June 2021

QIAreach® QuantiFERON®-TB Test Instructions for Use

50 (622724)

Version 1

IVD

For In Vitro Diagnostic Use

For use with QIAreach® eHub

CE

REF 622724

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Sample to Insight

QIAGEN

Contents

Intended Use

The QIAreach® QuantiFERON-TB (QIAreach QFT) assay is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of interferon gamma (IFN-γ) by nanoparticle fluorescence is used to identify in vitro responses to these peptide antigens that are associated with *Mycobacterium tuberculosis* infection.

QIAreach QFT is a semi-automated, indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

QIAreach QFT is an indirect test to screen for *M. tuberculosis* infection (including disease) and is intended for use in at-risk populations. There are no known population restrictions for the use of QIAreach QFT.

Intended User

This kit is intended for professional use.

The intended users for QIAreach QFT are laboratory personnel, including phlebotomists to draw patient blood through venipuncture, and sample handling technicians that are able to process blood.

Description and Principle

Pathogen information

Tuberculosis is a communicable disease caused by infection with *M. tuberculosis* (MTB) complex organisms (*M. tuberculosis, M. bovis, M. africanum*), which typically spread to new hosts via airborne droplet nuclei from patients with respiratory tuberculosis disease. A newly infected individual can become ill from tuberculosis within weeks to months, but most infected individuals remain well. Latent tuberculosis infection (TB infection), a noncommunicable asymptomatic condition, persists in some who might develop tuberculosis disease months or years later. The main purpose of diagnosing TB infection is to consider medical treatment for preventing tuberculosis disease. Until recently, the tuberculin skin test (TST) was the only available method for diagnosing TB infection. Cutaneous sensitivity to tuberculin develops from 2 to 10 weeks after infection. However, some infected individuals, including those with a wide range of conditions hindering immune functions, but also others without these conditions, do not respond to tuberculin. Conversely, some individuals who are unlikely to have *M. tuberculosis* infection exhibit sensitivity to tuberculin and have positive TST results after vaccination with Bacille Calmette-Guérin (BCG) or infection with mycobacteria other than *M. tuberculosis* complex, or undetermined other factors.

TB infection must be distinguished from tuberculosis disease, a reportable condition which usually involves the lungs and lower respiratory tract but may also affect other organ systems. Tuberculosis disease is diagnosed from historical, physical, radiological, histological, and mycobacteriological findings.

Summary and explanation

QIAreach QFT is a test for cell-mediated immune (CMI) responses to peptide antigens that simulate mycobacterial proteins. These proteins, ESAT-6 and CFP-10, are absent from all BCG strains and from most nontuberculous mycobacteria with the exception of *M. kansasii, M.*

szulgai, and M. marinum (1). Individuals infected with MTB-complex organisms usually have lymphocytes in their blood that recognize these and other mycobacterial antigens. This recognition process involves the generation and secretion of the cytokine IFN-γ. The detection and subsequent quantification of IFN-γ forms the basis of this test.

The antigens used in QIAreach QFT are a peptide cocktail simulating the proteins ESAT-6 and CFP-10. Numerous studies have demonstrated that these peptide antigens stimulate IFN-γ responses in T cells from individuals infected with *M. tuberculosis*, but generally not from uninfected or BCG-vaccinated persons without disease or risk for TB infection (1–32). However, medical treatments or conditions that impair immune functionality can potentially reduce IFN-γ responses. Patients with certain other mycobacterial infections might also be responsive to ESAT-6 and CFP-10, as the genes encoding these proteins are present in *M. kansasii, M. szulgai, and M. marinum* (1, 23). QIAreach QFT is both a test for TB infection and a helpful aid for diagnosing *M. tuberculosis* complex infection in sick patients. A positive result supports the diagnosis of tuberculosis disease, but infections by other mycobacteria (e.g., *M. kansasii*) could also lead to positive results. Other medical and diagnostic evaluations are necessary to confirm or exclude tuberculosis disease.

The QIAreach QFT Blood Collection Tube contains peptides from ESAT-6 and CFP-10 that are designed to elicit CMI responses from both CD4+ T-helper lymphocytes and CD8+ cytotoxic T lymphocytes. In the natural history of MTB infection, CD4+ T cells play a critical role in immunological control through their secretion of the cytokine IFN-γ. Evidence now supports a role for CD8+ T cells participating in the host defense to MTB by producing IFN-γ and other soluble factors, which activate macrophages to suppress growth of MTB, kill infected cells, or directly lyse intracellular MTB (33–35). IFN-γ producing MTB-specific CD8+ cells have been detected in subjects with TB infection and with active TB disease (36–38). Moreover, ESAT-6 and CFP-10 specific CD8+ T lymphocytes are described as being more frequently detected in subjects with active TB disease versus TB infection, and may be associated with a recent MTB exposure (39–41). In addition, MTB-specific CD8+ T cells producing IFN-γ have also been detected in active TB subjects with HIV co-infection (42, 43) and in young children with TB disease (44).

Principles of the assay

The QIAreach QFT assay uses a specialized Blood Collection Tube, which is used to collect whole blood. Incubation of the blood occurs in the tube for 16–24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens.

The QIAreach QFT test is performed in two stages. First, whole blood is collected into a QIAreach QFT Blood Collection Tube.

The QIAreach QFT Blood Collection Tube is mixed and should be incubated at 37°C as soon as possible, and within 16 hours of collection. Following a 16–24 hour incubation period, the tube is centrifuged, the plasma is removed and mixed in a sample Processing Tube and the amount of IFN-γ is measured in a cartridge integrated with digital detection.

To perform the detection assay, QIAreach QFT Diluent Buffer is first added to the Processing Tube and reconstitutes an anti-IFN-γ antibody-nanoparticle conjugate that is spray-dried on an immobilized accretion pad within the tube. Plasma is removed from the QIAreach QFT Blood Collection Tube and added to the Processing Tube and mixed with the resuspended conjugate. If IFN-γ is present in the sample, it will bind to the conjugate. The sample is then transferred from the Processing Tube to the eStick sample port.

Once in the eStick, the test sample migrates on a nitrocellulose membrane and across the test line. The IFN-γ antibody-nanoparticle conjugate will bind to immobilized anti-IFN-γ capture antibody at the test line. A photosensor will detect light emitted from the fluorescent nanoparticles in the presence of excitation light filtered onto the test line. Signal is interpreted on the eStick firmware and transmitted to the eHub, which then communicates a positive or negative test result to the user by means of a visual display.

A QIAreach QFT test result with an IFN-γ response that is above the signal threshold is considered positive for MTB infection. IFN-γ responses below this threshold are considered negative for MTB infection.

Materials Provided

Kit contents

QIAreach® QuantiFERON®-TB		
Catalog no.		**622724**
Number of tests/pack		50
QIAreach QFT Blood Collection System Components		
QIAreach QuantiFERON-TB Blood Collection Tubes (white cap, black ring)		50
QIAreach QFT Detection System Components*		
eStick (packaged together with Processing Tube in foil wrapper)	Contains anti-human IFN-γ antibody and human serum albumin	50
Processing Tube (packaged together with eStick in foil wrapper)	Coated with anti-human IFN-γ antibody, normal mouse serum and bovine serum albumin	50
QIAreach QFT Diluent Buffer (10 ml)	Contains bovine serum albumin and ProClin® 300	2
QIAreach QuantiFERON-TB Instructions for Use (Handbook)		1

* See Warnings and Precautions for precautions and hazard statements.

Components of the kit

Controls and calibrators

All QIAreach QFT eSticks have built-in controls to ensure reliable performance of the eStick optoelectronics and lateral flow strip and also monitor procedural steps after sample addition to confirm suitability. A failure alert will be communicated to the user in the form of a test error if any fault conditions are detected on the eStick firmware.

