QUANTIFERON - TB GOLD

Pre-analytical Process

Sherman Way Service Areas

Blood Collected from:

- South Bay
- Woodland Hills
- LAMC
- West LA
- Antelope Valley
- Bakersfield
- Panorama City

Incubated and Centrifuged

Chino Hills Service Areas

Blood Collected from:

- Fontana
- Ontario
- Riverside
- Baldwin Park
- Irvine
- Downey
- San Diego
- Anaheim
- Moreno Valley

Incubated and Centrifuged

Plasma samples can be stored/transported for up to 28 days at 2°C to 8°C

Current Process

Quest Diagnostics®

Sherman Way Service Areas

Chino Hills Service Areas

New Process

Blood Collected from:
- South Bay
- Woodland Hills
- LAMC
- West LA
- Antelope Valley
- Bakersfield
- Panorama City

Blood Collected from:
- Fontana
- Ontario
- Riverside
- Baldwin Park
- Irvine
- Downey
- San Diego
- Anaheim
- Moreno Valley

Prior to incubation, maintain tubes at RT (22°C ± 5°C)

within 16 hours of collection

Sherman Way Lab
- **Incubated**
- **Centrifuged**

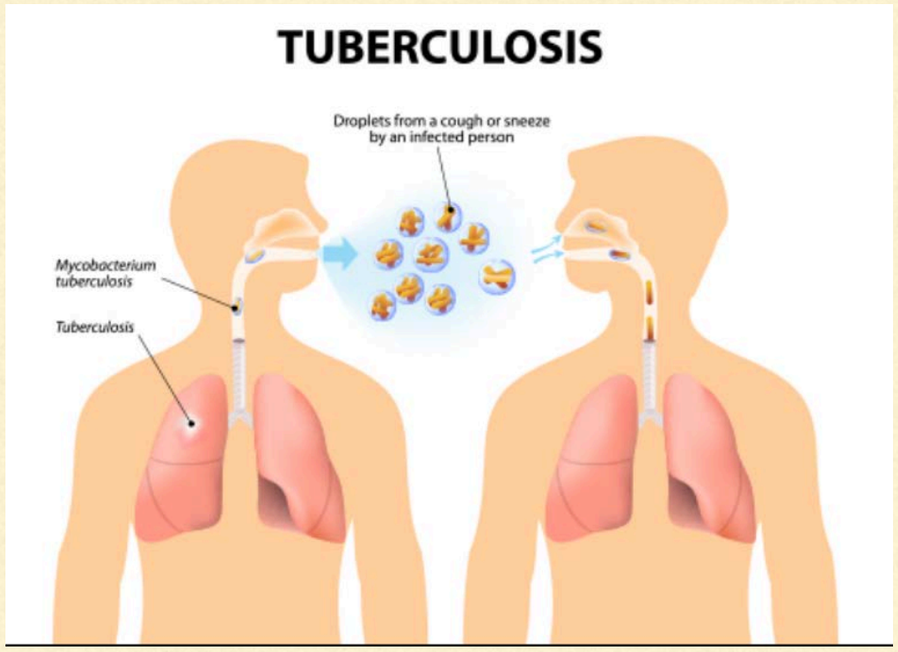
Plasma samples can be stored/transported for up to 28 days at 2°C to 8°C

Chino Hills Lab
- **Incubated**
- **Centrifuged**

Sherman Way Lab

SWL Immunology Department

WHAT IS TB & HOW IS TB SPREAD ?



TB germs get into the air when someone who has TB:

- sneezes
- coughs
- laughs
- sings
- speaks

- TB is a contagious, infectious disease caused by bacteria (*Mycobacterium tuberculosis*). TB bacteria usually attack the lungs, but can affect other parts of the body such as the kidney, bones, and brain.
- The most common way to get TB germs is by spending a lot of time indoors with someone who has TB disease. (TB germs are NOT spread on dishes, drinking glasses or other objects.)
- Millions of people have TB germs and don’t feel sick but people with TB germs may need treatment to keep from getting sick- or even dying.

Facts about Tuberculosis

1.5 million TB-related deaths occur worldwide each year

At least one person becomes infected every second.

