QUANTIFERON® TEST (INTERFERON-γ)

Test # 19320

Synonyms QuantiFERON-TB
TB
M. tuberculosis by QuantiFERON-TB

Category Special Chemistry

Indication/ Use · Along with historical, physical, radiological, and histological findings his test can help diagnose tuberculosis.

Specimen Requirements

Specimen One each of three QuantiFERON-TB Gold IT blood collection tubes

Volume 1 mL in each of the three tubes (fill tubes to black line marked on tube)

Handling Samples must be shaken vigorously for 5 seconds immediately after collection; blood should appear frothy. Samples may then be sent to the laboratory if they will be received within 16 hours of collection—specimens should be labeled "NOT INCUBATED". Alternatively, specimens may be incubated prior to shipment to the laboratory. Incubate upright tubes at 37ºC for 16 – 24 hours. If incubation is not started immediately after shaking the tubes, the tubes should be reshaken prior to incubation. Ship incubated tubes within 3 days; if longer than 3 days, specimen tubes must be centrifuged and refrigerated.

Assay Parameters

Methodology Enzyme-linked Immunosorbent Assay (ELISA)

CPT code 86480

Interpretation

Positive	*M. tuberculosis infection likely*
Negative	*M. tuberculosis infection not likely*
Indeterminate	*Results are indeterminate for TB antigen responsiveness*

Clinical Information

- The QuantiFERON-TB Gold IT is a test for Cell Mediated Immune (CMI) responses to peptide antigens that simulate mycobacterial proteins. Individuals infected with M. tuberculosis complex organisms (M. tuberculosis, M. bovis, M. africanum, M. microti, M. canetti) usually have lymphocytes in their blood that recognize these and other mycobacterial antigens. This recognition process involves the generation and secretion of the cytokine, IFN-γ. The detection and subsequent quantification of IFN-γ forms the basis of this test.
- Latent tuberculosis infection (LTBI), a non-communicable asymptomatic condition, persists in some, who might develop tuberculosis disease months or years later. The main purpose of diagnosing LTBI is to consider medical treatment for preventing tuberculosis disease.
- Until recently the tuberculin skin test (TST) was the only available method for diagnosing LTBI. Cutaneous sensitivity to tuberculin develops from 2 to 10 weeks after infection. However, some infected individuals, including those with a wide range of conditions hindering immune functions, but also others without these conditions, do not respond to tuberculin. Conversely, some individuals who are unlikely to have M. tuberculosis infection exhibit sensitivity to tuberculin and have positive TST results after vaccination with bacilli Calemette-Guerin (BCG), infection with mycobacteria other than M. tuberculosis complex, or undetermined other factors.
- Numerous studies have demonstrated that the peptide antigens used in QuantiFERON-TB Gold IT stimulate IFN-γ responses in T-cells from individuals infected with M. tuberculosis but generally not from uninfected or BCG vaccinated persons without disease or risk for LTBI.

References

1. QuantiFERON®-TB Gold Package Insert, Cellestis Inc., Valencia CA, US05990301E, January 2009.
2. QuantiFERON®-TB Gold Collection Quick Reference Guide, Cellestis Inc., Valencia, CA, L05995012B, February 2008.