# Vermont Department of Health Laboratory
# Recommendations for the Use of the Cellestis QuantiFeron®-TB Gold In-Tube test (QFT-GIT)

The Cellestis QuantiFeron®-TB Gold In-Tube test (QFT-GIT) is a qualitative laboratory test using whole blood specimens. The QFT-GIT test can be used to assess for the presence of latent tuberculosis infection (LTBI) or to aid in the diagnosis of active tuberculosis (TB). The QFT-GIT test cannot distinguish between LTBI and active TB, so the test should be used in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations. The QFT-GIT should **not** be used exclusively in diagnosing tuberculosis or for patients currently receiving treatment for active or LTBI.

The QFT-GIT test detects interferon-gamma (INF-γ), which is released from lymphocytes present in blood after exposure to the *M. tuberculosis* complex antigens ESAT-6, CFP-10 and TB7.7 (p4). These proteins are absent from all Bacille-Calmette-Guerin (BCG) strains and from most non-tuberculosis mycobacteria, resulting in fewer false positive reactions as seen with the tuberculin skin test (TST). Other advantages of the QFT-GIT include:

- Only one patient visit is required for blood draw versus 2 for TST
- Not subject to reader bias and errors that can occur with TST
- No effect from repeated TST "booster phenomenon"

The QFT-GIT test does have limitations which include:

- The need for phlebotomy
- Specimens must be incubated at 37°C within 16 hours of collection
- Accuracy data is limited for children <5 years of age and for immunocompromised persons
- Accuracy of the QFT-GIT may be affected if there are errors in specimen collection or specimen transport

The incidence of TB in the state of Vermont is relatively low with a median of 6 cases reported each year. In order to maintain sensitivity and specificity, it is imperative to perform careful screening of patients and only test those persons who are at high risk for active TB or LTBI. The Vermont Department of Health Laboratory (VDHL) will only perform QFT-GIT testing on patients who are considered to be at high risk of TB disease or infection, especially in the setting of prior BCG. High-risk populations in Vermont may include:

- Persons who have received the BCG vaccine and have had contact with persons known to have active TB or are suspected to have active TB
- Close contacts of persons known or suspected to have active TB
- Foreign-born persons from areas that have a high incidence of active TB
- People who have had frequent or prolonged visits to areas with a high prevalence of active TB
- Persons considered at risk for TB/LTBI and may not return to have the TST read.
- Persons who have received BCG (either as a vaccine or for cancer therapy). The VDHL does not require documented BCG as a vaccine. If an individual is from a country where a patient is suspected to have received the vaccine, QFT-GIT will be considered the preferred test.
- Persons from groups that historically have poor rates of return for TST reading.

If any of the criteria listed above applies to a patient, QFT-GIT testing can be performed by the VDHL. For collection instructions, please refer to page 2-3 of this document. For more information, you may refer to the Centers for Disease Control and Prevention website that further discusses Interferon Gamma Release Assays such as the QFT-GIT at: http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm.

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1-800-660-9997 (VT only) or 1-802-338-4724

# Instructions for Collecting and Shipping Specimens for the Cellestis Quantiferon®-TB Gold In-Tube Test (VDHL Kit # 10)

**The kit should contain:**

- One Red top specimen tube labeled "TB Antigen"
- One Purple top specimen tube labeled "Mitogen"
- One Grey topped specimen tube labeled "Nil"
- One small clear Ziploc plastic bag
- One biohazard bag
- One VDHL Clinical Test Request form the QuantiFeron®-TB Gold In-Tube Test (Micro 220)

**Collection Instructions**

There are very strict requirements for the collection and handling of specimens for QFT-GIT testing. Please follow the instructions precisely to ensure the accuracy of results. To view a QFT-GIT instructional video on specimen collection, go to **www. gnowee.net**. There is no cost to register with this website. The test uses **three** specialized blood collection tubes: Nil Control Tube (Grey Cap), TB Antigen Tube (Red Cap), and the Mitogen Control Tube (Purple cap).

**1.** If the blood collection tubes had been stored at 4°C, remove the tubes and allow them to reach room temperature (17-25°C).

**2.** Using standard venipuncture technique, draw 1ml (0.8–1.2ml) of blood into each of the three specimen tubes (black mark on the side of the tube indicates the 1ml fill volume). As the tubes will fill 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. If a "butterfly needle" is being used to collect the blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT-GIT tubes being used. Fill the tube as close as possible to the black indicator line. **Under or over-filling of the tubes outside the 0.8-1.2ml range may lead to erroneous results.**

**3.** Mix each tube by shaking 10 times just firmly enough to ensure the entire inner surface of the tube is coated with blood in to solubilize antigens on tube walls. Over-energetic shaking can result in the gel dislodging and mixing into the blood. This can result in erroneous results and must be avoided.

**4.** Label each specimen tube with the patient's name or other unique identifier and the date and time collected.

**5.** After the specimen has been collected, there are two options available depending on the availability of an incubator at the collection site:

**Option 1:** If an incubator is available, incubate tubes at the collection site in an upright position at 37˚C ± 1˚C for 16-24 hours. Store at 4˚C to 27˚C until ready to ship the specimens. Record on the requisition form "Incubated at 37˚C".

**Option 2:** If an incubator is **NOT** available at the collection site, ship the tubes directly to the VDHL. Store at 22˚C ± 5˚C until ready to ship the specimens. Record on the requisition form "**NOT** incubated at 37˚C".

**Shipment of Specimens**

**1.** Place the three specimen tubes into the small clear plastic bag. Securely seal the Ziploc bag.

**2.** Place the small clear plastic bag into the larger biohazard bag. Securely seal the Ziploc biohazard bag.

**3.** Fill out the requisition form (Micro 220) completely. Be sure to indicate on the form whether the tubes have been incubated or not incubated.

**4.** Place the completed requisition form in the outside pocket of the biohazard bag.

**5.** Shipping conditions:

a. **Incubated Tubes:** Ship at room temperature or cold (4-27°C). Specimens **MUST** be received at the laboratory within **3 days** after incubation.

b. **Non-Incubated Tubes:** Ship at room temperature **only** (17-27°C). Specimens **MUST** be received at the laboratory within 1**6 hours** of collection.

**NOTE:** The VDHL business hours are from 7:45am to 4:30pm, Monday through Friday. Please plan accordingly when sending specimens.

**Specimen Rejection**

**The Vermont Department of Health Laboratory will reject any specimens that:**

**1.** Have not been incubated at 37°C and are transported on ice or refrigerated. Specimens that have not been incubated should be maintained at room temperature (22˚C ± 5˚C).

**2.** Have NOT been incubated at 37°C ± 1°C and are received after 16 hours from the time of specimen collection.

**3.** Have been incubated at 37˚C for 16-24 hours and are received more than 3 days after incubation. Specimens must be received within 3 days after incubation at 37˚C.

**4.** Have been exposed to excessive heat.

**5.** Are received in expired blood collection tubes.

**6.** Are not collected in the tubes made specifically for the QFT test. A grey cap, red cap, and purple capped blood tube must be submitted.

**7.** Are missing any of the three QFT blood collection tubes.

**8.** Do not contain the proper amount of blood, whether under- or overfilled.

If you have any comments or questions regarding these instructions, please call one of the telephone numbers listed on page two of this form. Thank you.