Approximately 50% of all TB cases in the US were located in California,Florida, New York & Texas

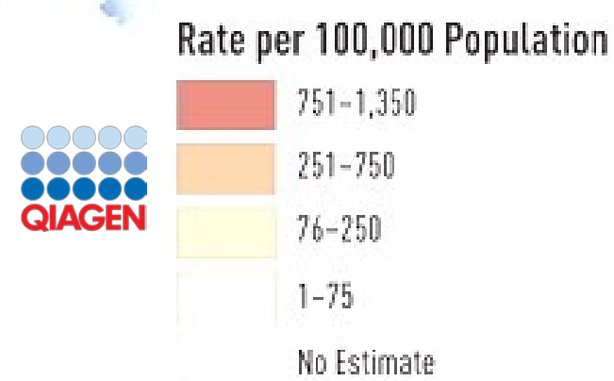
There were an estimated 480,000 cases of multi-drug resistant (MDR) TB in 2013.

At least two billion people are thought to be infected with TB bacteria.

TB takes one life every 21 seconds.

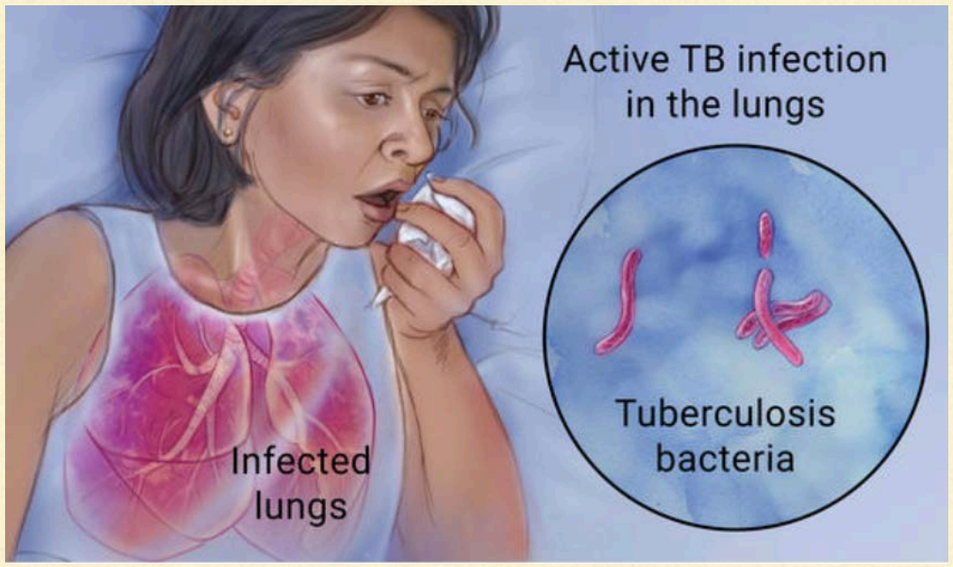
TB is the leading cause of death of people who are HIV-infected.

Each year, approximately nine million people around the world become sick with TB disease.



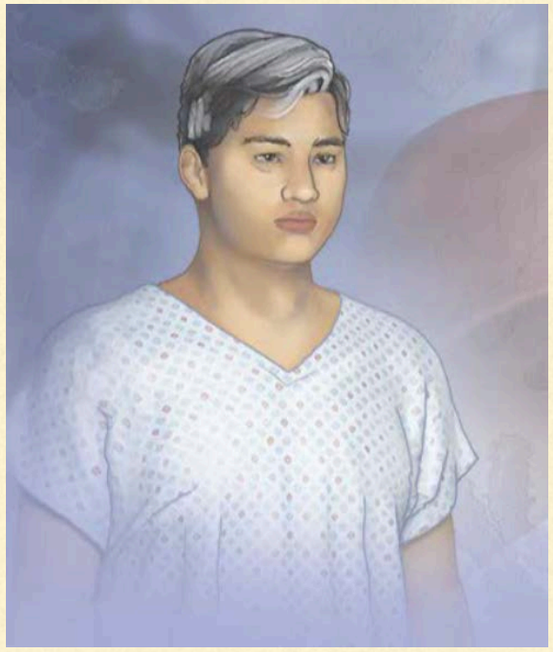
Tuberculosis Symptoms

WHAT IS THE DIFFERENCE BETWEEN TB INFECTION (LATENT TB) AND ACTIVE TB?