Platform and software

The QIAreach eHub serves as a power source for the QIAreach QFT eStick and transmits test results to the user by visual display or transmits data to the QIAreach Software (optional for use). The QIAreach eHub can be purchased separately. For instructions on proper use and care of the equipment, refer to *QIAreach eHub User Manual*.

QIAreach Software is optional for use and can be used to display and record QIAreach QFT eStick results. It is available for download at www.qiagen.com. For instructions, setup, and use of this software, refer to *QIAreach Software User Manual*.

Note: QIAreach Software is not required to perform the QIAreach QFT test.

Materials Required but Not Provided

Equipment

- QIAreach eHub (including USB adaptor and cable)*
- 37°C ± 1°C incubator†; CO_2 not required
- Calibrated pipette* for delivery of 150 µl with disposable tips
- Optional: Centrifuge capable of centrifuging the blood tubes at least to 2000 RCF (g)
- Optional: QIAreach Software (downloadable from www.qiagen.com)

* See Warnings and Precautions for precautions and hazard statements.
† Prior to use, ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

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.

- All chemicals and biological materials are potentially infectious. Discard sample and assay waste according to your local safety procedures.
- Specimens and samples are potentially infectious and must be treated as biohazardous materials.
- A negative QIAreach QFT result does not preclude the possibility of *M. tuberculosis* infection or tuberculosis disease: false-negative results can be due to stage of infection (e.g., specimen obtained prior to the development of cellular immune response), co-morbid conditions that affect immune functions, incorrect handling of the Blood Collection Tube following venipuncture, incorrect performance of the assay, or other immunological variables.
- A positive QIAreach QFT result should not be the sole or definitive basis for determining infection with *M. tuberculosis*. Incorrect performance of the assay may cause false-positive responses.

- A positive QIAreach QFT result should be followed by further medical evaluation and diagnostic evaluation for active tuberculosis disease (e.g., AFB smear and culture, chest X-ray).
- While ESAT-6 and CFP-10 are absent from all BCG strains and from most known nontuberculous mycobacteria, it is possible that a positive QIAreach QFT result may be due to infection by *M. kansasii*, *M. szulgai*, or *M. marinum*. If such infections are suspected, alternative tests should be performed.

Precautions

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

The following hazards and precautionary statements apply to components of the QIAreach QFT kit.

	QIAreach QuantiFERON-TB Diluent Buffer Contains: Alkyl Carboxylate, mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1). Harmful to aquatic life with long lasting effects. Avoid release to the environment.

	QIAreach eHub Do not open the eHub. No serviceable parts inside. Opening of the eHub device could lead to electric shock or damage of the device.

	QIAreach QuantiFERON-TB eStick Do not open the eStick. No serviceable parts inside. Opening of the eStick could lead to user exposure of infectious patient body fluids. Opening the eStick could also damage the eStick device.

Further information

- Deviations from the *QIAreach QuantiFERON-TB Instructions for Use* may yield erroneous results. Please read the instructions carefully before use.
- Important: Inspect materials prior to use. Do not use kit if the Diluent Buffer, Processing Tube, or eStick show signs of damage or leakage, or if the seals have been compromised prior to use.
- Do not handle or use broken eSticks.
- Discard used or unused materials and biological samples in accordance with local and government regulations.
- Do not use the QIAreach QFT kit after the expiration date.
- Do not mix consumables and reagents from multiple lots.
- QIAreach QuantiFERON-TB Blood Collection Tubes can be used to draw blood up to an altitude of 810 meters above sea level.

- QIAreach QuantiFERON-TB Blood Collection Tubes should be between 17–30°C at the time of blood filling and shaking.
- Overly vigorous shaking of QIAreach QuantiFERON-TB Blood Collection Tubes may cause gel disruption and could lead to aberrant results.

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.

In-use stability

- Store Blood Collection Tubes at 2–30°C.
- Store kit reagents at 2–30°C.
- Refer to the expiration date printed on the device labeling for component shelf life.
- The QIAreach QFT test should be performed in a test environment with ≤ 65% relative humidity.
- The test must be initiated within 60 minutes of opening the foil wrapped eStick and Processing Tube.
- The QIAreach QFT Diluent Buffer must be used within 3 months after opening the bottle.

Specimen Storage and Handling

The QIAreach QuantiFERON-TB assay is for use with QIAreach QuantiFERON-TB Blood Collection Tubes. All samples should be treated as potentially infectious. Discard sample and assay waste according to your local safety procedures. See Warnings and Precautions for more information.

- Blood samples may be held for a total of up to 16 hours at ambient temperatures up to 30°C prior to 37°C incubation.
- Blood samples may be refrigerated for a total of up to 48 hours prior to 37°C incubation. The total specimen handling time for refrigerated samples must not exceed 53 hours prior to 37°C incubation.

- Post 37°C incubation, blood may be stored uncentrifuged in the QIAreach QFT Blood Collection Tube at ambient temperatures up to 30°C for up to 3 days prior to performing the detection assay.
- Post 37°C incubation, blood that is centrifuged and stored refrigerated at 2–8°C may be held for up to 28 days prior to performing the detection assay.
- Plasma harvested from QIAreach QFT Blood Collection Tubes may be stored frozen at ≤ –20°C for up to 2 years. Minimize freezing and thawing of plasma samples.

Protocol: Blood Collection

Important points before starting

Setting up (Time required for performing assay)

The time required to perform the QIAreach QFT test is estimated below; the time of testing multiple samples when batched is also indicated:

- 37°C incubation of blood tubes: 16–24 hours
- Digital detection: Approx. 20 minutes for one test (1 individual)

  <25 minutes labor
  Add up to 3 minutes for each extra eStick

  Up to 8 eSticks can be run in parallel

  Multiple eHubs can be used

Pipette use

This assay requires use of an adjustable volume pipette. Users should familiarize themselves with pipette use prior to performing the QIAreach QFT test.

Stage 1 – Specimen collection and handling

Antigens have been dried onto the inner wall of the Blood Collection Tube so it is essential that the contents of the tube are thoroughly mixed with blood. Blood draw into the Blood Collection Tube must be maintained and transported at room temperature (17–30°C) and be transferred to a 37°C incubator as soon as possible and within 16 hours of collection.

Procedure

Draw Option 1: Direct draw into QIAreach QFT Blood Collection Tube

1. Label tube appropriately.
2. Note: It is recommended that you record the patient ID, time, and date of blood collection.
3. For each patient, collect 1 ml of blood by venipuncture directly into the QIAreach QFT Blood Collection Tube (See Figure 1). This procedure should be performed by a trained phlebotomist.

   Important: Tubes should be between 17–30°C at the time of blood filling.

   Note: The QIAreach QFT Blood Collection Tubes can be used up to an altitude of 810 meters above sea level.

   - 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.

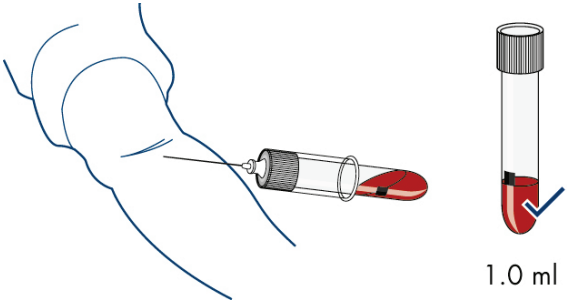


Figure 1. Direct blood draw into QIAreach QFT Blood Collection Tube and proper fill volume.

