

**QuantiFERON®-TB Gold
Testing At the Utah Public
Health Laboratory**

**ALEJANDRO FIGUEROA MEMORIAL
TB CONFERENCE
SEPTEMBER 28, 2007**

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OBJECTIVES

- **BRIEF REVIEW OF QUANTIFERON TESTING**
- **CURRENT LAB TESTING**
- **FUTURE PLANS**
- **QUESTIONS**

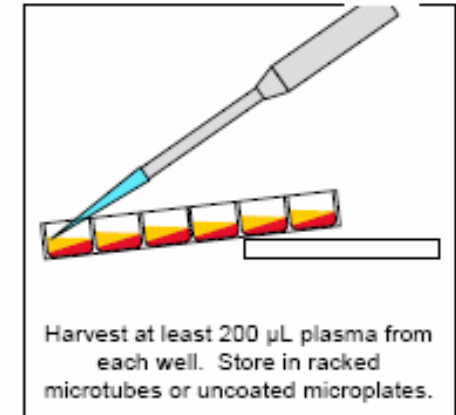
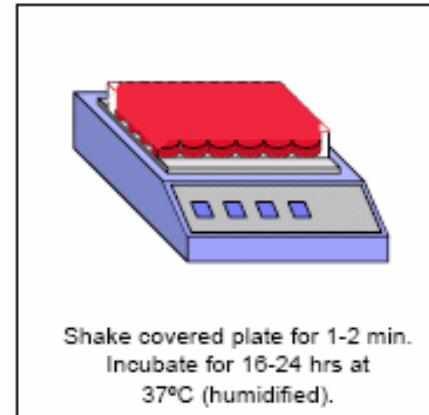
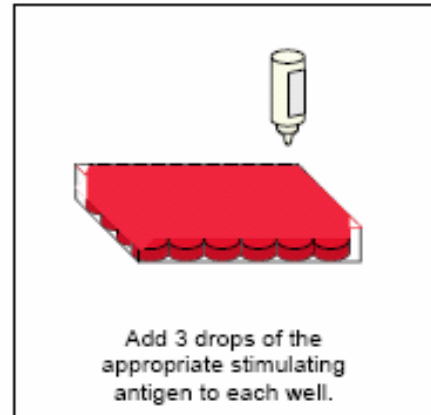
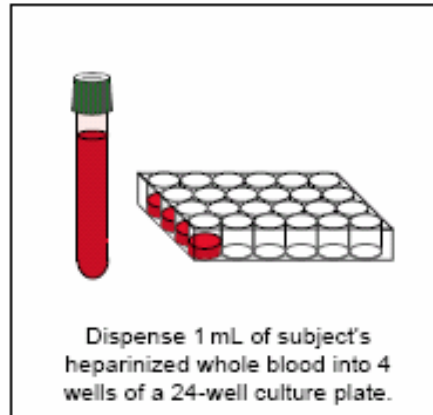
QuantiFERON®-TB GOLD
IS A LABORATORY TEST
THAT AIDS IN THE
DETECTION OF INFECTION
WITH *MYCOBACTERIUM*
TUBERCULOSIS



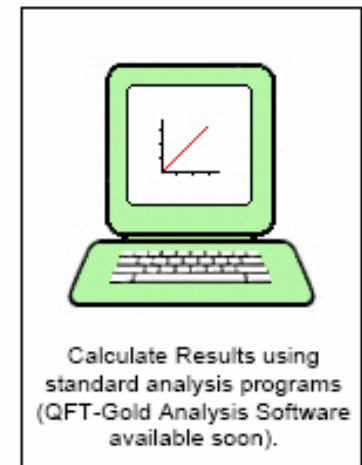
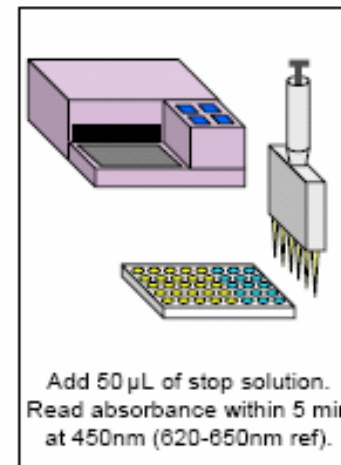
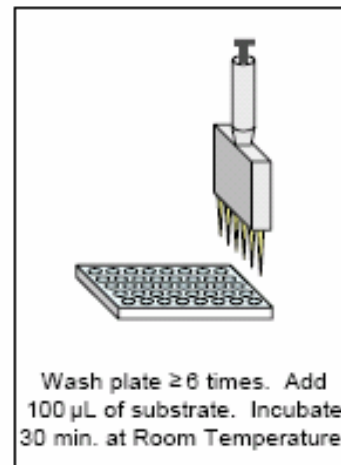
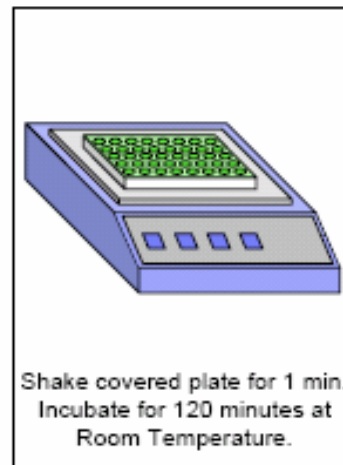
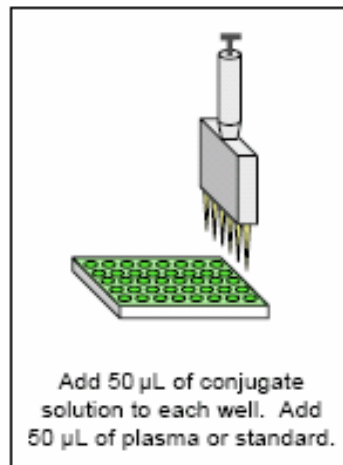
QuantiFERON®-TB
CELLESTIS LIMITED
AUSTRALIA