Active TB occurs when the TB bacteria overcomes a person's immune system and symptoms (e.g., cough, night sweats and weight loss) appear.

A person who has active pulmonary TB is contagious.

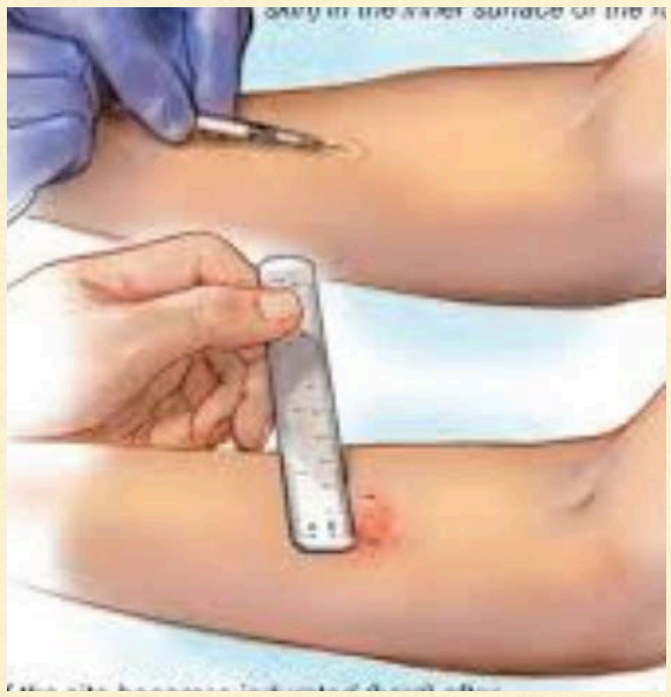


- Not everyone who becomes infected with TB bacteria develops TB disease. A person who is infected with the bacterium that causes TB, but who shows no symptoms and is not sick with the disease, is regarded as having **latent TB infection (LTBI).**
  - Approximately 1 in every 10 persons infected with TB bacteria will go on to develop active TB disease.
- Individuals with LTBI and a compromised immune system are more likely to progress to active TB.

HOW DO YOU DETECT A LATENT TB INFECTION?

There are two types of tests that can detect tuberculosis infection:

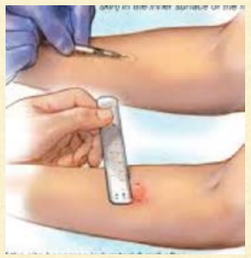
Tuberculin skin test (TST) also known as the Purified Protein Derivative (PPD) test



Blood test
QuantiFERON-TB Gold (QFT)

COMPARISON OF TB TESTING METHODS

Tuberculin skin test (TST)



- Two visits to the doctor (initial and after 48 - 72 hrs)
- Tuberculin is injected into the skin
- Results may be affected by the BCG vaccine
- Results determined by subjective/visual assessment
- 110-year-old TB skin test
- less specific & 70 % sensitive

QuantiFERON-TB Gold (QFT)

- One visit to the doctor
- A small sample of blood is taken
- Results are unaffected by the BCG vaccine
- Results determined in a laboratory
- FDA-approved blood test for TB infection
- >99 percent specific & 84% sensitive

QIAGEN

BLOOD COLLECTION TUBES DISPENSER PACK

QuantiFERON- TB Gold Dispenser Pack

- **Catalog number: T0597-0403**
- **100 sets of tubes packaged in 4 dispenser pack boxes = 4 x25 Ct**

