



What is it?

- ◆ QuantiFERON®-TB Gold (QFT-G) is a whole-blood test for use as an aid in diagnosing *Mycobacterium tuberculosis* infection, including latent tuberculosis infection (LTBI) and tuberculosis (TB) disease.
- ◆ The test was approved by the U.S. Food and Drug Administration in 2005.
- ◆ Recommended by the CDC to be utilized in place of the tuberculin skin test¹ (see below).

Evaluating the Tuberculin Skin Test

- ◆ Tuberculin Skin Test (TST) offers the clinician only 70% specificity**
- ◆ Unreliable results due to false positives from BCG Vaccinations*
- ◆ Subject to inconsistent readings and experience of the clinician**

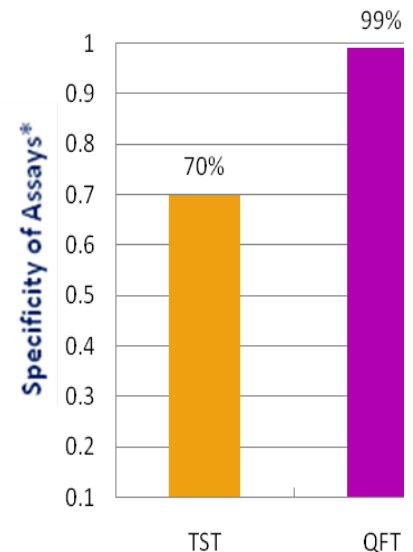
Test Code: 51265

Specimen Requirements:

- **Preferred Specimen:** 3 QFT-G Tube System (QFT-G Grey, Purple & Red). Draw all 3 tubes, shake for 5 seconds (16 hr. life)
- **Alternate Specimen:** 6 to 8 ml Green Top tube, (12 hr. life)
- **Accepted Monday – Friday only**
- Send in Orange Specimen Bag at room temperature
- **Do not freeze or refrigerate specimens**

Clinical Advantages Over TST

- ◆ Requires only a **single patient visit***
- ◆ Less affected by BCG vaccination*
- ◆ Highly specific (>99%) and sensitive (~92%)** for tuberculosis
- ◆ Does not cross-react with most mycobacteria other than tuberculosis, reducing common false positives with the skin test**
- ◆ No booster effects; best for repeated screening*
- ◆ Safe with no risk of adverse reactions in hypersensitive patients*
- ◆ Qualitative positive/negative answer (no risk stratification required)**
- ◆ Not subject to reader bias that can occur with TST. QFT-G is a highly reproducible lab test**
- ◆ Likely to yield cost savings (reduced staff time, unnecessary chest x-rays, & unnecessary treatment of false positive subjects)
- ◆ FDA approved in 2005 for *in vitro* diagnostic use



CDC Recommendations:

The CDC recommends that QFT-G can be used in all circumstances in which the tuberculin skin test (TST) is currently used including contact investigations, evaluation of recent immigrants who have had BCG vaccination, and TB screening of health care workers and others undergoing serial evaluation for *M. tuberculosis*.¹

¹CDC Manual – 12/16/05; 54(R15);49-55.

*Frequently Asked Questions Health Professionals, retrieved from www.cellestis.com on 7/7/2009.

**QuantiFeron®-TB Gold Features and Benefits, retrieved from www.cellestis.com on 7/7/2009.

Species specificity of ESAT-6 and CFP-10

Tuberculosis Complex	Antigens		Environmental Strains	Antigens	
	ESAT	CFP		ESAT	CFP
M tuberculosis	+	+	M abcessus	-	-
M africanum	+	+	M avium	-	-
M bovis	+	+	M branderi	-	-
			M celatum	-	-
BCG substrain			M chelonae	-	-
Gothenburg	-	-	M fortuitum	-	-
Moreau	-	-	M gordonii	-	-
Tice	-	-	M intracellulare	-	-
Tokyo	-	-	M kansasii	+	+
Danish	-	-	M malmoense	-	-
Glaxo	-	-	M marinum	+	+
Montreal	-	-	M oenavense	-	-
Pasteur	-	-	M	-	-
			scrofulaceum	-	-
			M smegmatis	-	-
			M suzulgai	+	+
			M terrae	-	-
			M vaccae	-	-
			M xenopi	-	-

*Table Provided by Cellestus

Experience you can trust: MACL performs the second largest number of QuantiFERON® tests in the U.S.

QuantiFERON®-TB Gold is a highly sensitive enzyme linked immunoassay (ELISA) used to aid in the detection of tuberculosis

How it Works

Blood samples are mixed with two synthetic peptides representing M. tuberculosis proteins, ESAT-6 and CFP-10. After incubation for 16 to 24 hours, an instrument measures the amount of Interferon-gamma (IFN-γ) secreted from stimulated T-cells. Additional tests (such as a chest radiograph, sputum smear and culture) are needed to confirm the diagnosis of LTBI or TB disease.

QuantiFERON®-TB Gold Result	Report/Interpretation
POSITIVE (ESAT-6 and/or CFP-10 responsiveness detected)	<i>M. tuberculosis</i> infection likely
NEGATIVE (No ESAT-6 or CFP-10 responsiveness detected)	<i>M. tuberculosis</i> infection not likely, but cannot be excluded especially when: <ol style="list-style-type: none"> 1. Any illness is consistent with tuberculosis disease 2. Likelihood of progression to disease (e.g., because of immunosuppression) is increased
INDETERMINATE	Test not interpretable