QuantiFERON®-TB Gold Plus Collection Instructions into Lithium-Heparin Tube

Collection Kit

Contact ICL Client Care at 416.422.3000 x300 or info@iclabs.ca

Specimen type

Whole blood collected in lithium-heparin tube 6.0 mL

Volume

Minimum 5 mL

Lithium-Heparin Tube Collection Procedures

Option 1: Lithium-heparin tubes stored at room temperature

1. For each patient, collect a minimum of 5 mL of blood by venipuncture into a single lithium heparin tube (green top) at room temperature (17-25°C). Label the tubes accordingly with appropriate patient and specimen identifiers, including time and date of the blood collection.
2. Gently mix the blood-filled lithium-heparin tube by inverting 10x to ensure the heparin is dissolved.

Lithium-heparin tubes can be held at room temperature for a **maximum of <u>12 hours</u>** from the time of blood collection prior to transfer to Quantiferon-Plus Blood Collection Tubes.

3. Within 12 h of blood collection into lithium-heparin tubes, transfer heparinized blood into each QuantiFERON-Plus (QFT-Plus) Blood Collection Tube. Delays in incubation can cause false-negative or indeterminate results.
   a) Label each QFT-Plus collection tube with appropriate patient and specimen identifiers. Specimen labels should not cover the tube identifying label (e.g. mitogen) or should be identifiable by other means to prevent confusing tube type once caps are removed. If tube type is mislabeled during this step, invalid or inaccurate results will be generated.
   b) Gently invert heparin tubes again before dispensing into the QFT-Plus Blood Collection Tubes.
   c) Using aseptic technique, remove caps from QFT-Plus Blood Collection Tubes and add 1 mL of blood to each tube in the following order: mitogen, TB1, TB2, and Nil. Re-cap the tubes securely.
   d) Immediately mix the QFT-Plus Blood Collection Tubes by gently inverting them 10x and ensure the entire inner surface of the tube is coated in blood to dissolve antigens on the tube wall. Improper mixing at this step can cause false-negative or indeterminate results.
4. Following labelling, filling, and gentle mixing, the QFT-Plus Blood Collection Tubes must be transferred to a 37°C +/- 1°C incubator (no CO_2 or humidification required) **<u>within 2 hours</u>**. If tubes are not directly incubated after filling, invert the tubes 10x again prior to incubation.
5. Incubate the QFT-Plus Blood Collection Tubes **<u>upright at 37°C +/- 1°C for 16 to 24 hours</u>**.
6. After incubation of the blood collection tubes at 37°C +/- 1°C, centrifuge all QFT-Plus Blood

Collection Tubes for 15 minutes at 2000 to 3000 *g.* The gel plug will separate cells from the plasma. If this does not occur, the tubes should be recentrifuged. Tubes may be held between 4°C to 27°C for up to 3 days prior to centrifugation.

Option 2. Lithium-heparin tubes stored at refrigerated temperatures (2-8°C)

1. For each patient, collect a minimum of 5 mL of blood by venipuncture into a single lithium heparin tube (green top) at room temperature (17-25°C). Label the tubes accordingly with appropriate patient and specimen identifiers, including time and date of the blood collection.
2. Gently mix the blood-filled lithium-heparin tube by inverting 10x to ensure the heparin is dissolved.

Lithium-heparin tubes can be refrigerated (2-8°C) for a **maximum of 48 hours** from the time of collection prior to transfer to Quantiferon-Plus Blood Collection Tubes.

3. Place heparin tubes in the refrigerator (2-8°C) for a maximum of 48 hours from the time of collection. If undergoing refrigeration storage, blood drawn into lithium-heparin tubes cannot be held at room temperature for more than 3 hours after blood collection.
4. Prior to transferring into the QuantiFERON-Plus (QFT-Plus) Blood Collection Tubes, hold refrigerated heparinized blood at room temperature (17-25°C) for 20 minutes.
5. Label each QFT-Plus collection tube with appropriate patient and specimen identifiers. Specimen labels should not cover the tube identifying label (e.g. mitogen) or should be identifiable by other means to prevent confusing tube type once caps are removed. If tube type is mislabeled during this step, invalid or inaccurate results will be generated.
6. Once the heparin tube has equilibrated to room temperature, gently invert heparin tubes 10x.
7. Using aseptic technique, remove caps from QFT-Plus Blood Collection Tubes and add 1 mL of blood to each tube in the following order: mitogen, TB1, TB2, and Nil. Re-cap the tubes securely.
8. Immediately mix the QFT-Plus Blood Collection Tubes by gently inverting them 10x and ensure the entire inner surface of the tube is coated in blood to dissolve antigens on the tube wall. Improper mixing at this step can cause false-negative or indeterminate results.
9. Following labelling, filling, and gentle mixing, the QFT-Plus Blood Collection Tubes must be transferred to a 37°C +/- 1°C incubator (no CO_2 or humidification required) **within 2 hours**. If tubes are not directly incubated after filling, invert the tubes 10x again prior to incubation.
10. Incubate the QFT-Plus Blood Collection Tubes **upright at 37°C +/- 1°C for 16 to 24 hours**.
11. After incubation of the blood collection tubes at 37°C +/- 1°C, centrifuge all QFT-Plus Blood Collection Tubes for 15 minutes at 2000 to 3000 *g.* The gel plug will separate cells from the plasma. If this does not occur, the tubes should be recentrifuged. Tubes may be held between 4°C to 27°C for up to 3 days prior to centrifugation.

NOTES:

- Specimen collection locations between 1020 and 1875 meters above sea level should use High Altitude QFT-Plus Blood Collection Tubes). ICL Client Care should be contacted to make special arrangements.

Transport Container

QFT-Nil control (grey cap tube)

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QFT-TB1 antigen (green cap tube)

QFT-TB2 antigen (yellow cap tube)

QFT-Mitogen control (purple cap tube)

Transport Temperature
Refrigerated (2-8°C) (cold packs)

Specimen Stability Centrifuged specimens: Refrigerated 28 days

Reject Criteria
Non-incubated specimens; Received frozen; Received at Room temperature; NSQ

Methodology
Immunoassay (ELISA)

Performing Laboratory
Hospital for Sick Children, Toronto, ON