**The Test Uses Human Whole Blood
& Patented Technology based on
the measurement of Interferon-
gamma (IFN- γ) secreted from
stimulated White Blood Cells
previously exposed to
*Mycobacterium tuberculosis (MTB)***

Stage One – Blood Stimulation and Harvesting



Stage Two – Human IFN- γ ELISA



Test Interpretation

- **A Positive Test Result means that infection with MTB is likely**
- **A Negative Result means MTB is unlikely but cannot be excluded especially when illness is consistent with MTB**
- **An Indeterminate result means:**
 - **Repeat Blood Draw May Be Necessary or**
 - **MTB status must be determined by other means**

**THE QuantiFERON®-TB
GOLDTEST SHOULD NOT BE THE
SOLE BASIS FOR DETERMINING
TB INFECTION AND RESULTS
MUST BE INTERPRETED WITH
ALL OTHER CLINICAL AND
HISTORICAL PATIENT DATA TO
DETERMINE THE RISK OF TB
INFECTION. A NEGATIVE TEST
ALONE DOES NOT EXCLUDE THE
POSSIBILITY OF TB INFECTION.**

CDC Guidelines recommend that QFT-G may be used in all circumstances in which TST is currently used including:

- **Contact Investigation**
- **Evaluation of Recent Immigrants**
- **Surveillance Testing for Programs such as:**
 - **Healthcare Worker Screening**
 - **Prison, Nursing Homes, Shelter Populations**
 - **Injection Drug Users**

Current Testing at Utah Public Health Laboratory

- **Blood must be received at UPHL Monday-Thursday by 2 PM**
- **Draw blood in a sodium heparin or lithium heparin (green top) tube (7 ml of blood is needed but 10 ml is preferred).**
- **Do NOT draw in EDTA or ACD (fluoride or citrate preservatives should also be avoided) blood tubes (purple, pink, yellow, gray and/or blue top) since this interferes with the test**
- **Keep tubes at room temperature till delivery at UPHL. Do NOT refrigerate blood**

Current Testing at UPHL cont.

- **Test MUST be received at UPHL within 12 hours of blood draw**
- **Currently tests are batched and run once a week on Friday**
- **Current cost of Test is \$40 (UPHL is subsidizing some of the cost of this test to keep it this low).**
- **QFT-G has been validated at UPHL per federal regulatory standards**
- **UPHL will test for patients under 17 years of age with clients' understanding that the test has not been adequately studied in this population**

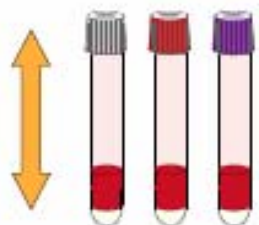
Future for QuantiFERON Testing in USA & UPHL

- **FDA approval is pending on an In-tube test that currently is used in most countries other than USA & Japan**
- **Current estimate of FDA approval is November or December**
- **UPHL will need time to validate the current Gold method test with the new In-tube test**
- **ESTIMATED time to bring new test to UPHL is two months after FDA approval AND kits are available for Marketing in the USA**
- **Cost will remain the same**