   - The white mark on the side of the tube 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, a new blood sample should be obtained. Under or over-filling of the tube 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 QIAreach QFT tube being used.
- If using the QIAreach QFT Blood Collection Tube at an altitude higher than 810 meters, or if low blood draw volume occurs, users can collect blood with a syringe, or can collect blood into a lithium or sodium heparin tube (see Draw Option 2) and immediately transfer 1 ml into the QIAreach QFT Blood Collection Tube.

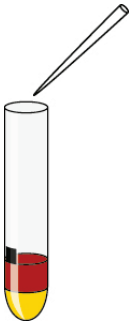


Figure 2. Blood may also be drawn into a separate lithium heparin tube and 1 ml transferred to the QIAreach QFT Blood Collection Tube.

- For safety reasons, transfer using a syringe is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the cap from the QIAreach QFT Blood Collection Tube, and adding 1 ml of blood (to the center of the white mark on the side of the tube label). Replace the cap securely and mix as described below. Ensure the tube is identifiable by its label or other means once the cap is removed.

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

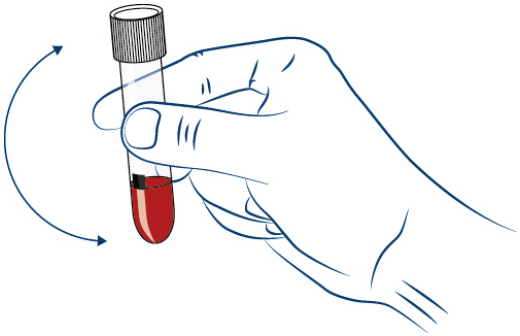


Figure 3. Immediately after filling with blood, shake the QIAreach QFT Blood Collection Tube 10 times to coat the inner tube walls.

Important: Tubes should be between 17–30°C at the time of shaking. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

5. Following labelling, filling, and shaking, the tube must be transferred to a 37°C ± 1°C incubator. Hold time and temperature options for the QIAreach QFT Blood Collection Tubes prior to 37°C incubation are below:

   BCT Hold Option 1: Room Temperature Storage and Immediate Transfer

   Note: Refer to Figure 5 for the Blood Collection Tube hold workflow.

   5a. Prior to incubation, maintain and transport the tube at room temperature (17–30°C).

   5b. Transfer the QIAreach QFT Blood Collection Tube to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection.

   5c. If the QIAreach QFT Blood Collection Tube is not incubated at 37°C directly after blood collection and shaking, invert the tube to mix 10 times prior to incubation at 37°C.

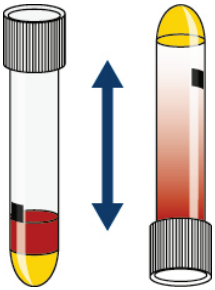


Figure 4. If the QIAreach QFT Blood Collection Tube is not incubated at 37°C directly after blood collection and shaking, invert the tube to mix 10 times prior to incubation at 37°C.

5d. Incubate the QIAreach QFT Blood Collection Tube upright at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO_2 or humidification. Proceed to Stage 2 – Harvesting of plasma.

BCT Hold Option 2: QIAreach QFT Blood Collection Tube Refrigerated Storage

Note: Refer to Figure 5 for the Blood Collection Tube hold workflow.

Important: Steps 5a–5c must be followed in sequence.

5a. If refrigerated blood storage is planned, blood drawn into QIAreach QFT Blood Collection Tubes may be held at room temperature (17–30°C) up to 3 hours after blood collection and prior to refrigeration.

5b. Blood drawn into QIAreach QFT Blood Collection Tubes may be refrigerated (2 to 8°C) for up to 48 hours before 37°C incubation.

5c. Incubate the QIAreach QFT Blood Collection Tube upright at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO_2 or humidification. Proceed to Stage 2 – Harvesting of plasma.

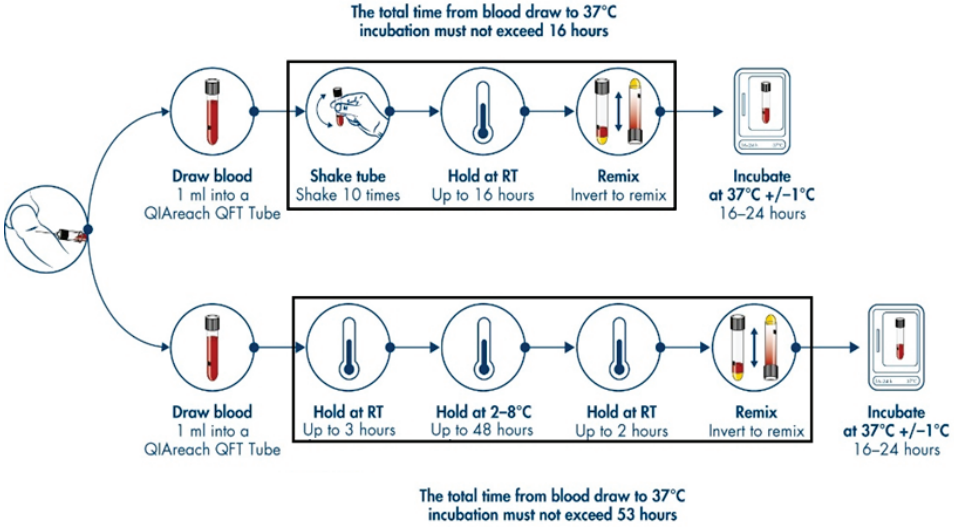


Figure 5. Blood collection and workflow options for blood directly drawn into QIAreach QFT Blood Collection Tubes (Draw Option 1).

Draw Option 2: Blood collection into a single heparin tube and then transfer to QIAreach QFT Blood Collection Tube

1. Collect the blood in a single Blood Collection Tube containing heparin as the anticoagulant, then transfer to the QIAreach QFT Blood Collection Tube. Only use lithium or sodium heparin as a blood anticoagulant as other anticoagulants may interfere with the assay. Label all tubes appropriately.

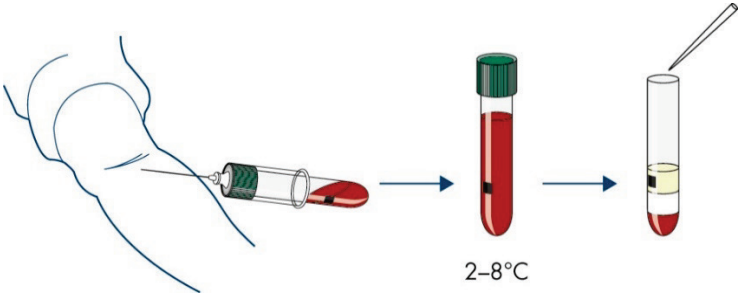


Figure 6. General workflow for blood collection into a heparin tube and transfer to a QIAreach QFT Blood Collection Tube (Draw Option 2).

Note: It is recommended that you label all tubes with the time and date of the blood collection.

Important: Blood collection tubes should be at room temperature (17–30°C) at the time of blood collection.

- Fill a heparin Blood Collection Tube (minimum volume 2 ml) and gently mix by inverting the tube several times to dissolve the heparin. This procedure should be performed by a trained phlebotomist.
- Hold time and temperature options for heparin tubes prior to transfer and incubation in QIAreach QFT Blood Collection Tubes are listed in Hold Option 1 and Hold Option 2.

Hold Option 1: Heparin Tube Room Temperature Storage and Handling

Note: Refer to Figure 7 for the Blood Collection Tube hold workflow.

1a. Blood collected in the heparin tube must be maintained at room temperature (17 to 30°C) for no more than 16 hours from the time of collection prior to transfer to the QIAreach QFT Blood Collection Tube and subsequent incubation.
Note: It is recommended to transfer the recorded patient ID, time, and date of blood collection from the heparin tube to the QIAreach QFT Blood Collection Tube.

