

**Montana Department of Public Health and Human Services
Public Health Laboratory**

QuantiFERON®-TB Gold In-Tube Testing

QuantiFERON®-TB Gold In-Tube (IT) is an *in vitro* diagnostic test using a peptide cocktail containing three different proteins to stimulate cells in heparinized whole blood. Detection of interferon- γ (IFN- γ) by Enzyme-Linked Immunosorbent Assay (ELISA) is used to identify *in vitro* responses to these peptide antigens that are associated with *Mycobacterium tuberculosis* infection. QuantiFERON®-TB Gold IT is an 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.

Please read and follow the complete directions carefully!

Collection and Transport of Whole Blood Specimens

QuantiFERON®-TB Gold IT uses the following collection tubes; the set will be provided for you free of charge by calling 800-821-7284, or e-mailing to mtphl@mt.gov.

1. Nil Control (Grey cap with white ring).
2. TB Antigen (Red cap with white ring).
3. Mitogen Control (Purple cap with white 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 \pm 1°C incubator as soon as possible and within 16 hours of collection.

The following procedures should be followed for optimal results:

1. For each subject collect 1 mL of blood by venipuncture directly into each of the QuantiFERON®-TB Gold IT blood collection tubes.
 - 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, to ensure that the correct volume is drawn.
 - The black mark on the side of the tubes indicates the 1mL fill volume. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample. Under or over-filling of the tubes 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 QuantiFERON®-TB Gold IT tubes being used.
2. Immediately after filling, shake tubes 10 times just firmly enough to ensure that the inner surface of the tube is coated in blood.
 - Thorough mixing is required to ensure complete integration of the tube’s contents into the blood, but over-energetic shaking may cause get disruption and could lead to aberrant results.
3. Label tubes appropriately.
 - Ensure each tube (Nil, TB Antigen, Mitogen) is identifiable by its label or other means once the cap is removed.

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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 specimens.
5. If the blood is not incubated immediately after collection, **re-mixing** of the tubes by vigorous shaking **for 5 seconds** must be repeated **immediately prior to incubation**.
6. Incubate the tubes **UPRIGHT** at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO₂ or humidification.
7. Following 37°C ± 1°C incubation, blood collection tubes may be transported between 2°C and 27°C. **Specimens must be received in the Public Health Laboratory within 3 days of incubation.**
8. Complete a blue MTPHL requisition form; **include date and TIME of draw**, and **whether or not the specimen(s) have been incubated** prior to shipment. Please note this information in the Comments/Pertinent Information section of the blue form.

Additional information, including the collection, mixing, and storage of blood collection tubes is available from the manufacturer of the QFT-GIT is available at the link below. Under QFT Resources, click on 'Technical Resources', then click on 'Technical Documents'.

QUESTIONS? Contact the MTPHL at 800-821-7284 or mtphl@mt.gov