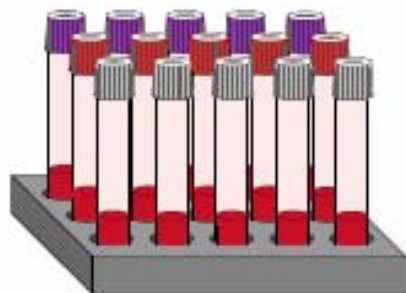
QuantIFERON[®]-TB Gold In-Tube

Assay Quick Reference Guide

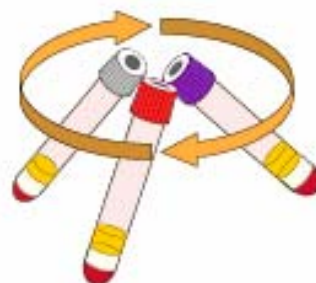
Stage One – Blood Incubation and Harvesting



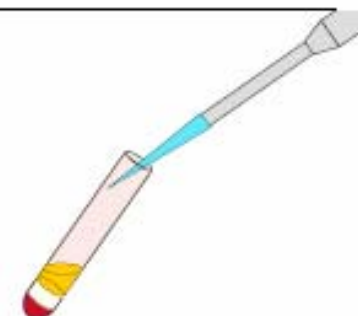
After blood collection, mix QuantIFERON[®]-TB Gold tubes thoroughly, by shaking vigorously for 5 seconds.



As soon as possible, and within 18 hours of collection, incubate tubes upright at 37°C for 16-24 hours.

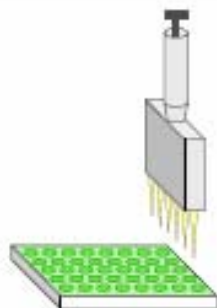


Centrifuge tubes at 2000-3000g (RCF) for 15 minutes.

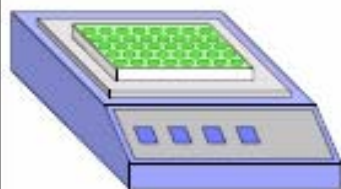


Harvest at least 200 μ L plasma from each tube. Store in racked microtubes or uncoated microplates.

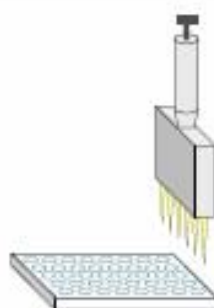
Stage Two – Human IFN- γ ELISA



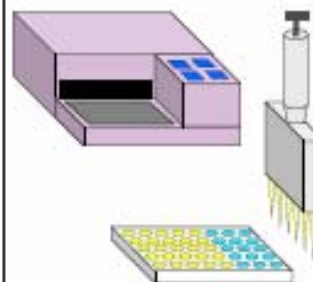
Add 50 μ L of conjugate solution to each well. Add 50 μ L of plasma or standard.



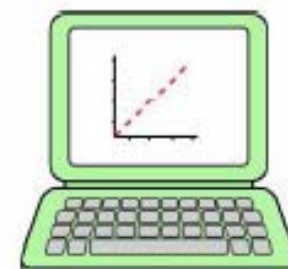
Shake covered plate for 1 min. Incubate for 120 minutes at Room Temperature.



Wash plate ≥ 6 times. Add 100 μ L of substrate. Incubate 30 min. at Room Temperature.



Add 50 μ L of stop solution. Read absorbance within 5 min at 450nm (620-650nm ref).



Calculate Results using QuantIFERON[®]-TB Gold In-Tube Analysis Software.

What In-Tube Testing Improves

- **Customers will be provided with the specially prepared blood drawing tube by UPHL & this eliminates the need to add sensitizing reagents-this allows delivery at UPHL later than current 2 PM since lab does not need to do initial step.**
- **Blood may be returned to UPHL within 16 hours (instead of 12) OR**
- **Client may incubate the blood at 37°C at their own facility, centrifuge tube and then delay delivery to UPHL for up to 3 days**

Problem Areas

- **Still have to get blood to UPHL within time limit**
- **Three specialized tubes must be drawn using the correct 3 tubes**
- **Facility will still need a blood drawing person**
- **Most public health facilities may not have an incubator and/or centrifuge**

Conclusions

- **QFT-G is a laboratory screening test useful for TB programs**
- **UPHL offers QuantiFERON Gold testing under the current parameters of the test kit provided by Cellestis**
- **The new In-tube method will make testing more convenient for clients but still has many constraints**
- **UPHL is always open to suggestions**

DISCUSSION OR QUESTIONS



HELP WIPE OUT TB!

ACKNOWLEDGEMENTS

- **CELLESTIS INC. QUANTIFERON-TB PACKAGE INSERTS AND WEB PAGE**
- **CDC MMWR VOL.54/RR-15 Dec. 16,2005**
- **FDA APPROVAL OF MEDICAL DEVICES FACT SHEET ON QUANTIFERON**