QFT™
QuantiFERON-TB Gold

Single Patient Pack

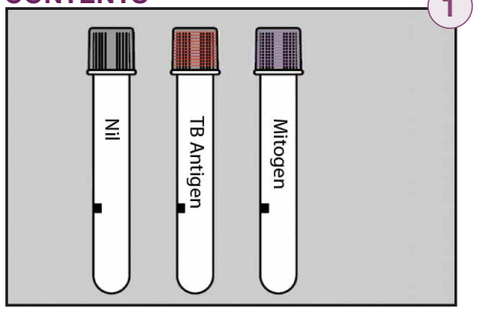
Standard
Catalog No: 0597-0403

High Altitude
Catalog No: 0597-0405

For use with QFT ELISA kit
(Catalog No: 0594-0201)

cellestis

CONTENTS 1

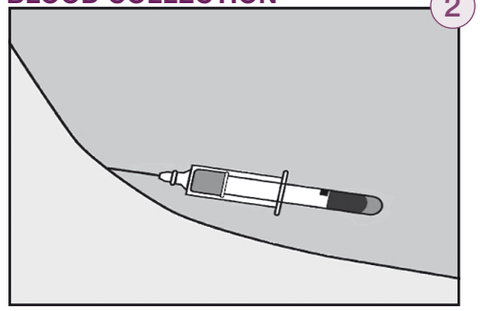


3x 1mL QFT™ blood collection tubes

1x Package Insert

⚠ WARNING: Standard blood handling precautions apply. See reverse side for detailed instructions.

BLOOD COLLECTION 2



Collect 1mL blood by venepuncture, up to the black mark.

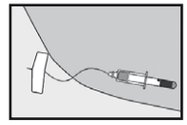
Tubes may be stored and should be at 17°C–27°C at the time of use.

Tubes fill slowly—hold tube on needle for 2–3 seconds after flow ceases.

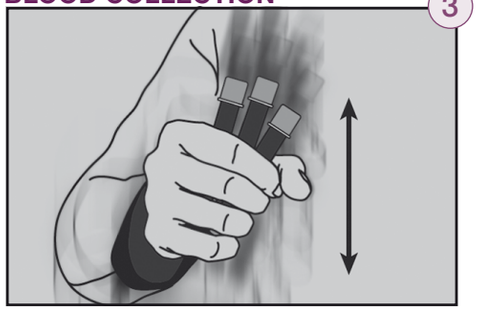
Repeat tube if not close to black mark.

Technical Tip

Butterfly needles—prime tubing with normal tube (not supplied) before filling QFT tubes.



BLOOD COLLECTION 3



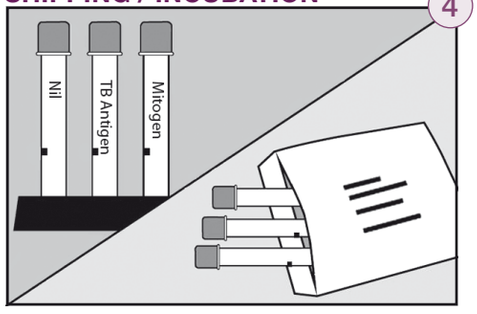
Immediately after filling, **shake** tubes **vigorously** for 5 seconds (10X).

Ensure that entire inner surface of each tube has been coated with blood.

Proper shaking will result in frothing of blood. This will not affect the results, and should be observed for correct performance of the test.

Label tubes appropriately.

SHIPPING / INCUBATION 4



Option 1—Incubate at Laboratory

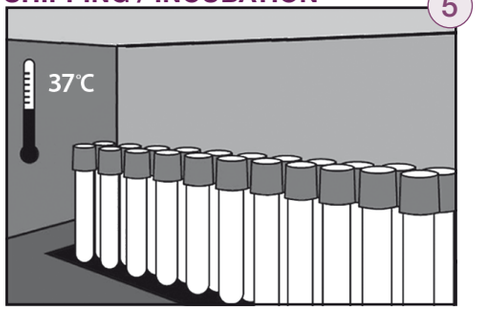
Ship tubes to laboratory at 17°C–27°C. Blood must be incubated at 37°C as soon as possible (and within 16 hours of collection).

Laboratory staff must re-shake tubes immediately prior to 37°C incubation.

Technical Tip

Label tubes as “Not Incubated”.

SHIPPING / INCUBATION 5



Option 2—Incubate at Collection site

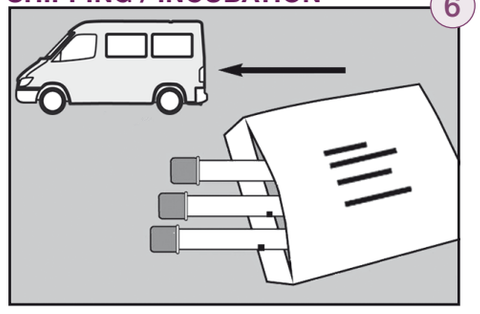
Blood must be incubated as soon as possible (and within 16 hrs of collection). Incubate tubes **upright** at 37°C for 16–24 hours.

