

QuantiFERON[®]-TB Gold In-Tube and *Mycobacterium tuberculosis* Antibody, IgG by ELISA

FOR USE IN THE DIAGNOSIS OF LATENT OR ACTIVE MYCOBACTERIUM TUBERCULOSIS INFECTION

Test Highlights

- New panel combines the QuantiFERON[®]-TB Gold in-tube test (QFT- GIT) with the *Mtb* IgG ELISA.
- Requires only a single patient visit to draw blood sample.
- The nil tube required for the QuantiFERON[®]-TB Gold in-tube test provides plasma for use in the IgG ELISA, so no extra draw is required.
- Panel increases the ability to differentiate active and latent cases of TB.

Disease Overview

- Tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis* (*Mtb*) and typically presents as a lung infection.
- *Mtb* is transmitted via airborne droplets that contain the infectious bacilli.
- Persons who have latent tuberculosis infection (LTBI) are infected but do not have TB.
- About 10 percent of latent infections develop into active TB disease. However, the risk increases in immunosuppressed individuals, especially those with HIV infection.
- Mortality in untreated active disease is upwards of 50 percent.

Epidemiology

- Over one-third of the world's population has been exposed to *Mtb*, making it one of the most common infectious diseases in the world.
- TB causes nearly two million deaths per year.
- Seventy-five percent of all *Mtb* infections occur in developing countries.

Indications for Ordering

This panel should be ordered if any form of TB disease is suspected.

Interpretation

- A positive QFT-GIT result indicates latent TB infection.
- A positive IgG result indicates progression to active disease.

Limitations

- This panel has not been validated for use on patients with HIV/ TB co-infection and is not recommended for this population.
- AFB culture may be helpful in further characterizing active disease.

Methodology

- Patient blood is collected into three specialized blood-collection tubes.
- The amount of INF- γ produced by each tube (nil, mitogen, antigen) is measured using a standard ELISA format.
- Plasma in the nil tube is used for the TB IgG assay, which operates using a standard ELISA format.

References

1. Mandell G, Bennett J, Dolin R, eds. 2000. *Principles and Practice of Infectious Diseases*, 5th ed. New York: Churchill Livingstone.
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3. Nyamande K, et al. TB presenting as community-acquired pneumonia in a setting of high TB incidence and high HIV prevalence. *Int J Tuberc Lung Dis* 2007;11(12):1308–13.
4. Shinnick TM, et al. National plan for reliable tuberculosis laboratory services using a systems approach. Recommendations from CDC and the Association of Public Health Laboratories Task Force on Tuberculosis Laboratory Services. *MMWR Recomm Rep* 2005;54(RR-6):1–12.
5. Carvalho AC, et al. QuantiFERON[®]-TB Gold test in the identification of latent tuberculosis infection in immigrants. *J Infect* 2007;55(2):164–8.
6. Mazuerk GH, et al. Guidelines for using the QuantiFERON[®]-TB Gold test for detecting *Mycobacterium tuberculosis* infection, United States. *MMWR Recomm Rep* 2005;54:49–55.
7. Active TbDetect[™] Kit. Package Insert InBios, 2008.

Test Information

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QuantiFERON®-TB Gold In Tube & *Mycobacterium tuberculosis* Antibody, IgG

For specific collection, transport, and testing information, refer to the ARUP Web site at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.