



**NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

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***QuantiFERON®-TB Gold Fact Sheet***

**What is QuantiFERON®-TB Gold?**

QuantiFERON®-TB Gold (QFT-G; Cellestis, Ltd., Carnegie, Australia) is a new FDA approved blood test for the detection of tuberculosis (TB) infection. As a modern alternative to the 100 year old tuberculin skin test (TST), QFT-G may offer clinicians a simpler and more accurate, reliable, and convenient TB diagnostic tool. QFT-G is highly specific and a positive test result is strongly predictive of true infection with *Mycobacterium tuberculosis* (*M. tb*). The test is approved as an aid for diagnosing both active TB disease and latent TB infection (LTBI); however, it does not differentiate the two.

**How does QuantiFERON®-TB Gold work?**

The QFT-G test is an indirect test for *M. tb* infection; it measures a cell-mediated immune response in infected individuals. The T-lymphocytes of infected individuals are sensitized to *M. tb* proteins. When whole blood is incubated with the *M. tb* specific antigens used in the test, the T- lymphocytes secrete interferon-gamma (IFN- $\gamma$ ) which is measured via a sensitive enzyme-linked immunosorbent assay (ELISA).

QFT-G specifically detects responses to two proteins (early secretory antigenic target-6 [ESAT-6] and culture filtrate protein-10 [CFP-10]), which are made by *M. tb*. and are absent from all BCG vaccine preparations and environmental, i.e., nontuberculous mycobacteria (NTM), with the exception of *M. kansasii*, *M. marinum*, and *M. szulgai*. As a result, the QFT-G test is completely unaffected by BCG vaccination status and sensitization to the majority of NTMs, thus providing a more accurate test of TB infection.

**What are the advantages of QuantiFERON®-TB Gold test?**

QFT-G	vs.	TST
<ul style="list-style-type: none"> <li>• <i>in vitro</i>, controlled laboratory test with minimal inter-reader variability</li> <li>• <i>M. tb</i> specific antigens used</li> <li>• No boosting; 2 step testing not needed</li> <li>• 1 patient visit possible</li> <li>• Unaffected by BCG and most environmental mycobacteria</li> <li>• Simple positive/negative result</li> </ul>		<ul style="list-style-type: none"> <li>• <i>in vivo</i>, subject to errors during implantation and interpretation</li> <li>• Less specific PPD antigen used</li> <li>• Boosting with repeated testing</li> <li>• 2 patient visits minimum</li> <li>• False-positive results can occur after BCG and environmental mycobacteria exposure</li> <li>• Interpretation based on patient’s risk of TB exposure or development of disease</li> </ul>

**What are the current limitations of the QuantiFERON®-TB Gold?**

- Blood samples must be processed within 12 hours of blood draw.
- The test has not been extensively studied in many groups, such as those with impaired immune function, contacts to active TB cases, and children. However, the CDC currently approves of its use even in these individuals, based on available data.
- The ability of QFT-G to predict the risk of LTBI progression to TB disease has not been determined. The risk may be different than in those with a positive TST.

### Who is eligible to receive the QuantiFERON®-TB Gold?

The QFT-G test can be used to assess for the presence of LTBI in anyone who is a candidate for a TST. It can also be used to aid in the diagnosis of active TB. However, it should **not** be used for patients currently receiving treatment for active or latent TB. High-risk populations to screen include:

- Immunocompromised individuals (e.g. HIV-infected persons or those receiving immunosuppressive medications, including TNF-alpha antagonists, pre-organ transplant patients)
- Contacts to cases of active TB
- Individuals with medical risk factors for TB reactivation (e.g. diabetes, chronic renal failure, silicosis, malnutrition, certain cancers)
- Recent immigrants (<5 years) to the U.S. from TB endemic areas, regardless of age
- Homeless individuals
- Injection drug users
- Patients with an abnormal CXR consistent with old or active TB
- Residents and employees of high-risk congregate settings (e.g. shelters, nursing homes, jails, substance abuse treatment facilities)
- Health care workers, including screening following an exposure to *M. tb.* (2005 CDC guidelines introduced QFT-G as an alternative to the TST for initial and serial screening of health care workers for TB infection)

### How do you interpret the results of QuantiFERON®-TB Gold?

**Negative:** Same interpretation as negative TST. No further TB evaluation is needed unless indicated by clinical judgment.

**Positive:** Same interpretation as positive TST. Medical evaluation and chest x-ray are needed to exclude TB disease and confirm LTBI.

**Indeterminate:** Test failure. Repeat QFT-G or administer TST. QFT-G results may be indeterminate due to laboratory error or patient anergy. If two different specimens from a patient yield indeterminate results, do not repeat QFT-G for that person.

**Like the TST, the QFT-G is a useful but imperfect diagnostic aide. It should not replace clinical judgment.** For more information see *City Health Information: Testing and Treatment for Latent Tuberculosis Infection* (<http://www.nyc.gov/html/doh/downloads/pdf/chi/chi25-4.pdf>)

### What is the cost of QuantiFERON®-TB Gold?

The cost is likely to be \$30-60. It is not yet approved for reimbursement by NY State Medicaid but is approved by Medicare. QFT-G can yield cost savings in terms of medical staff time by elimination of a second patient visit for test interpretation, and the elimination of common false-positive results, the latter involving both unnecessary follow-up testing and treatment for LTBI.

QFT-G can eliminate the need for the repeat (i.e. 2 step) testing that is required when TST is used for screening health care workers and may lower the administrative cost of maintaining testing compliance in health care facilities, which may offset the slightly higher reagent cost compared to the TST.

### Where are QuantiFERON®-TB Gold tests offered?

The QFT-G test is now available for free at most of the Bureau of TB Control chest centers. Please see <http://www.nyc.gov/html/doh/html/tb/tbcc.shtml> for the list of clinics and their hours. Providers interested in making QFT-G testing directly available to their patients may contact Cindy Jacke at Quest Diagnostics (1-800-222-0446, extension 5162) or Cellestis (1-800-519-4627).

### References

1. CDC. Guidelines for Using QuantiFERON-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States. MMWR 2005;54 -RR-15:49-55.
2. CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Settings, 2005. MMWR 2005;54 RR-17:1-141.
3. Richeldi L. An update on the diagnosis of tuberculosis infection. Am J Respir Crit Care Med. 2006;174:736-42.