QuantiFERON®-TB Gold Plus (QFT Plus)

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 Mycobacterium tuberculosis infection.
Test use	QFT-Plus is an indirect test for M. tuberculosis 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 laboratory immediately and within 16 hours after collection (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. 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 M. kansasii, M. szulgai, or M. marinum. 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 ≥25% of Nil	Any	Any	Positive†	*M. tuberculosis* infection likely
	Any	≥0.35 and ≥25% of Nil			
	<0.35 or ≥0.35 and <25% of Nil	<0.35 or ≥0.35 and <25% of Nil	≥0.50	Negative	*M. tuberculosis* 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 *M. tuberculosis* 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