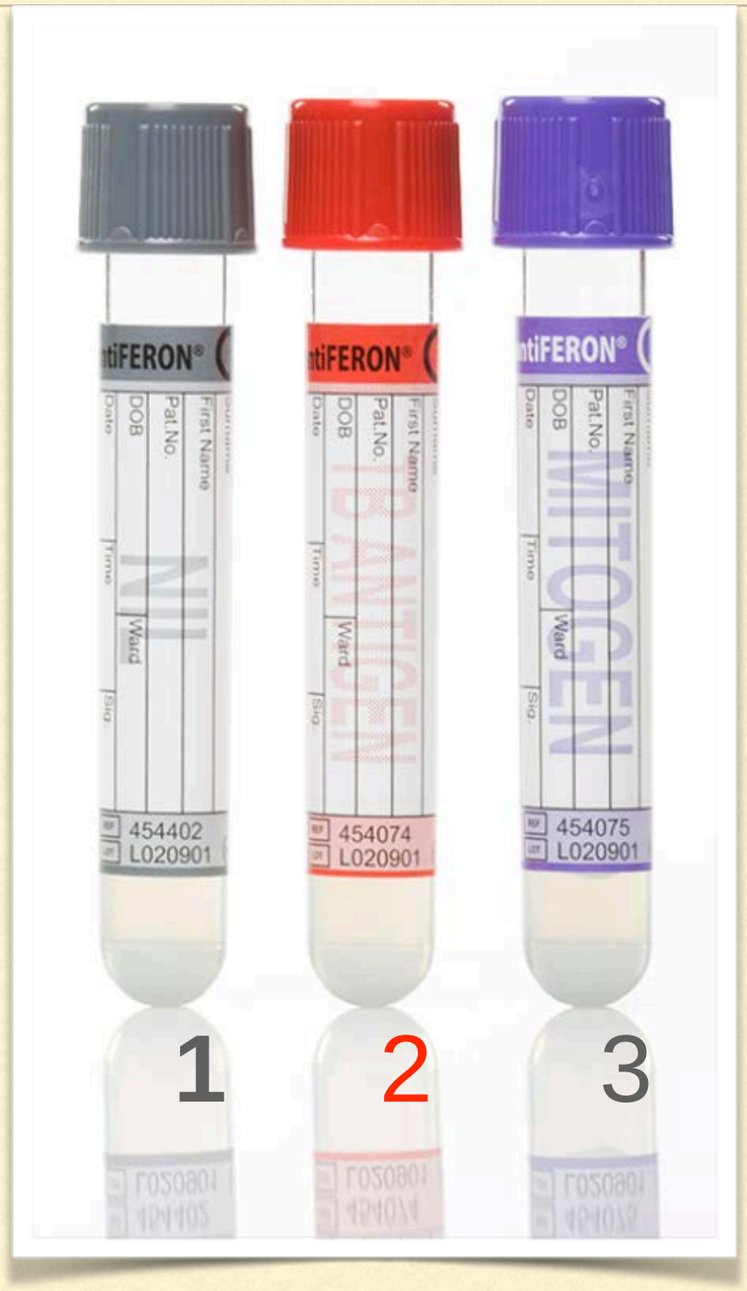
Onelink Item ID: 10607859

Supplier, Manufacturer and Manufacturer ID : QIAGEN INC

Supplier ID: 100020458

Price: US$950.00

QFT COLLECTION TUBE

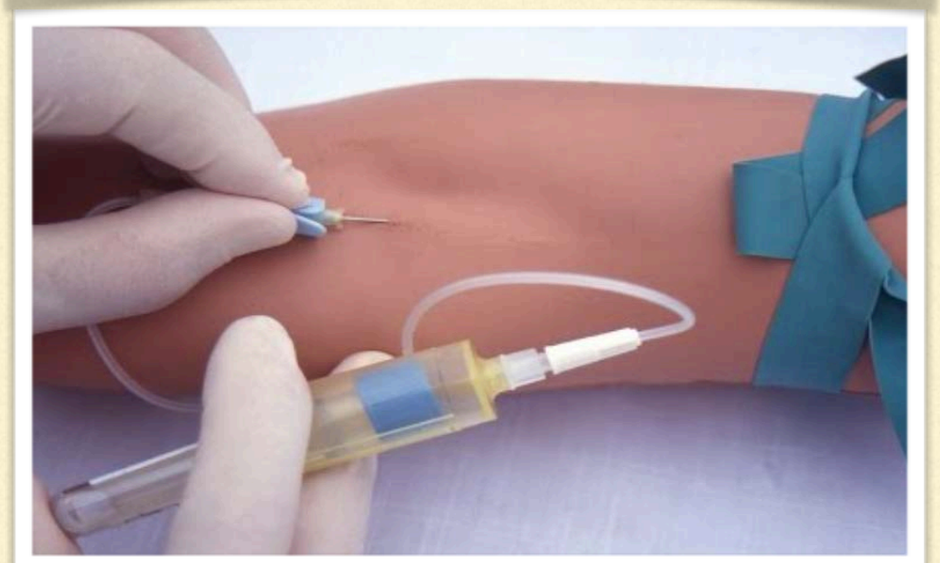


Nil control tube - **GREY** cap with white ring (negative Control)

TB Antigen tube - **RED** cap with white ring. The inside of this tube is coated with the M tuberculosis specific antigens.

