QuantiFERON®-TB Gold Plus (QFT Plus)

Test description	Qualitative diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood for the detection of interferon-γ (IFN-γ) response
Test use	To identify *in vitro* responses associated with latent *Mycobacterium tuberculosis* infection.
Test department	Virology Phone: (860) 920- 6662, FAX: (860) 920- 6661
Methodology	Enzyme-Linked Immunosorbent Assay (ELISA)
Availability	Test is performed Monday – Thursday, as needed.
Specimen Requirements	Whole blood collected into 4 specialized blood 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 (17-27°C). Deliver to laboratory immediately and within 16 hours after collection; 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 (select **QuantiFeron-TB Test**) QuantiFERON® TB Gold Collection and Testing Instructions
Required Information	Name and address of submitter (and/or Horizon profile #) Patient name or identifier, town of residence (city, state, zip), date of birth Specimen type or source of collection, date collected, **time collected**, test requested Please ensure patient name on requisition matches that on the specimen
Limitations	A negative test result does not preclude the possibility of *M. tuberculosis* infection. Infections by other mycobacteria (*M. kansasii, M. szulgai, M. marinum*) may cause false positive results. Medical treatments or conditions that impair immune functionality can potentially reduce IFN-γ responses. Interpretation of results should always include a risk assessment, radiography and other medical and diagnostic evaluations. QFT-Plus should not be used to distinguish between active tuberculosis disease and LTBI. The performance of the USA format of the QFT-Plus test has not been extensively evaluated with specimens from the following groups of individuals: • Individuals who have impaired or altered immune functions, such as those who have HIV infection or AIDS, those who have transplantation managed

	with immunosuppressive treatment or others who receive immunosuppressive drugs (e.g., corticosteroids, methotrexate, azathioprine, cancer chemotherapy), those who have other clinical conditions, such as diabetes, silicosis, chronic renal failure, and hematological disorders (e.g., leukemia and lymphomas), or those with other specific malignancies (e.g., carcinoma of the head or neck and lung) • Individuals younger than age 17 years • Pregnant women.
Additional Comments	Studies have demonstrated that the peptide antigens used in the QFT stimulate IFN-γ responses in T-cells from individuals infected with *M. tuberculosis* but generally not from BCG vaccinated persons without disease or risk for latent infection.