1b. Samples must be evenly mixed by gentle inversion before dispensing into the QIAreach QFT Blood Collection Tube.

1c. Dispensing should be performed aseptically, ensuring appropriate safety procedures, by removing the cap from the QIAreach QFT Blood Collection Tube and adding 1 ml of blood to the tube. Replace the tube cap securely. Proceed to Step 2.

Hold Option 2: Heparin Tube Refrigerated Storage and Handling

Note: Refer to Figure 7 for the Blood Collection Tube hold workflow.

Important: Steps 1a–1c must be followed in sequence.

1a. Blood drawn into heparin tubes may be held at room temperature (17–30°C) up to 3 hours after blood collection.

1b. Blood drawn into heparin tubes may be refrigerated (2–8°C) for up to 48 hours.

1c. Within 2 hours of removing the heparin tube from refrigerated storage, the blood must be aliquoted into the QIAreach QFT Blood Collection Tube and placed in the 37°C incubator. The total time from blood draw to 37°C incubation in the QIAreach QFT Blood Collection Tube should not exceed 53 hours.

2. Immediately after transferring blood from the heparin tube to the QIAreach QFT Blood Collection Tube, shake 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: Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

3. Following labelling, filling, and shaking, the tube must be transferred to a 37°C ± 1°C incubator. If the QIAreach QFT Blood Collection Tube is not incubated at 37°C directly

after blood collection and shaking, invert the tube to mix 10 times (10x) prior to incubation at 37°C.

4. Incubate the QIAreach QFT Blood Collection Tube upright at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO_2 or humidification.

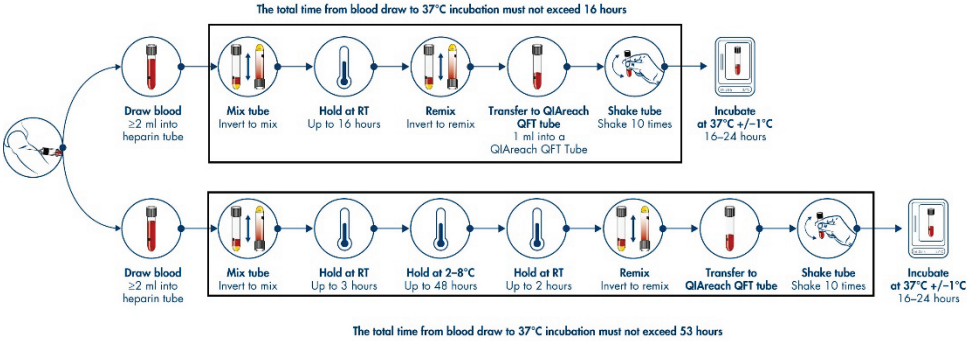


Figure 7. Blood collection and workflow options for blood drawn into a heparin tube and then transfer to a QIAreach QFT Blood Collection Tube (Draw Option 2).

Stage 2 – Harvesting of plasma

Procedure

1. After incubation at 37°C, the QIAreach QFT Blood Collection Tube may be held between 2°C and 30°C for up to 3 days prior to testing. The sample may be stored for a longer period of time if the plasma is harvested from the Blood Collection Tube.
2. After the incubation of the tubes at 37°C, harvesting of plasma is facilitated by centrifuging the tubes for 15 minutes at 2000–3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the tube should be re-centrifuged.

   Note: It is possible to harvest the plasma without centrifugation, but additional care is required to remove the plasma without disturbing the cells.

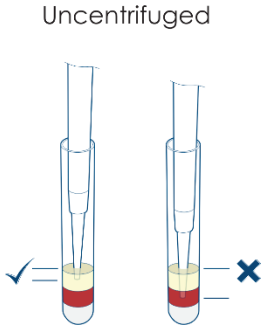


Figure 8. Harvesting plasma from uncentrifuged tubes. Plasma may be harvested from uncentrifuged tubes but additional care is required to remove 150 µl of plasma without disturbing the cells.

3. Plasma samples can be stored in centrifuged tubes for up to 28 days at 2–8°C or, if harvested, below –20°C for up to 2 years.

   Note: Plasma samples should only be harvested using a pipette. 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.
4. If harvesting the plasma to a separate tube for storage prior to testing, plasma can be loaded directly from the stored tubes into the QIAreach QFT Processing Tube when performing the QIAreach QFT test (Stage 3).

Note: For adequate test sample, it is recommended to harvest at least 350 µl of plasma.

Stage 3 – IFN-γ detection

Materials required

- QIAreach QFT Processing Tube (packaged together with eStick in foil wrapper).
- QIAreach QFT eStick (packaged together with Processing Tube in foil wrapper)
- QIAreach QFT Diluent Buffer
- QIAreach eHub (with associated power cable and adaptor)

Things to do before starting

- All plasma samples and reagents (if stored in the refrigerator), must be brought to room temperature (17–30°C) before use. Allow at least 60 minutes for equilibration.
- The eStick and Processing Tube are packaged together in a foil wrapper. The packaging should only be opened before performing the assay.

  Important: The QIAreach QFT assay must be started within 60 minutes of removing the components from the packaging.

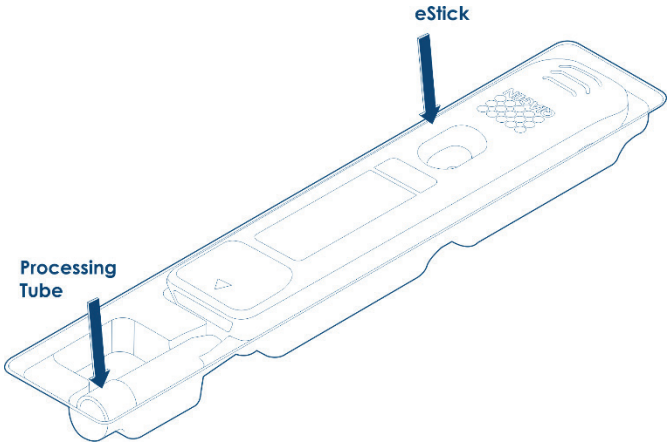


Figure 9. Contents of foil wrapper packaging – Processing Tube and eStick.

- The eStick is a single use device. It is recommend to label the eStick with test information using either a permanent marker or by applying a label directly on the eStick. If a label is applied to the eStick, ensure that the label is not placed over the sample port or the sloped front end (with arrow) of the eStick as this could affect connection between the eStick and eHub.
- There is a small white pad contained within the Processing Tube that is critical component of the QIAreach QFT assay. DO NOT remove the pad from the Processing Tube. This pad will not be dislodged or come loose during pipetting.
- If not connected to a power source, the eHub should have sufficient battery power to complete the test. A fully charged eHub should maintain internal battery power for 8 hours. The battery LED indicator will display the battery status. The QIAreach QFT test should not be performed if the eHub is not connected to a power source and the battery power is less than 10%, as designated by a red LED indicator. The battery level can also be checked by connecting the eHub to a laptop via the provided USB cable and launching the QIAreach software. The software displays the level of battery charge in the bottom right hand corner of the screen. Refer to *QIAreach eHub User Manual* and *QIAreach Software User Manual* for details.
- The eHub comes with a cover to protect the internal ports from dust buildup and contamination. The cover should be placed over the front panel of the eHub when the eHub is not in use.

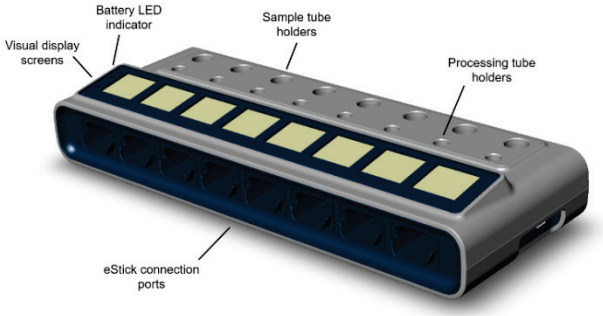


Figure 10. QIAreach eHub layout. Note: The cover should be in place when the eHub is not in use.