Mitogen control tube - **PURPLE** cap with white ring (positive control). Also serves as a control for correct blood handling and incubation.

PROPER BLOOD COLLECTION

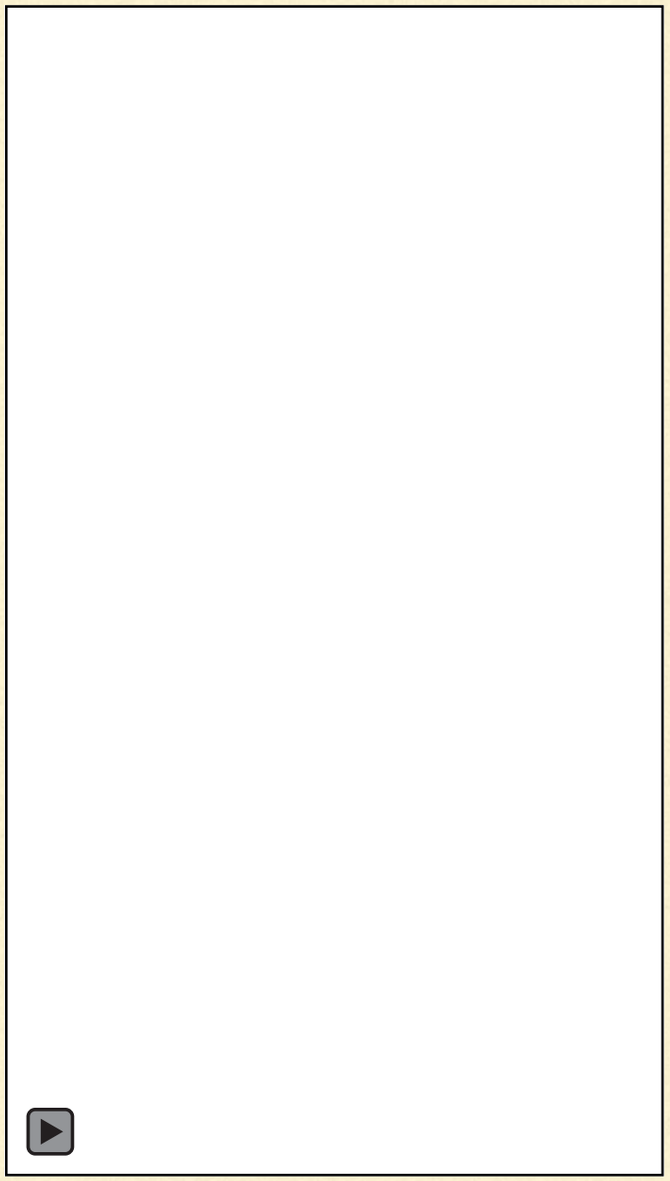


- Collect **1mL** of blood by venipuncture directly into each of the QuantiFERON-TB blood collection tubes.
- Tubes should be drawn in the following order: **GREY**, **RED**, **PURPLE**
- As 1mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling to ensure that the correct volume is drawn.

- If a "**butterfly needle**" is being used to collect blood, a "**purge**" tube should be used to ensure that the tubbing is filled with blood prior to the QuantiFERON -TB tubes.
- Tubes should be drawn in the following order: **GREY**, **RED**, **PURPLE**

