

NEW TEST

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QuantiFERON TB-Gold Plus, 1-Tube

3017554, QFT PLUS

Specimen Requirements:

Patient Preparation:

Collect: QuantiFERON Gold Plus 1-tube (ARUP Supply #54015) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. For collection and transport instructions, refer to QuantiFERON under Special Handling at <https://www.aruplab.com/testing/quantiferon#collection>. NOTE: The specimen must be submitted in the ARUP-provided collection tube due to the requirements of the laboratory automation.

Specimen Preparation: Transport 6 mL whole blood. (Min: 5 mL).

Transport Temperature: Refrigerated. Must be collected and shipped directly to ARUP the same calendar day.

Unacceptable Conditions: Clotted specimens.

Remarks: Do not collect or ship on holidays or the day before holidays.

Stability: Ambient: 3 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Methodology: Semi-Quantitative Chemiluminescent Immunoassay (CLIA)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

Performed: Sun-Sat

Reported: 1-4 days

Note: If the stability requirements cannot be met, please refer to ARUP test code 3017562, QuantiFERON-TB Gold Plus, 4-Tube.

CPT Codes: 86480

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Interferon gamma release is measured for specimens from each of the four collection tubes. A qualitative result (Negative, Positive, or Indeterminate) is based on interpretation of the four

values: NIL, MITOGEN minus NIL (MITOGEN-NIL), TB1 minus NIL (TB1-NIL), and TB2 minus NIL (TB2-NIL). The NIL value represents nonspecific reactivity produced by the patient specimen. The MITOGEN-NIL value serves as the positive control for the patient specimen, demonstrating successful lymphocyte activity. The TB1-NIL tube specifically detects CD4+ lymphocyte reactivity, specifically stimulated by the TB1 antigens. The TB2-NIL tube detects both CD4+ and CD8+ lymphocyte reactivity, stimulated by TB2 antigens. An overall Negative result does not completely rule out TB infection.

A false-positive result in the absence of other clinical evidence of TB infection is not uncommon. Refer to: Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection -- United States, 2010 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm>), for more information concerning test performance in low-prevalence populations and use in occupational screening.

Reference Interval:

| Test Number | Components | Reference Interval | |
|-------------|--------------------------------|-----------------------|--|
| | QuantiFERON-Mitogen minus NIL | | |
| | | No Reference Interval | |
| | QuantiFERON NIL | | |
| | | No Reference Interval | |
| | Quantiferon-Plus TB1 minus NIL | | |
| | | 0.34 IU/mL or less | |
| | Quantiferon-Plus TB2 minus NIL | | |
| | | 0.34 IU/mL or less | |

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.