

# QFT-Plus FAQ

## 1. What is the QuantiFERON®-TB Gold Plus (QFT-Plus) test?

The QuantiFERON®-TB Gold Plus (QFT-Plus) is an in-vitro diagnostic test for the detection of Mycobacterium tuberculosis infection. QFT-Plus is one of the two TB blood tests, or interferon-gamma release assays (IGRAs), approved for use in the United States and is an indirect test for TB infection, including disease, intended for use in conjunction with a risk assessment, radiography, and other medical and diagnostic evaluations.

## 2. How is the QFT-Plus assay interpreted?

Positive results by TB1, TB2, or both are considered positive. See the table below.<sup>1</sup>

Interpretation of QFT-Plus results					
Nil	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 or ≥0.35 and <25% of Nil			
	<0.35 OR ≥0.35 and <25% of Nil		≥0.5	Negative	M. tuberculosis infection NOT likely
			<0.5	Indeterminate	Likelihood of M. tuberculosis infection cannot be determined
≥8.0	Any				

## 5. Can the QFT-Plus differentiate between active TB disease and TB infection?

Current evidence may suggest higher CD8 activity in active TB, however, there is insufficient evidence to indicate that QFT-Plus can distinguish between active TB disease and TB infection. Therefore, QFT-Plus should never be used in isolation to diagnose active TB disease or TB infection. Anyone testing positive should be assessed for active TB disease with a medical evaluation, chest radiograph and other tests indicated by the clinical symptoms and medical evaluation.

## 6. What is the sensitivity and specificity of the QFT In-Tube and QFT-Plus for TB infection?

In peer reviewed reports, the reported sensitivity of the QFT-Plus assays for TB infection were 83-91%, and the specificity of the QFT-Plus assays for TB infection were 97%-98%.<sup>2,3</sup>

## 7. How often does QFT-Plus yield an indeterminate result?

QFT-Plus indeterminate results generally occur very infrequently in healthy individuals. In clinical studies for QFT-Plus, the indeterminate rate was less than 2.5% for active TB. However, in populations where the level of immunosuppression is high, past studies of QFT show that indeterminate rates can be correspondingly higher.<sup>1</sup>

## 8. What should I do if the QFT-Plus result is indeterminate?

When presented with an indeterminate result, physicians may choose to redraw a specimen or perform other procedures, as appropriate. However, an indeterminate QFT-Plus is meaningful, suggesting possible error in performing the test or immunosuppression – particularly in patients with known or suspected immunosuppression, chronic disease, malnutrition or on medications known to decrease immunity.

**9. Why would I see false-negative results in patients with active TB?**

Individuals who progress to active TB do so because their immune system cannot control their infection. This can result from a large infectious exposure to *M. tuberculosis*. It may also be due to individuals having an impaired immune response, typical for malnourished individuals, those with advanced TB, those who are severely immunosuppressed or whose immune function has altered. Some individuals may develop active TB disease as a result of a genetic deficiency in their immune system, such as an inability to produce sufficient IFN- $\gamma$  and/or IL-12. Others may develop active TB as a result of iatrogenic immune suppression, for example, individuals taking anti-TNF- $\alpha$  medications. It is important to note that QFT-Plus is a test for *M. tuberculosis* infection and is approved as a diagnostic aid for indirect detection of *M. tuberculosis* infection (whether active TB disease or TB infection). Clinicians may use QFT-Plus to assist in the diagnosis of active TB disease (in conjunction with risk assessment, radiography and other medical and diagnostic evaluations). A negative QFT-Plus result in a person with obvious symptoms of active TB disease should by no means be used to rule out active disease. Culture of *M. tuberculosis* remains the gold standard for confirming a diagnosis of active TB disease.

**10. Where can I find more information on the QFT-Plus?**

For more information, see these links to the provider FAQ: [http://www.quantiferon.com/wp-content/uploads/2017/10/PROM-11186-001\\_1107785\\_BRO\\_QFT-Plus\\_GeneralSales\\_0717\\_US.pdf](http://www.quantiferon.com/wp-content/uploads/2017/10/PROM-11186-001_1107785_BRO_QFT-Plus_GeneralSales_0717_US.pdf)

Providers in LA County with questions about the QFT-Plus may also contact the LA County TB Control Program at 213-745-0800 and request medical consultation.

**References:**

1. QFT-Plus package insert: <http://www.quantiferon.com/wp-content/uploads/2017/10/QFT-Plus-ELISA-IFU-L1095849-R02.pdf>
2. QFT-Plus Provider FAQ: [http://www.quantiferon.com/wp-content/uploads/2017/10/PROM-11186-001\\_1107785\\_BRO\\_QFT-Plus\\_GeneralSales\\_0717\\_US.pdf](http://www.quantiferon.com/wp-content/uploads/2017/10/PROM-11186-001_1107785_BRO_QFT-Plus_GeneralSales_0717_US.pdf)
3. Telisinghe et al., “The sensitivity of the QuantiFERON-TB Gold Plus assay in Zambian adults with active tuberculosis”, IUATLD, 21(6), June 2017
4. Yi et al., “Evaluation of QuantiFERON-TB Gold Plus for Detection of Mycobacterium tuberculosis infection in Japan”, Scientific Reports, 6, 2016.

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