

TEST BULLETIN

QuantIFERON[®]-TB Gold

The breakthrough **Interferon-Gamma Release assay (IGRA)** for the detection of immune responses to tuberculosis (TB) infection

Merits of QuantIFERON-TB Gold vs. Tuberculin Skin Test

- Eliminates false positive results due to BCG vaccination and most other non-tuberculous mycobacteria
- Objective, highly reproducible test that yields a "positive" or "negative" answer with no need for interpretation
- Because it is a blood test, there is no possibility of side effects or adverse reactions due to patient hypersensitivity
- No need for patient follow-up visits to obtain results (requires only one patient visit)

CLINICAL SUMMARY

The tuberculin skin test (TST) has been used to diagnose latent TB infection (LTBI) and active TB infection for almost 100 years. The TST has many limitations. It requires two patient visits to obtain a reading. It is estimated that 30% of individuals who receive a TST do not return to have the test read. There is a great deal of variability in measuring the size of a skin test even by trained health care providers. Patient factors such as prior BCG vaccination, immunosuppression, hypersensitivity to TST reagents, and infection with non-TB mycobacteria affect the TST and result in both false negative and false positive readings. The QuantIFERON Gold diagnostic blood test addresses many of the limitations of the TST.

The QuantIFERON Gold test is based upon a cell-mediated immune response in TB-infected individuals. The T cells of these people are sensitized to Mycobacterium tuberculosis antigens. Upon exposure to Mycobacterium tuberculosis peptides used in the QuantIFERON Gold test, the T cells are stimulated to secrete the cytokine interferon- γ . An ELISA test is then used to accurately measure the interferon- γ response.

SENSITIVITY AND SPECIFICITY

Since there is no definitive standard for TB infection, an estimate of sensitivity and specificity for QuantIFERON Gold cannot be practically evaluated. In order to approximate sensitivity and specificity a number of studies have been done. Three studies out of Japan, Australia, and the USA demonstrated a sensitivity of 87% in subjects with culture-confirmed TB. In these studies, the sensitivity of the TST was 65-79%. Three additional studies from the same countries demonstrated a specificity of 97-99%. In these studies the specificity of the TST ranged from 68% to 99%. In a 2004 Danish study, 85 contacts of a high school student with active tuberculosis were tested with both the TST and QuantIFERON Gold. The overall agreement with the TST was 94%.

CDC GUIDELINES

In December, 2005, the CDC published guidelines for the use of the QuantIFERON test. This publication states that the QuantIFERON could be used in any situation where the TST would be used. To view these guidelines go to: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm>.

FOR MORE INFORMATION

Contact Ike Northern, Microbiology/Serology Manager
CompuNet Clinical Laboratories, (937) 297-8334.

Test Order Information

Test Code: **74451R**

CPT Code:* **86480**

Samples accepted: Monday through Friday

Specimen Requirement:
**SPECIMEN SHOULD BE DRAWN AT
COMPUNET PATIENT SERVICE CENTER**

*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.