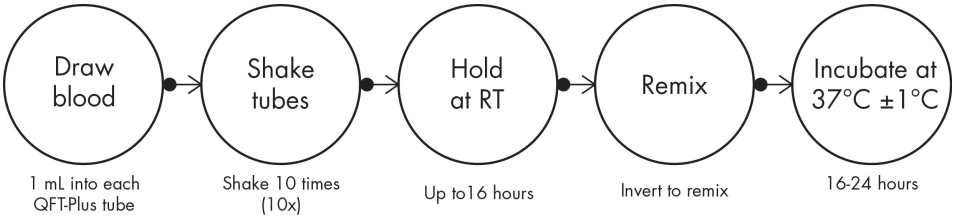


Figure 1. Blood collection option: Direct draw into QFT-Plus Blood Collection Tubes and hold at room temperature. The total time from blood draw in QFT-Plus Blood Collection Tubes to 37°C incubation must not exceed 16 hours.

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

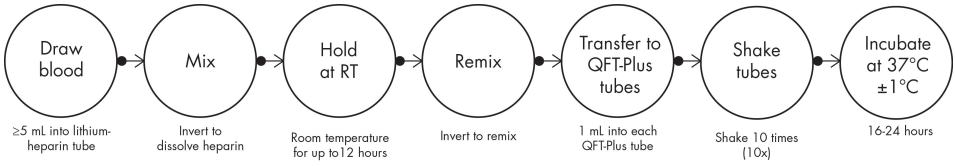
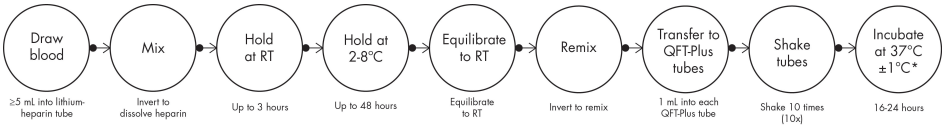


Figure 2. Blood collection option: Draw into lithium or sodium-heparin tube and hold at room temperature. The total time from blood draw in lithium or sodium-heparin tube to 37°C incubation must not exceed 12 hours.

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



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

4.3. Post-incubation of blood collection tubes and harvesting of plasma

Before harvesting plasma, samples in QFT-Plus Blood Collection Tubes must be incubated at 37°C for 16–24 hours. The incubator does not require CO_2 or humidification.

1. After incubation, blood collection tubes may be held between 4–27°C for up to 3 days pre or post centrifugation.
2. After incubation of the tubes at 37 ± 1°C, harvesting of the plasma is facilitated by centrifuging 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, the tubes should be re-centrifuged.
3. It is possible to harvest the plasma without centrifugation, but additional care is required to remove the plasma without disturbing the cells.
4. Plasma samples should only be harvested using a pipette.

   Important: After centrifugation, avoid pipetting up and down or mixing plasma by any means before 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 either the QFT-Plus ELISA plate , or onto the LIAISON XL Analyzer or LIAISON XS Analyzer.

   Plasma samples can be stored in centrifuged QFT-Plus Blood Collection Tubes for up to 28 days at 2–8°C. Harvested plasma samples can be stored for up to 28 days at 2–8°C. Harvested plasma samples can also be stored below -20°C (preferably less than -70°C) for extended periods.

   For adequate test samples, harvest at least 150 µL of plasma.

Symbols

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

Symbol	Symbol title/ Number	Symbol description
Rx ONLY	Rx Only / NA	Federal law restricts this device to sale by or on the order of a physician*
	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†
LOT	Batch code / 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified†
REF	Catalog number / 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified†
STERILE R	Sterilized using irradiation / 5.2.4	Indicates a medical device that has been sterilized using irradiation†
	Do not resterilize / 5.2.6	Indicates a medical device that is not to be resterilized†
	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†

Symbol	Symbol title/ Number	Symbol description
	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†
	Unique device identifier / 5.7.10	Indicates a carrier that contains unique device identifier information†

* Regulation: 21 CFR 809.10 (a)(4)

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

5. Contact Information

For technical assistance and more information, please see our Technical Support Center at **support.qiagen.com**.

6. Document Revision History

Revision	Description
R10, September 2023	Added new Diasorin LIAISON QuantiFERON-TB Gold Plus assay reference
R11, March 2026	Updated "Symbol" section Clarified that BCTs can be stored up to 3 days pre or post configuration Clarified centrifugation time of 5–15 minutes
Rev. 12, March 2026	Addition of optional automated aliquoting with the Tecan or Hamilton Aliquoters Added new Diasorin LIAISON QuantiFERON-TB Gold Plus II assay (REF: 311080 or 311085) references. Updated Contact Information section Template update

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:

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