- Note: It is recommended to fully charge the eHub in a switched off state overnight (when not in use) or to charge for 4 hours before use. To charge the unit, connect the eHub to a power outlet using the provided USB power adaptor and USB cable. It is also recommended that the eHub is connected to a USB power source (either a USB adaptor or PC) during operation.

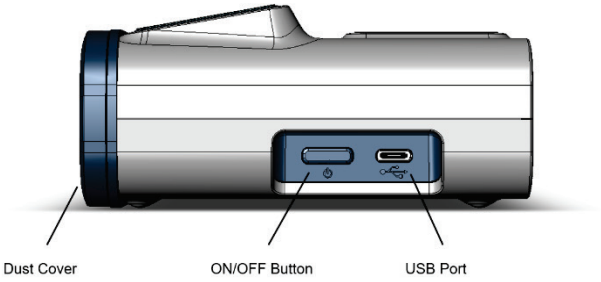
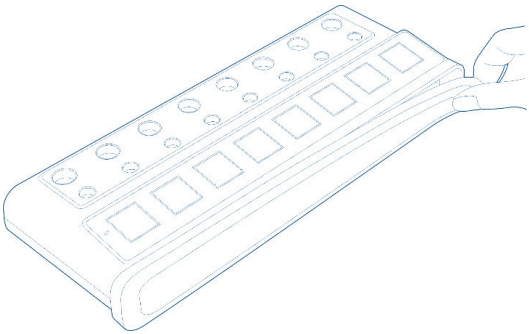


Figure 11. Side panel view of eHub with dust cover, ON/OFF switch, and USB connection port.

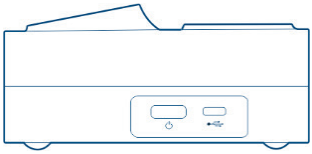
- If performing the assay using plasma that has already been harvested from the QIAreach QFT Blood Collection Tube, skip step 3 of this procedure. In step 6, add the plasma sample directly to the Processing Tube.

Procedure

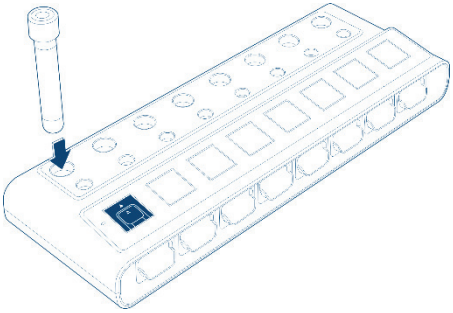
1. Remove the dust cover from the front panel of the QIAreach eHub and set aside.



2. Press the ON/OFF switch on the right side of the eHub to turn it on.

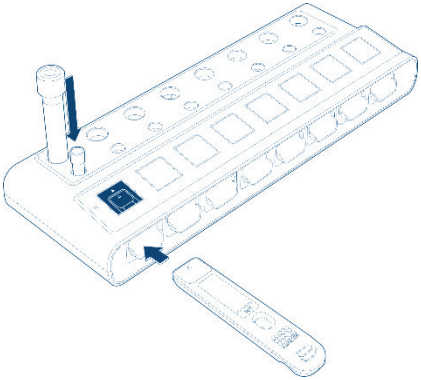


3. Place the BCT into the holder of the QIAreach eHub.

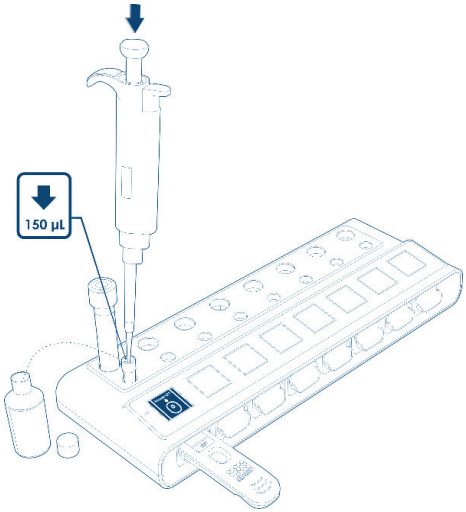


4. Remove the eStick from the packaging, label with patient identifier, and insert into the QIAreach eHub. Place the Processing Tube in the slot directly in line with the eStick.

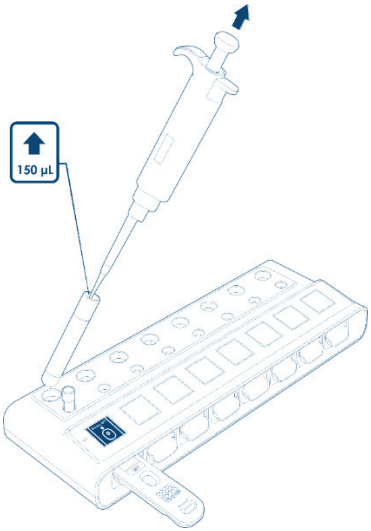
   Note: The test sample must be added to the eStick sample port within 60 minutes of removal from the foil packaging.



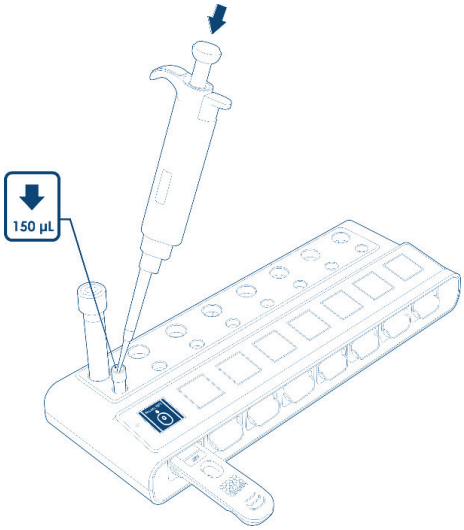
5. Add 150 µl of QIAreach QFT Diluent Buffer to the QIAreach QFT Processing Tube using a pipette.



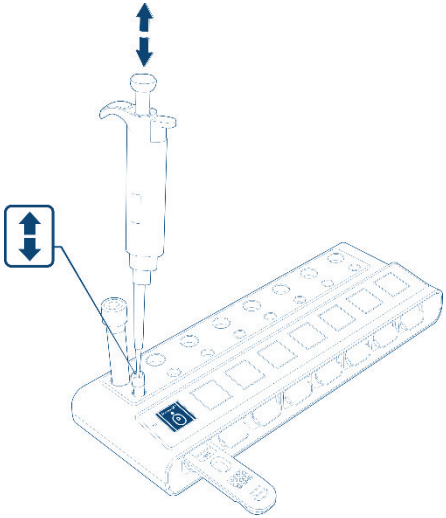
6. Remove the cap from the BCT and set aside. Carefully, remove 150 µL of plasma from the BCT.



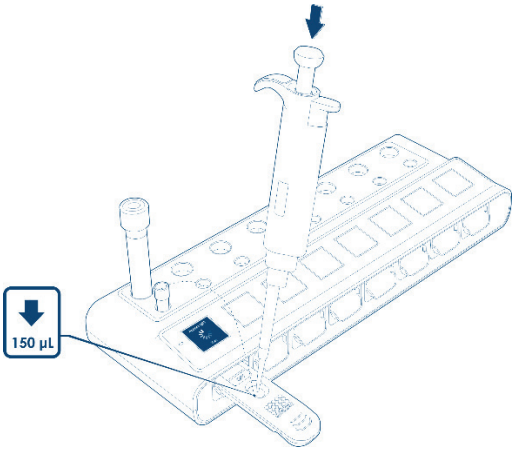
7. Add 150 µl of plasma to the QIAreach QFT Processing Tube containing the QIAreach QFT Diluent Buffer.



