Regional West Laboratory Services

TEST CHANGE

NOTIFICATION DATE: January 13, 2018
EFFECTIVE DATE: February 13, 2018

QUANTIFERON-TB GOLD IN-TUBE FOR DETECTION TUBERCULOSIS, BLOOD
MAYO Test ID: QFT3

EXPLANATION: This test will become obsolete on effective date due to manufacturer transitioning to the new, FDA-cleared QuantiFERON-TB Gold Plus (QTB-Plus) 4-tube assay.

RECOMMENDED ALTERNATIVE TEST:
QUANTIFERON-TB GOLD PLUS, BLOOD
Test ID: QFT4

USEFUL FOR: Indirect test for Mycobacterium tuberculosis infection, to be used in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

METHOD: Enzyme-Linked Immunosorbent Assay (ELISA)

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS:
Supplies:
Standard Altitude: QuantiFERON-TB Gold Plus Collection Kit (T794)
High Altitude: QuantiFERON-TB Gold Plus High Altitude Collection Kit (T795)
Collection Instructions:
1. Special collection, incubation, and centrifugation procedures must be followed.
2. Prepare and transport specimen per QuantiFERON-TB (QFT) Gold Plus Collection and Processing Instructions (T688).
Specimen Minimum Volume: 4 mL-1 mL per tube (4 tubes)

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time	Special Container
Whole Blood	Refrigerated	28 Days	QTBKIT

Questions: contact April Madden, Laboratory Director
Telephone: 888-522-7962
Email: April.Madden@rwhs.org

Regional West Laboratory Services

CAUTIONS:

- A negative QuantiFERON-TB Gold Plus (QFT-Plus) result does not preclude the possibility of *Mycobacterium tuberculosis* infection or tuberculosis disease. False-negative results can be due to the stage of infection (eg, specimen obtained prior to the development of cellular immune response), comorbid conditions that affect immune functions, incorrect handling of the blood collection tubes following venipuncture, or other individual immunological factors. Additionally, heterophile antibodies or nonspecific interferon-gamma (IFN-gamma) production from other inflammatory conditions may mask specific responses to ESAT-6 or CFP-10 peptides.
- A delay in incubation may cause false-negative or indeterminate results, and other technical parameters may affect the ability to detect a significant IFN-gamma response.
- A positive QFT-Plus result should not be the sole or definitive basis for determining infection with *M tuberculosis*. Positive results should be followed by further medical evaluation for active tuberculosis disease (eg, acid-fast bacilli smear and culture, chest X-ray).
- While ESAT-6 and CFP-10 are absent from all bacille Calmett-Guerin (BCG) strains and from most known nontuberculous mycobacteria, it is possible that a positive QFT-Plus result may be due to infection with *M kansasii, M szulgai,* or *M marinum*. If such infections are suspected, alternative tests should be performed.
- The effect of lymphocyte count on reliability is unknown. Lymphocyte counts may vary over time for any individual person and from person to person. The minimum number required for a reliable result has not been established and may also be variable.
- The predictive value of a negative QFT-Plus result in immunosuppressed patients has not been determined.

CPT CODE: 86480
DAY(S) SET UP: Monday through Friday; 9 a.m. **ANALYTIC TIME:** 2 days

This notice is viewable online: www.rwhs.org/lab-special-announcements

Questions: contact April Madden, Laboratory Director
Telephone: 888-522-7962
Email: April.Madden@rwhs.org