

Mycobacterium tuberculosis IgG Antibody Detection by ELISA

FOR ASSESSMENT OF ACTIVE MYCOBACTERIUM TUBERCULOSIS INFECTION

Test Highlights

- Rapid serologic assay to detect *Mycobacterium tuberculosis* (*Mtb*) antibodies suggesting current, active infection.
- Can be used to differentiate active and latent cases.
- Antigens utilized are not present in *Mycobacterium bovis*, thereby allowing BCG-vaccinated individuals to be tested.

Disease Overview

- Tuberculosis is caused by a bacterium, *Mycobacterium tuberculosis* (*Mtb*), and typically presents as a lung infection (pulmonary TB). *Mtb* is transmitted via airborne droplets that contain the infectious bacilli and are deposited in the terminal airspaces within the lungs.
- 10 percent of individuals exposed to *Mtb* develop active pulmonary infection which, if left untreated, has a 50 percent mortality rate.

Epidemiology

- *Mtb* is one of the most common infectious diseases in the world, with over one-third of the world's population having been exposed.
- The World Health Organization estimates that two billion people currently have latent TB and another three million people die each year from TB.
- Seventy-five percent of all *Mtb* infections occur in developing countries.

Indications for Ordering

- May be used in conjunction with PPD or QuantiFERON® testing to diagnose active (as opposed to latent) *Mtb* infection in patients with appropriate clinical symptoms and/or exposure history.
- May predict which exposed patients are likely to have or to advance to active disease.
- Can be used to monitor the success of therapeutic intervention.

Interpretation

A positive result represents a detectable level of *Mtb* IgG antibodies, which suggests current, active infection.

Limitations

- This test has been validated for serum samples only. No other sample types may be used.
- This assay has not been validated for use on patients with HIV/Tb co-infection and is not recommended for this population.
- This test is for use on patients with clinical symptoms and is not intended for use as a screening assay.
- Results should be interpreted in conjunction with PPD or QuantiFERON® testing, as well as the complete clinical history of the patient.
- Samples with high levels of bilirubin have shown erroneous results and should be interpreted with caution.

Methodology

Inbios Active TbDetect™ IgG follows the 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.
2. Shi, R., Itagaki, N., Sugawara, I. Overview of anti-tuberculosis (TB) drugs and their resistance mechanisms. Mini Rev Med Chem 2007; 7(11): 1177-85.
3. Nyamande K, Lalloo UG, John M. 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, Lademarco MF, Ridderhof JC. 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. Package Insert for Active TbDetect™ Kit. Inbios, 2008.

Test Information

0051698

Mycobacterium tuberculosis Antibody, IgG by ELISA

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.