8. Mix the contents of the QIAreach QFT Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.

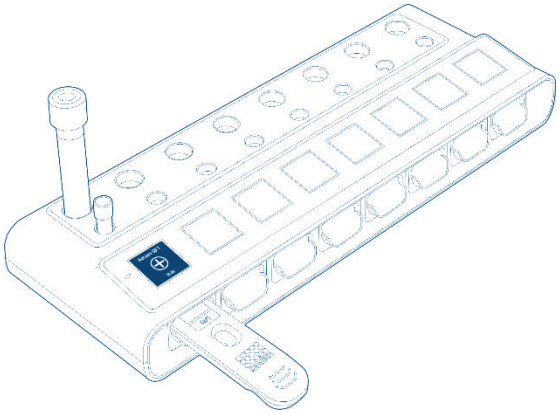


9. Remove 150 µl of sample from the QIAreach QFT Processing Tube and dispense into the sample port of the inserted eStick.

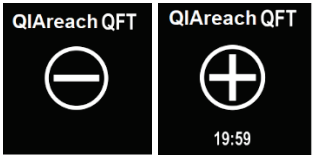


10. Following sample addition, the loading icon may appear on the eHub display for an additional 10–15 seconds before the sample is detected by the eStick. Once sample is detected, the test will start automatically, which is signaled by a countdown timer on the eHub display.

    Important: Do not remove the inserted eStick until the test is complete and a result is displayed.



11. After completion of the test, a result will be displayed on the QIAreach eHub.



Results

The standard time from sample addition to eStick to test result is 20 minutes. The time to result will be less than 20 minutes for samples containing high levels of IFN-γ (high QIAreach QFT Positive samples). The time to test result will be displayed on the QIAreach eHub following a Positive result.

QIAreach QFT raw data is analyzed on the eStick firmware, which then interprets a Positive or Negative QIAreach QFT result based on an internal algorithm. The result is transmitted to the eHub, which displays the result. If the optional software is used, the eHub will allow transfer of the test result to a computer for data backup and report printing.

Quality control of the test

All QIAreach QFT eSticks have built-in controls to ensure reliable performance of the eStick optoelectronics and lateral flow strip and also monitor procedural steps after sample addition to confirm suitability. A failure alert will be communicated to the user in the form of a test error if any fault conditions are detected on the eStick firmware.

Mechanical performance controls are in place to confirm that the eStick components are functioning correctly and are not compromised due to improper handling or transport. Once the sample is added to the eStick, the eStick will continually monitor progress, including the proper flow rate of sample across the strip as well as the correct range of detector particles in the sample. The eStick has extensive controls built into the firmware to alert the user if the test has not been successfully completed or if the test strip has been compromised, providing an additional level of control over standard lateral flow tests that rely on a single control line.

External positive and negative controls are not supplied with this kit. Laboratories wanting to test external positive and negative controls should do so consistent with good laboratory practice and local regulations.

If the test is invalid, an error code will be displayed on the eHub. The test should be repeated if there is ≥ 150 µl of patient sample remaining. See Appendix B: Error Codes for the list of QIAreach QFT error codes.

Interpretation of Results

QIAreach QFT results are interpreted using the following criteria in Table 1.

Important: Diagnosing or excluding tuberculosis disease and assessing the probability of TB infection, requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting QIAreach QFT results.

Table 1. Interpretation of QIAreach QFT results

QIAreach QFT result	**Report/Interpretation**
Positive*	*M. tuberculosis* infection likely
Negative	*M. tuberculosis* infection NOT likely

* Where *M. tuberculosis* is not suspected, initially positive results can be confirmed by retesting the original plasma sample and/or testing an additional patient sample.

Limitations

Results from QIAreach QFT testing must be used in conjunction with each individual's epidemiological history, current medical status, and other diagnostic evaluations.

Significantly hemolyzed (reddish brown) samples can potentially interfere with the optical measurement system. QIAreach QFT eStick firmware features built-in controls to determine unacceptably high levels of hemolysate (> 5mg/ml) and will return an invalid result in the form of an error code if interference is present. Refer to the troubleshooting section if observing elevated hemolysate in samples.

Unreliable results may occur due to deviations from the instructions for use.

Performance Characteristics

Analytical Performance

Repeatability

Intra- and inter- assay repeatability was evaluated using multiple lots of both QIAreach QFT Blood Collection Tubes and QIAreach QFT eSticks/Processing Tubes in two test configurations.

In the first test configuration, blood was collected from one QIAreach QFT negative subject and one QIAreach QFT low positive subject into three separate lots of QIAreach QFT Blood Collection Tubes, with each subject collected into 10 Blood Collection Tubes from each lot, for a total of 60 test observations across both subjects. The positive and negative agreement levels to the expected positive or negative QIAreach test result for each QIAreach QFT Blood Collection Tube lot is shown in Table 2.

Table 2. QIAreach QFT BCT inter-lot repeatability / eStick intra-lot repeatability

	Positive Agreement	Negative Agreement	Overall agreement	Overall % Agreement (95% CI)
Tube lot 1 / eStick lot A	10/10	10/10	20/20	100% (83.2–100%)
Tube lot 2 / eStick lot A	10/10	10/10	20/20	100% (83.2–100%)
Tube lot 3 / eStick lot A	10/10	10/10	20/20	100% (83.2–100%)
Aggregate Agreement	30/30	30/30	60/60	100% (94.0–100%)

In the second test configuration, blood was collected from one QIAreach QFT negative subject and one QIAreach QFT low positive subject into a single lot of QIAreach QFT Blood Collection Tubes. Plasma from each subject was then tested on three separate lots of eSticks/Processing

Tubes, with each subject tested 10 times on each lot, for a total of 60 test observations across both subjects. The positive and negative agreement levels to the expected positive or negative QIAreach test result for each eStick lot is shown in Table 3.

Table 3. QIAreach QFT BCT intra-lot repeatability / eStick inter-lot repeatability

	Positive Agreement	Negative Agreement	Overall agreement	Overall % Agreement (95% CI)
Tube lot 1 / eStick lot A	10/10	10/10	20/20	100% (83.2–100%)
Tube lot 1 / eStick lot B	10/10	10/10	20/20	100% (83.2–100%)
Tube lot 1 / eStick lot C	10/10	10/10	20/20	100% (83.2–100%)
Aggregate Agreement	30/30	30/30	60/60	100% (94.0–100%)

For both repeatability test configurations, the test agreement to the expected positive or negative QIAreach QFT result was 100% (95% CI: 94.0–100%).

Reproducibility

The reproducibility of QIAreach QFT was evaluated by testing 12 QIAreach QFT Positive and 12 QIAreach QFT Negative subjects across three separate sites (with each site using separate equipment) by two individual operators at each site, for a total of 6 tests results per subject and a total of 144 observations. The true status of each subject was blinded at each test site and confirmed by an independent lab. The reproducibility at each test site and across all test sites is shown in Table 4 below.