Humidity/CO_2 is not required.

Portable incubators are available from Cellestis.

If tubes are not incubated at 37°C soon after collection, re-shake tubes immediately prior to incubation.

SHIPPING / INCUBATION 6



Option 2 (continued)

Ship **incubated** tubes to testing laboratory (within 3 days, if not centrifuged).

Maintain tubes at 2°C–27°C.

Technical Tip

Label tubes as “Incubated”.

CONTACT DETAILS

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cellestis

SSI Technology
www.ssi.dk
Antigens licensed from Statens Serum Institut

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QuantiFERON®-TB Gold Dispenser Pack

QuantiFERON-TB Gold In-Tube uses the following collection tubes:

Standard (Catalog No: 0597-0403)
for use between sea-level and 2,650 feet

1. Nil Control (grey cap with white ring)
2. TB Antigen (red cap with white ring)
3. Mitogen Control (purple cap with white ring)

High Altitude (Catalog No: 0597-0405)
for use between 3,350 feet and 6,150 feet

1. Nil Control (grey cap with yellow ring)
2. TB Antigen (red cap with yellow ring)
3. Mitogen Control (purple cap with yellow ring)

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. The tubes must be transferred to a 37°C ± 1°C incubator as soon as possible and within 16 hours of collection.

The following procedures should be followed for optimal results.

1. Blood Collection

1.1 For each subject collect 1mL of blood by venipuncture directly into each of the QuantiFERON-TB Gold IT blood collection tubes.

- As 1mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling, to ensure that the correct volume is drawn.
- The black mark on the side of the tubes indicates the 1mL fill volume. QuantiFERON-TB Gold IT blood collection tubes are manufactured to draw 1mL ± 10% and perform optimally within the range of 0.8 to 1.2mL. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample or to collect blood via a syringe as described below. Under or over-filling of the tubes outside the 0.8 to 1.2mL range may lead to erroneous results.
- Standard QFT-Gold IT blood tubes have been validated to draw between 0.8mL and 1.2mL at altitudes from sea-level to 2,650 feet. High Altitude (HA) tubes should be used at altitudes between 3,350 and 6,150 feet. If using the QuantFERON blood collection tubes outside these altitude ranges (between 2,650 and 3,350 feet or above 6,150 feet), or if low blood draw volume does occur, blood can be collected using a syringe and 1mL transferred to each of the three tubes. For safety reasons, this is best performed by removing the syringe needle, **ensuring appropriate safety procedures**, removing the caps from the three QFT-Gold IT tubes and adding 1mL of blood to each (to the black mark on the side of the tube label). Replace the tube caps securely and mix as described below.
- 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 QuantiFERON-TB Gold IT tubes being used.

1.2 Mix the tubes by **shaking vigorously** for 5 seconds (10X) to ensure that the **entire inner surface of the tube** has been coated with the blood.

- Thorough mixing is required to ensure complete integration of the tube's contents into the blood.

1.3 Label tubes appropriately.

- Ensure each tube (Nil, TB Antigen, Mitogen) is identifiable by its label or other means once the cap is removed.

1.4 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 tubes at room temperature (22°C ± 5°C). Do not refrigerate or freeze the blood samples.

2. Incubation of Blood and Harvesting of Plasma

2.1 If the blood is not incubated immediately after collection, **re-mixing of the tubes by vigorously shaking for 5 seconds (10X) must be repeated immediately prior to incubation,** as described in Section 1.2.

2.2 Incubate the tubes **upright** at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO_2 or humidification.

2.3 Following 37°C ± 1°C incubation, blood collection tubes may be held between 2°C and 27°C for up to 3 days prior to centrifugation.

2.4 After incubation of the tubes at 37°C ± 1°C, 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, the tubes should be re-centrifuged at a higher speed.

2.5 Plasma samples can be loaded directly from blood collection tubes into the QuantiFERON-TB Gold IT ELISA plate, especially when automated ELISA workstations are being used.

2.6 Alternatively, plasma samples can be stored prior to ELISA, either in the centrifuged tubes or collected into plasma storage containers. For example, harvest > 150µL of plasma into microplate wells or racked microtubes in 96 well format and seal to prevent spills and evaporation if samples are to be stored.

- Plasma samples can be stored for up to 28 days at 2°C to 8°C or below -20°C (preferably less than -70°C) for extended periods.
- Plasmas may clot during extended storage. If clots are present refer to **Trouble Shooting** section of QuantiFERON-TB Gold IT Package Insert.

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