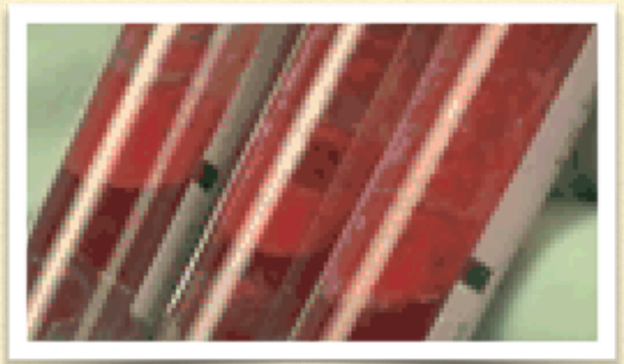
The black mark on the side of the tubes indicates the **1mL** fill volume. QuantiFERON®-TB Gold blood collection tubes are manufactured to draw1mL ± 10% and perform optimally within the range of **0.8 to 1.2mL.** If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample. Under or over-filling of the tubes outside of the 0.8 to 1.2mL range may lead to erroneous results. QuantiFERON®-TB Gold IT blood tubes have been validated to draw between 0.8mL and 1.2m at altitudes from sea-level to 3,000 feet.

PROPER SHAKING OF TUBES

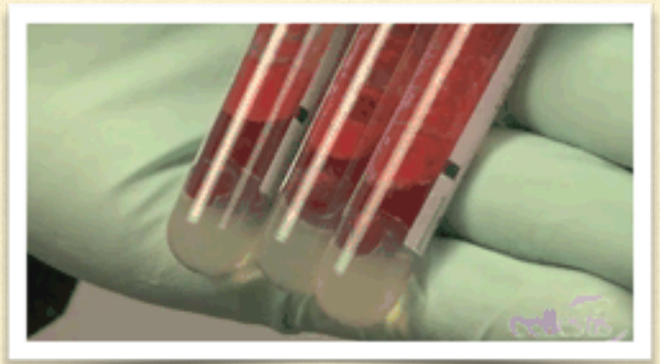


- Mix the tubes by shaking them **10 times** (up and down motion) just firmly enough to coat the entire inner surface of the tube with the blood. Note: Over energetic shaking may cause gel disruption and could lead to inaccurate results.
- Place tubes upright in a test tube rack. Mixing is required to ensure complete integration of the tube's contents into the blood.
- Label tubes appropriately with **time and date** of collection.
- Ensure each tube (Nil, TB Antigen, Mitogen) is identifiable by its label or other means once the cap is removed.

