

QuantiFERON®-TB Gold Plus (QFT Plus)

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| Test description | QuantiFERON-TB Gold Plus (QFT-Plus) is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of interferon-γ (IFN-γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to these peptide antigens that are associated with <i>Mycobacterium tuberculosis</i> infection. |
| Test use | QFT-Plus is an indirect test for <i>M. tuberculosis</i> infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations. |
| Test department | Virology Phone: (860) 920- 6662, FAX: (860) 920- 6661 |
| Methodology | Enzyme-Linked Immunosorbent Assay (ELISA) |
| Availability | Test is performed weekly as needed |
| Specimen Requirements | 1mL of whole blood collected into each 4 specialized QFT-Plus collection tubes |
| Collection Kit/Container | Nil control tube, TB1 antigen tube, TB2 antigen tube & Mitogen tube. To obtain collection tubes, refer to Collection Kit Ordering Information. |
| Collection Instructions | Routine venipuncture at 17-25°C. Mix tubes by firmly shaking after collection to ensure the entire inner surface of the tube has been coated with the blood. |
| Specimen Handling & Transport | Maintain tubes at room temperature (17-25°C). Deliver to the laboratory the day of collection by 3pm (Monday -Thursday, not the day before a holiday); or incubate at 37°C ± 1°C for 16-24 hours. After incubation, hold at 4-27°C and deliver to the laboratory within 3 days (Monday -Friday by 3pm). Do not centrifuge. |
| Unacceptable Conditions | Unlabeled specimen Specimens that have leaked or containers that have broken in transit. Improperly collected specimens Specimens not handled as described above |
| Requisition Form | Clinical Test Requisition OL-9B (select QuantiFeron-TB Test) QuantiFERON® TB Gold Plus Collection and Testing Instructions |
| Required Information | Name and address of submitter. Two patient identifiers (ie.name, DOB, Acc.#, MRN), Town of residence (city, state, zip), specimen source/type, date collected, time collected , test(s) requested. Please ensure information on the requisition matches that on the specimen. |
| Limitations | While ESAT-6 and CFP-10 are absent from all BCG strains and from most known nontuberculous mycobacteria, it is possible that a positive QFT-Plus result may be due to infection by <i>M. kansasii</i> , <i>M. szulgai</i> , or <i>M. marinum</i> . If such infections are suspected, alternative tests should be performed. |
| Additional Comments | The magnitude of the measured IFN-γ level cannot be correlated to stage or degree of infection, level of immune responsiveness, or likelihood for progression to active disease. A positive TB response in persons who are negative to Mitogen is rare, but has been seen in patients with TB disease. This indicates the IFN-γ response to TB antigens is greater than that to Mitogen, which is possible as the level of Mitogen does not maximally stimulate IFN-γ production by lymphocytes. For Interpretation of results please refer to the attached table and pages 34-35 of the QuantiFERON-TB Gold Plus (QFT-Plus) Package Insert, Rev 09, January 2023 at: https://www.qiagen.com/us/resources/resourcedetail?id=ac068fc7-a994-4443-ac7c-dda43ce2bc5e&lang=en |

Interpretation of QFT-Plus test results

Table 4. Interpretation of QFT-Plus test results

| Nil (IU/ml) | TB1 minus Nil (IU/ml) | TB2 minus Nil (IU/ml) | Mitogen minus Nil (IU/ml)* | QFT-Plus Result | Report/interpretation |
|-------------|---|---|----------------------------|----------------------------|---|
| ≤ 8.0 | ≥ 0.35 and $\geq 25\%$ of Nil | Any | Any | Positive [†] | <i>M. tuberculosis</i> infection likely |
| | Any | ≥ 0.35 and $\geq 25\%$ of Nil | | | |
| | <0.35 or ≥ 0.35 and $<25\%$ of Nil | <0.35 or ≥ 0.35 and $<25\%$ of Nil | ≥ 0.50 | Negative | <i>M. tuberculosis</i> infection NOT likely |
| | <0.35 or ≥ 0.35 and $<25\%$ of Nil | <0.35 or ≥ 0.35 and $<25\%$ of Nil | <0.50 | Indeterminate [‡] | Likelihood of <i>M. tuberculosis</i> infection cannot be determined |
| $>8.0^§$ | Any | | | | |

* Responses to the Mitogen positive control (and occasionally TB Antigen) can be outside the range of the microplate reader. This has no impact on test results. Values >10 IU/ml are reported by the QFT-Plus software as >10 IU/ml.

† Where *M. tuberculosis* infection is not suspected, initially positive results can be confirmed by retesting the original plasma samples in duplicate in the QFT-Plus ELISA. If repeat testing of one or both replicates is positive, the test result is considered positive.

‡ Refer to "Troubleshooting Guide", page 58 for possible causes.

§ In clinical studies, less than 0.25% of subjects had IFN- γ levels of >8.0 IU/ml for the Nil value.

Results table excerpted from QuantiFERON-TB Gold Plus Package Insert, Rev 09, January 2023