Table 4. QIAreach QFT Reproducibility across different sites and operators

Site	Operator	Positive reproducibility	Negative reproducibility	Overall reproducibility	**Overall % agreement (95% CI)**
Site 1	Operator 1	12/12	12/12	24/24	100% (85.8–100%)
	Operator 2	12/12	12/12	24/24	100% (85.8–100%)
Site 2	Operator 1	12/12	12/12	24/24	100% (85.8–100%)
	Operator 2	12/12	12/12	24/24	100% (85.8–100%)
Site 3	Operator 1	12/12	12/12	24/24	100% (85.8–100%)
	Operator 2	12/12	12/12	24/24	100% (85.8–100%
Overall		**72/72**	**72/72**	**144/144**	**100% (97.5–100%)**

The diagnostic reproducibility was 100% (95% CI: 97.47–100.0%).

Interference

The effect of potentially interfering substances on QIAreach QFT was evaluated by spiking endogenous and exogenous interferents into negative plasma and low level IFN-γ plasma at recommended high level concentrations. No significant interference was observed at the following concentrations:

- Abacavir sulfate 12.7 µg/ml

- Bilirubin, conjugated 0.4 mg/ml
- Bilirubin, unconjugated 0.4 mg/ml
- Cyclosporine 1.8 µg/ml
- Hemoglobin* 5 mg/ml
- Prednisolone 0.12 mg/ml
- Protein, total 150 mg/ml
- Triglycerides 15 mg/ml

Analytical sensitivity

The limit of detection of QIAreach QFT is 0.3 IU/ml and there is no evidence of a clinically relevant high-dose hook (prozone) effect at IFN-γ concentrations up to 1000 IU/ml.

Clinical Performance

The clinical study compared the clinical accuracy (concordance) between the QIAreach QFT system and well-established internationally recognized reference TB infection diagnostic method QuantiFERON-TB Gold Plus (45, 46). QFT-Plus is CE-IVD marked and FDA approved.

A total of 225 subjects were tested with both the QFT-Plus ELISA reference method and the QIAreach QFT system, made up of 150 QFT-Plus negative subjects and 75 QFT-Plus positive subjects. The demographics are shown in Table 5.

* Hemoglobin levels above 5 mg/ml (reddish brown colored samples) can potentially interfere with the optical measurement system. QIAreach QFT eStick firmware features built-in controls to determine unacceptably high levels of hemolysate and will return an invalid result in the form of an error code if interference is present. See Appendix B: Error Codes for more information.

Table 5. Subject demographics information

Total subjects (225)	Identification	Number	**Percentage**
Gender	Male	185	82.6%
	Female	39	17.4%
Age (years)	Range	19–85	54 (median)

As part of study enrollment, subjects answered a questionnaire to identify TB risk factors. To be included in the study, subjects were required to have at least one identified risk factor for TB infection and to not have received TB treatment or less than 14 consecutive days of TB treatment. All subjects provided informed consent.

Risk factor distribution among subjects is shown in Table 6.

Table 6. Subject risk factor information (n=225)

Risk factor	Status	Number	**Percentage**
BCG vaccinated	Yes	37	16.4%
	No	182	80.9%
	Unknown	6	2.7%
HIV positive or tested positive for HTLV viruses	Yes	8	3.6%
	No	217	96.4%
Previously diagnosed with active TB	Yes	24	10.7%
	No	199	88.4%
	Unknown	2	0.9%
Had a positive Tuberculin Skin Test (TST)/Mantoux test for TB	Yes	33	14.7%
	No	190	84.4%
	Unknown	2	0.9%
Ever been treated for active or latent TB	Yes	9	4.0%
	No	215	95.6%
	Unknown	1	0.4%
Lived, worked, or volunteered (>1 month) in a jail or prison	Yes	113	50.2%
	No	111	49.3%
	Unknown	1	0.5%

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Table 6. Subject risk factor information (n=225)

Total subjects (225)	Identification	Number	**Percentage**
Lived, worked, or volunteered (>1 month) in a homeless shelter	Yes	171	76.0%
	No	53	23.6%
	Unknown	1	0.4%
Healthcare worker	Yes	2	0.9%
	No	221	98.2%
	Unknown	2	0.9%
Close contact of someone with or suspected of having active TB disease	Yes	39	17.3%
	No	175	77.8%
	Unknown	11	4.9%

Specimens were collected from a total of 4 sites. All QFT-Plus ELISA testing and QIAreach QFT testing was performed at a single site.

Clinical agreement

The clinical agreement levels of QIAreach QFT Positive and Negative results with QFT-Plus Positive and Negative results are reported in Table 7.

Table 7. Clinical Agreement: QIAreach QFT result vs. QFT-Plus result (reference)

QIAreach QFT	QFT-Plus		
	Negative (–)	**Positive (+)**	**Total**
Negative (–)	148	4	152
Positive (+)	2	71	73
Total	150	75	225

The positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA) between the results of QIAreach QFT and QFT-Plus as the reference method were as follows:

Table 8. QIAreach QFT versus QFT-Plus

	Frequency	Agreement	Upper 95% CI	**Lower 95% CI**
OPA*	219/225	97.3%	99.0%	94.3%
PPA	71/75	94.7%	98.5%	86.9%
NPA	148/150	98.7%	99.8%	95.3%

OPA: Overall percent agreement; **PPA:** Positive percent agreement; **NPA:** Negative percent agreement

* When factoring in 15 QFT-Plus indeterminate results, the OPA between QFT-Plus and QIAreach QFT is 91.3% (95% CI: 86.9 – 94.5%).

Expected values

QIAreach QuantiFERON-TB is a qualitative test that provides a Positive or Negative test result to the user within 20 minutes after starting the assay. For QIAreach QuantiFERON-TB Positive samples, the time to result is influenced by the level of IFN-γ in the patient sample and a Positive test result may be reported in as few as 3 minutes. Figure 12 shows the frequency of QIAreach QuantiFERON-TB Positive results reported in 5-minute intervals.

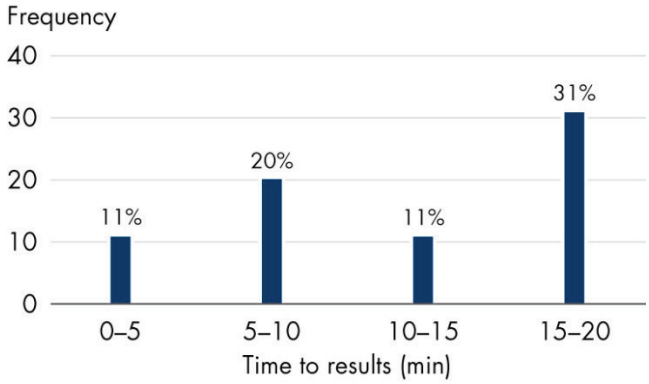

Figure 12. Frequency of QIAreach QuantiFERON-TB Positive results for range of time to results.

The IFN-γ -Nil IU/ml values from the QFT-Plus TB1 and TB2 antigen tubes were compared to the QIAreach QFT Positive time to result for all 75 QFT-Plus Positive subjects. Eleven (11) QFT-Plus subjects that returned a TB1 – Nil or TB2 – Nil result > 10 IU/mL were excluded from the analysis. Quadratic regression models were fitted to the data to model the relationship between TB1 – Nil and TB2 - Nil values and the QIAreach QFT Positive time to result. The quadratic regression models had R^2 values of 0.601 and 0.712 for TB1 – Nil and TB2 - Nil respectively.