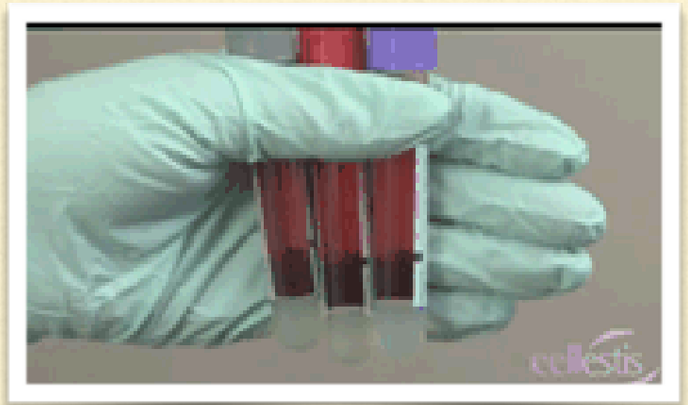
ALWAYS CHECK THE SAMPLE



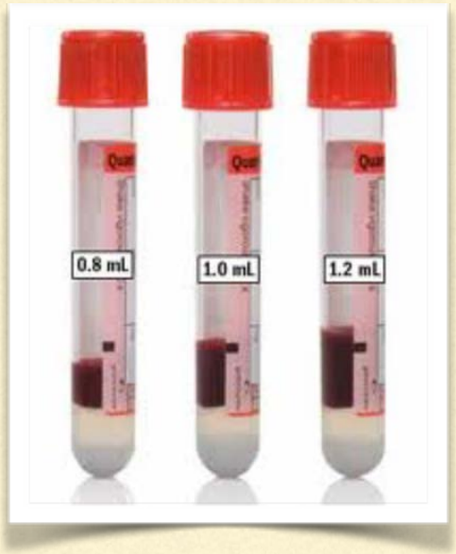
Frothing of blood should be expected

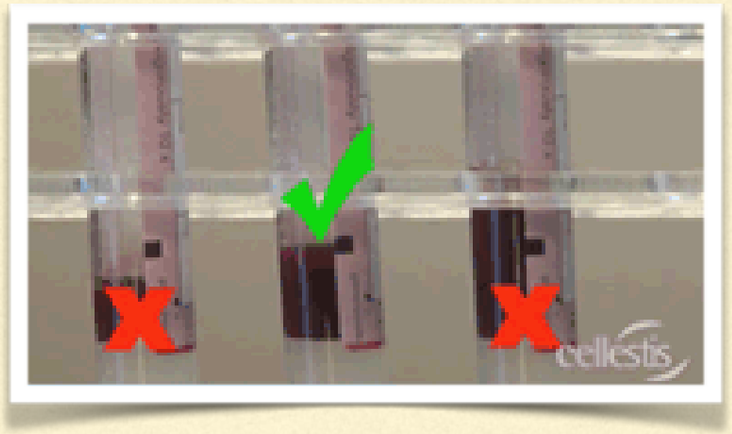


Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

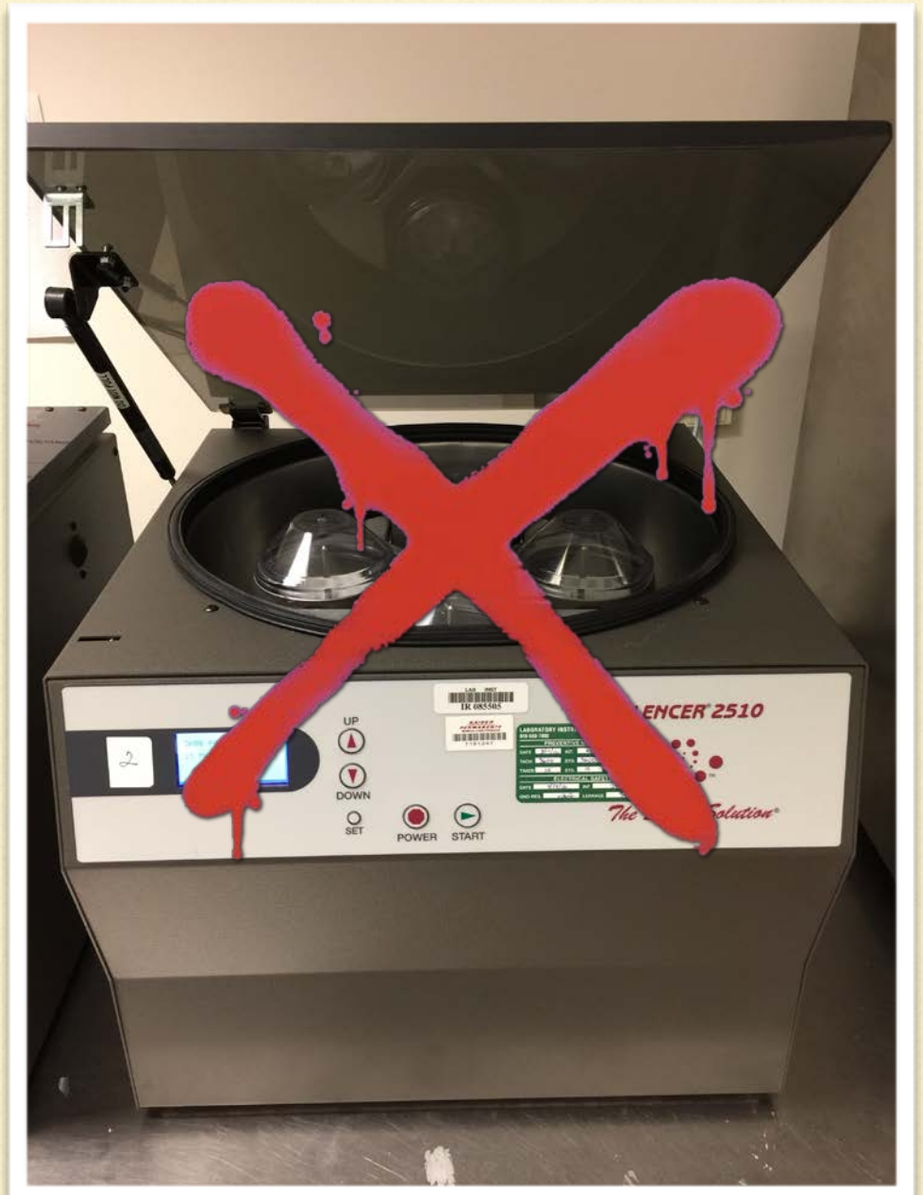


Ensure that the entire inner surface of the tube is coated with blood to dissolve antigens on tube walls.





DO NOT INCUBATE & CENTRIFUGE
AT THE
MEDICAL CENTERS OR MOBS



DO NOT INCUBATE & CENTRIFUGE
AT THE
MEDICAL CENTERS OR MOBS

Starting January 16, 2017. Please send all QuantiFERON-TB Gold test to CRL immediately

BLOOD SHOULD BE MAINTAINED AT ROOM TEMPERATURE (22°C ± 5°C)

DO NOT SEND IT TO QUEST DIAGNOSTICS

Use the Yellow bag

- **Do not freeze**
- **Do not use PCM**
- **Do not store in Ice**
- **Do not refrigerate**

DO NOT INCUBATE & CENTRIFUGE AT THE MEDICAL CENTERS OR MOBS

- Blood should be maintained at room temperature (22°C ± 5°C)

Samples must be delivered to CRL
within16 hours of collection

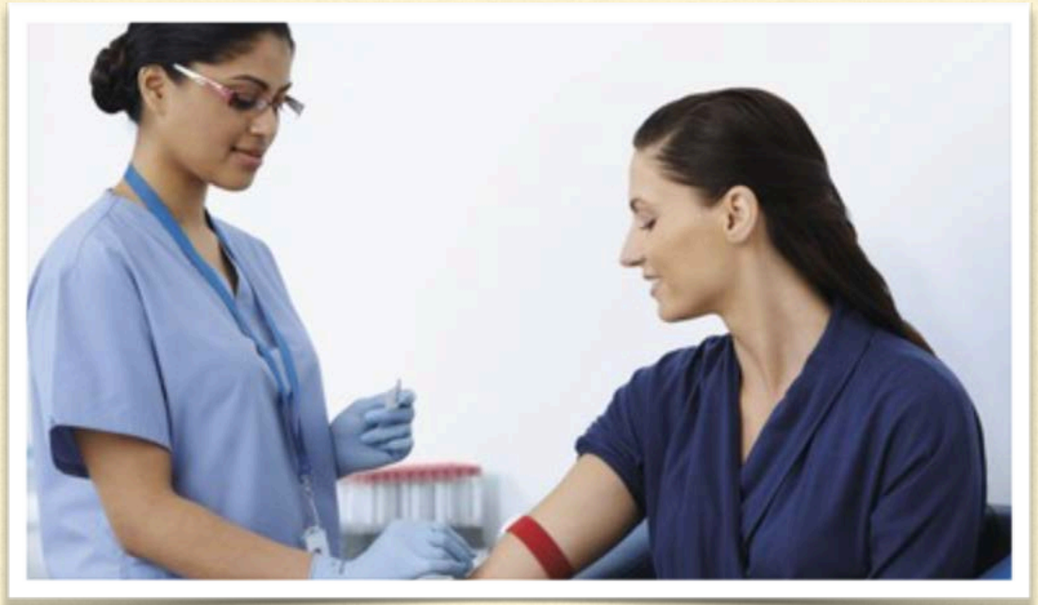
Please send the samples to SWL or CHL immediately

- **Do not freeze**
- **Do not use PCM**
- **Do not store in Ice**
- **Do not refrigerate**

WHAT CAUSES AN INDETERMINATE RESPONSE?

The 2 main causes of indeterminate results are:

- Lack of incubating the samples properly (such as not incubating the sample at all or over incubating)
- Insufficient mixing of blood collection tubes



Other less common causes of indeterminate results:

- Presence of heterophile antibodies in the patient sample
- Intrinsic IFN-γ secretion
- Recent patient illness
- Recent vaccinations
- Lymphocytes responding indiscriminately (recent patient bouts with poison ivy, rheumatoid arthritis, etc.)
- Lack of response to phytohaemagglutinin(occurs in less than 1 in 1,000 patients)
- Storage of filled blood collection tubes outside the recommended temperature range (22°C ± 5°C) prior to 37°C ± 1°C incubation
- Compromised mitogen transport tubes
- Compromised immune status of the individual being tested
- Insufficient lymphocytes
- Inability of the patient's lymphocytes to generate IFN-γ