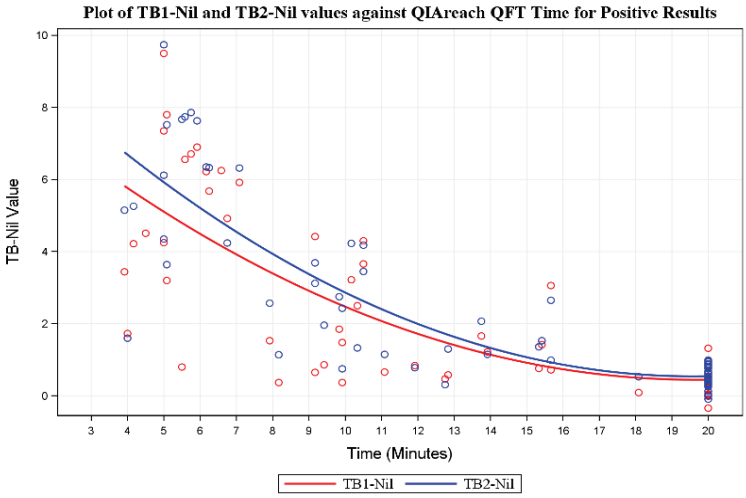

Figure 13. Plot of TB1-Nil and TB2-Nil values against QIAreach QuantiFERON-TB time for positive results, with quadratic regression lines overlaid.

Safety of the QIAreach QFT System

There were no adverse events reported for the clinical study.

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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**).

QIAreach QFT troubleshooting

See Appendix B: Error Codes for the list of error codes.

Significantly hemolyzed (reddish brown) samples can potentially interfere with the QIAreach QFT optical measurement system. QIAreach QFT eStick firmware features built-in controls to determine unacceptably high levels of hemolysate and will return an invalid result in the form of an error code if interference is present. If a reddish-brown test sample results in a "B" error code or if the sample is added to the eStick and the test will not start within 1 minute, then the sample may contain elevated levels of hemoglobin that interfere with the test. Causes of in vitro hemolysis may include improper sample collection from the patient and improper storage / handling of the sample prior to analysis. See Specimen Storage and Handling for guidelines and follow the sample collection instructions in Stage 1 – Specimen collection and handling.

Additional user warnings

- When cleaning, avoid any deliberate water ingress deep into the test ports. The eHub can be cleaned using mild detergent, 10% bleach or 70% EtOH.
- Only use the eHub with the USB cable and USB adaptor supplied with the device.

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 directive 98/79/EC for in vitro diagnostic medical devices.
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation
	Manufacturer

Symbol	Symbol definition
	Consult instructions for use
	Warning/caution
	Sterilized using irradiation
	Do not reuse
	Unique Device Identifier
	Biohazard
	Waste from Electrical and Electronic Equipment (WEEE)
	RoHS3

Contact Information

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

Appendix A: Technical Information

Clotted plasma samples

Should fibrin clots occur with long-term storage of plasma samples at or below 4°C, centrifuge the samples to sediment clotted material and facilitate pipetting of plasma.

eHub display icons

Table 9. eHub display icons

Icon	ID	Description
	Please Insert	The QIAreach eHub port is available for eStick use.
	Self-test	The eStick has been inserted and a self-test is being performed.
	Add sample	The eStick is ready for sample addition to the detection port. The sample must be added within 60 minutes of removing the eStick from the foil packaging.
	Processing	The eStick has detected sample and is processing the test. A test countdown timer is displayed. Do not remove the eStick until a result is displayed. Test times will vary based on Positive or Negative results.
	Positive	The test has returned a positive result.
	Negative	The test has returned a negative result.
	Error	The test has encountered an error. The letter denotes the type and the numbers are code for the error. See Appendix B: Error Codes for more information.

Appendix B: Error Codes

The following table lists the potential error codes in QIAreach QFT:

Table 10. QIAreach QFT error codes categories – general description

Error type	Error code format	**Description**
Self-Test	A-[Error code]	eStick electronic failure
Algorithm	B-[Error code]	Run error or user workflow error
Communication/ Other	C-[Error code]	Invalid data or missed communication between eStick and eHub

Table 11. "A" error codes

Error code	Description	**Recommended action**
A-1	Used eStick	Discard and use new eStick.
A-2	Metadata error	Discard and use new eStick.
A-4	Metadata error	Discard and use new eStick.
A-8	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-16	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-32	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.

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Table 11. "A" error codes

Error code	Description	**Recommended action**
A-64	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-128	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-256	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-512	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-1024	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-2048	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-4096	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-8192	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-16384	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.

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Table 11. "A" error codes

Error code	Description	**Recommended action**
A-32768	Dark Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-65535	Unknown value	Remove and re-insert the eStick. If error persists, discard and use new eStick.

Table 12. "B" error codes

Error code	Description	**Recommended action**
B-0	No result	Discard and use new eStick.
B-8	Conjugate Wave Too Early	Ensure eStick is inserted prior to adding sample. Discard and use new eStick.
B-9	Conjugate Wave Too Early	Check color of sample*. Discard and use new eStick.
B-10	High Dark Frequency	Ensure test is run out of sunlight. Discard and use new eStick.
B-12	No Frequency	Discard and use new eStick.
B-13	No Frequency	Discard and use new eStick.
B-14	No Conjugate Wave (Timeout)	Run test within 60 minutes of removing eStick from foil. Check color of sample. Discard and use new eStick.
B-15	Frequency Out of Range	Discard and use new eStick.
B-16	Low Frequency	Ensure sample is mixed in QIAreach QFT Processing Tube prior to adding test sample. Discard and use new eStick.
B-17	High Frequency	Discard and use new eStick.
B-18	Frequency Out of Range	Discard and use new eStick.
B-19	Low Frequency	Ensure sample is mixed in QIAreach QFT Processing Tube prior to adding test sample. Discard and use new eStick.
B-21	Flow rate error	Check color and viscosity of sample*. Discard and use new eStick.

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Table 12. "B" error codes

Error code	Description	**Recommended action**
B-22	Result Timeout	Discard and use new eStick.
B-23	Baseline Issue	Discard and use new eStick.
B-24	Baseline Issue	Discard and use new eStick.
B-25	Signal Noise	Discard and use new eStick.
B-255	Test Removed Early	Wait for test completion before removing eStick. Discard and use new eStick.

* See Troubleshooting Guide for information regarding hemolyzed samples.

Table 13. "C" error codes

Error code	Description	**Recommended action**
C-0	Connection Error	Remove and re-insert the eStick. If error persists, discard and use new eStick.
C-1	Expired eStick	Test is past expiry date. Use an eStick within expiration.
C-2	Sample Not Detected	Run test within 60 minutes of removing eStick from foil. Discard and use new eStick.
C-3	Start Not Acknowledged	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-4	Self Test Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-5	Metadata Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-6	Measurement Data Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-9	Algorithm Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.

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Table 13. "C" error codes

Error code	Description	**Recommended action**
C-10	Unexpected Result Time	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-11	eStick Timeout	Run test within 60 minutes of removing eStick from foil. Discard and use new eStick.
C-12	Test Removed Too Early	Wait for test completion before removing eStick. Discard and use new eStick.
C-13	Connection Error	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-14	eHub Low Battery	Charge eHub or connect to main power prior to repeating test. Remove and re-insert the eStick. If error persists, discard and use new eStick.
C-15	eHub Internal Error	The eHub can no longer be used. Contact QIAGEN Customer Support.
C-16	eHub RTC Failure	The eHub can no longer be used. Contact QIAGEN Customer Support.

* The eHub does not have to be fully charged before running a test, but it is recommend keeping the eHub plugged in to a power source and charging at all times, if possible.

Ordering Information

Product	Contents	Cat. no.
QIAreach QuantiFERON-TB Test Kit	50 QIAreach QFT Blood Collection Tubes 50 QIAreach QFT eSticks / Processing Tubes 2 x 10 ml Diluent Buffer	622724
Related products		
QIAreach eHub	QIAreach eHub, power adaptor, USB connector cable and user manual	9002969
QIAreach Software	N/A	Downloadable from www.qiagen.com

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
R1, March 2021	Initial release
R2, June 2021	Fixed Contents section; QIAreach now a registered trademark.

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